IMI2 821520 - ConcePTION

ConcePTION

WP6

D6.3 Report describing toolbox of methodologies and approaches for WPs to engage stakeholders regarding new evidence on the use of medicines in pregnancy and lactation

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Document History

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Draft_V1.0	04.03.2021	Draft for MB review

Contents

1. Abbreviations

NGD: Nominal group discussion

NGT: Nominal group technique

2. Context

ConcePTION interacts with several stakeholders such as pregnant and breast-feeding women, health care professionals, academics, regulators, payers and policy makers. Succesful interaction is of utmost importance i) to identify stakeholders' experiences, needs and concerns, ii) to collaborate with these stakeholders as partners in order to co-create solutions and iii) to reach consensus. ConcePTION makes use of qualitative (e.g. semi-structured interviews) and quantative (e.g. surveys) research methods to engage with these stakeholder groups. Within task 6.3 INtroduction To hEalth ReseArCh meThods' (INTERACT) guidelines are being established which describe several methodologies in order to guarantee successful interaction with stakeholders involved in ConcePTION.

3. INTERACT guidelines

3.1 Existing guidelines

The following INTERACT guidelines are already developed:

1. Systematic literature review guideline
2. Semi-structured interviews guideline
3. Focus group guideline
4. Guidelines to rank: e.g. nominal group technique (NGT) guideline
5. Guidelines to reach consensus: e.g. delphi study guideline

Moreover, a survey guideline is currently under development.

3.2 General description of the guidelines

The INTERACT guidelines are developed based upon available literature and experiences with research methods. These guidelines contain a stepwise description of methodologies, accompanied by concrete examples, templates and relevant references for further guidance.

3.3 Content of the guidelines

In this section, the content of each INTERACT guideline is summarized. The actual guides can be found in Appendix 1.

1. Systematic literature review guideline

As shown in figure 1, the INTERACT systematic literature review guideline describes 5 steps which are necessary to conduct a systematic literature review. Moreover, templates are included which are helpful when designing a search strategy and when screening and selecting literature retrieved from this strategy. Concrete examples can also be found on how a search strategy was designed in practice.

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Figure 1 Table of contents INTERACT systematic literature review guideline

2. Semi-structured interviews guideline

This 10-step INTERACT semi-structured interviews guideline supports the process of conducting semi-structured interviews. The different steps are presented in figure 2. It should be noted that several INTERACT guidelines can be linked to eachother. For example, the conduct of a literature review (step 1) is needed to become familiar with the context of a specific research topic and thus, to be able to prepare a well-designed interview guide (step 4). If a systematic literature review is chosen as the preferred methodology, the INTERACT systematic literature review guideline can be used.

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Figure 2 Table of contents INTERACT semi-structured interviews guideline

3. Focus group guideline

Figure 3 summarizes all steps that need to be undertaken when conducting focus groups. Moreover, the INTERACT focus group guideline contains templates with regard to an email invitation to potential focus group participants, an informed consent form that must be signed prior to participation in the focus group, an information sheet to adequately inform participants about the conduct of the focus group and the processing of their data, a focus group discussion guide and a template when collecting demographic and clinical information of focus group participants.

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Figure 3 Table of contents INTERACT focus group guideline

4. Guidelines to rank: e.g. Nominal group technique guideline

The table of contents of the INTERACT NGT guideline is shown in figure 4. Several steps, starting from a research question to concluding the nominal group discussion (NGD) are nessary when applying this technique. Additionally, 4 templates are included which are valuable for the design and conduct of NGT.

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Figure 4 Table of contents INTERACT NGT guideline

5. Guidelines to reach consensus: e.g. delphi study guideline

The INTERACT delphi study guideline contains an 8-step approach. This guideline provides more details on each of these steps which are necessary to identify a consensus position. Similar to the other INTERACT guidelines, templates are included to assist researchers when designing and conducting a delphi study.

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Figure 5 Table of contents INTERACT delphi study guideline

3.4 Awareness of the guidelines

Members of ConcePTION were made aware of the INTERACT guidelines by organizing several webinars. More concretely, these webinars took place on 15 June 2020 and 28 January 2021.
In addition, guides and the webinar material are hosted in the Members area of the ConcePTION project web site.

3.5 Use of the guidelines in ConcePTION

The INTERACT guidelines were already used within WP3 and WP7 of ConcePTION and were proven to be successful. Researchers involved in WP3 and WP7 made use of the systematic review guideline and the focus group guideline, respectively.

4. Next steps

Within task 6.3 of ConcePTION, several INTERACT guidelines have already been developed. Nevertheless, additional INTERACT guidelines on other methodologies used in ConcePTION are needed to enable successful engagement with stakeholders. Therefore, guidelines will also be developed regarding surveys, workshops, webinars, patient preferences studies, etc.

5. Appendix 1

The following INTERACT guidelines are in Appendix 1:

1. INTERACT Systematic literature review guideline
2. INTERACT Semi-structured interviews guideline
3. INTERACT Focus group guideline
4. INTERACT nominal group technique (NGT) guideline
5. INTEACT delphi study guideline

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INTERACT PRACTICAL GUIDES[1]

SYSTEMATIC LITERATURE REVIEW

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STEP 1: DEFINE RESEARCH QUESTIONS

Before starting your systematic literature review, it is important to think about the research questions to which your literature review should provide the answer. A research question is the question around which you centre your research. **Clear, specific, and answerable research questions** are the starting point for a comprehensive review. Your research question(s) should be:

- **Clear**: it is easy to understand the purpose of the questions without additional explanation.

[1] INtroduction To hEalth ReseArCh meThods' (INTERACT) guideline

- **Focused**: it is not too broad so the question can specifically be answered.
- **Complex**: it is not answerable with a simple "yes" or "no," but rather requires thorough analysis of ideas and sources.

Furthermore, it is useful to think about the following questions:

- What do you want to learn, and about what topics?
- What type of research findings will be relevant to address your research questions?
- Who will be your **audience**?
- Why will a review be useful?

Next, it is important to get a better idea of what has already been done in the field. For instance, has a literature review already been done in that area? Next**, start reading some of the literature** to form a better idea of what the literature looks like. This will give you the necessary background to define the scope of the review and already see some patterns in the literature. Furthermore, the existing literature may help to identify the types of research questions that could be examined to make an innovative contribution to scientific knowledge. Furthermore, reading literature within the area is **crucial to identify relevant search terms** and built a search strategy in the next step.

STEP 2: BUILD A SEARCH STRATEGY

See Template 1 – Search Strategy

SELECTION OF DATABASES

Many medical databases exist:

- PubMed (general biomedical)
- Embase (general biomedical)
- Cochrane Library (systematic reviews and RCTs)
- Web of Science (biomedical, exact sciences, sociology, phychology, …)
- CINAHL ("allied health": nursing, paramedical topics, …)
- Pedro (sports)
- PsycArticles (psychology)
- ERIC (pedagogy)
- LLBA (speech therapy and audiology)

The selection of the databases depends on your research questions. The most commonly used databases are PubMed and Embase.

DRAFTING SEARCH TERMS

Before starting your search, you need to define relevant search terms to operationalize your research questions and locate all potentially relevant work. First, break research questions down into **individual concepts** to create search terms.

For example: *Exploring mice as model organisms for cultivating corn on Mars*.

- Concept 1: mice
- Concept 2: corn cultivation
- Concept 3: Mars

For clinical topics you can use the **PICO framework:**

P = population	*patient, patient population, age, gender, …*
I = intervention	*intervention or treatment, diagnostic test, exposure to risk factor, …*
C = comparison	*comparative treatment, alternative drug, placebo, …*
O = outcome	*effect of the treatment, mortality, morbidity, …*

When you have subdivided your research question into individual concepts. These concepts will form the basis of the search terms. To identify relevant search terms, you can use the FOREST LOG scheme:

- Use **FOrms** or variants of the key words
  - *photograph, photographs, photo, photos, photographic, photography, ...*
- Use **RElated terms**: words often used in combination with the key terms
  - *Dental graphic, orthodontic photographs, intraoral photographs, ...*
- Use **Synonymous Terms**
  - *Image, picture, snapshot, ...*
- Use **Ladder of Generalization**: a continuum from specific (*dental DSLR*) to more general (*dental photograph*) to even more broad (*dental imaging*) and eventually to abstract (*oral diagnosis)*.

!! Be aware of different terminologies:

primary/elementary school, cornflour/cornstarch, chemist/drugstore, ...

Other examples:

- Add **synonyms** (“clinical”, “biomedical”, “medical”)
- add **plural forms, verbal forms, adjectives** (“communication”, “communicate”, “communicating”);
- consider different **spellings** (“color”, “colour”);
- look into **broader versus narrower** terms (“sarcomere”, “muscle fiber”, “muscle”)
- use classification terms used by databases to sort their contents into categories listed by headings and subheadings, if relevant to your search (**MeSH Terms or Emtree**). To

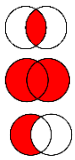
find these terms you can search within PubMed (MeSH) or within Embase (Emtree), see useful links.

There is a balance between sensitivity (finding as many articles as possible that may be relevant) and specificity (making sure those articles are indeed relevant). At this stage, it is better that your search is too broad and thus is less specific so that you do not miss anything. This broad search will give you more results but luckily a large pool of studies can easily be screened and will give you more certainty on including all important studies.

COMBINING SEARCH TERMS

After identifying the most fitting search terms, they still need to be combined in a coherent and relevant search strategy by using Boolean operators: AND, OR, NOT.

- **AND:** used to combine concepts
- **OR:** used to combine synonyms, related terms within one concept
- **NOT:** used to exclude a certain term



For examples, see below.

What if you find too many results (>700)?

- Don't be more broad than necessary
  Eg.: author - "Thierry Vandendriessche" not Vandendriessche
- Specifiy a time frame, document type, study type or language you want to find but **do not use build-in filters.**
- Delete a term (synonym, related term)
- Add an extra concept with AND

What if you find not enough results (<100)

- Check if your database is relevant for your topic
- Check for mistakes you made when entering your search strategy
- Add synonyms, related terms in one concept with OR
- Are the Boolean operators correctly used?

TIPS & TRICKS

When using advanced search in PubMed. First enter the search strategy per concept and add this to your history. Finally, you simply add every concept from your history to the builder to easily combine the different concepts to one large search strategy.

DEFINING INCLUSION AND EXCLUSION CRITERIA

You should establish inclusion and exclusion criteria based on the research question(s). These criteria are important to define the boundaries of the review by excluding unrelated studies and allowing you

to specifically address your research questions. Best practice involves formulating inclusion and exclusion criteria purely based on your research questions, not on literature you may find, and applying these consistently throughout the review process. Studies that are eligible for inclusion will meet the inclusion criteria and not meet the exclusion criteria. **Common inclusion and exclusion criteria concern**:

- research questions (topic, scope)
- measures or key variables (what is measured and how; e.g., whether measures need to meet particular criteria to be included)
- research design (e.g., observational studies, experimental studies, quantitative studies, qualitative studies)
- participants (e.g., adults, children, caregivers, government officials)
- time frame (e.g., since the start of the literature, the last 10 years, the last 5 years),

Example:

Inclusion criteria:

- Mention of the challenges for market access of gene therapies or engineered cell therapies
- OR Mention of the challenges for regulatory approval of gene therapies or engineered cell therapies
- European, US or Canadian context
- Published 2010-2019

Exclusion criteria:

- Not written in English
- No full text available

STEP 3: ARTICLE SCREENING AND SELECTION

See Template 2 – Article screening & selection

Start with reading the **title and/or abstract** of all the articles identified by your searches where often most work will not meet your inclusion criteria. During the abstract screening, it is better to include more articles or studies than to possibly exclude interesting papers. If the title and/or abstract suggest that the work is potentially eligible for inclusion in your review, you can start **screening the full texts** of the papers. At this stage, you need to be more specific and only include articles relevant for your research questions. You now need to read the full-text version of potentially eligible articles to see if each is indeed appropriate for inclusion.

When it comes to the overall screening procedure, many suggest **at least two reviewers work independently to screen the studies** against the inclusion and exclusion criteria. The individual assessment should be inclusive—**if in doubt, always include the studies**. It is possible that the two reviewers disagree whether to include an article or not. The process for resolving **disagreements**

between reviewers should be specified explicitly in the review. There are two steps to resolve discrepancies in the assessment results:

1. Two reviewers discuss the concerning article and resolve the issue by **consensus** after referring to the inclusion and exclusion criteria. If the discrepancy remains, move forward to step 2.
2. The two reviewers can then resolve the disagreement by involving a **third party**. Again, if in doubt, include the studies for further examination.

TIPS & TRICKS

To easily assess the PubMed results, you can import these results into Excel. In PubMed, when the search results are displayed, click on send to (upper right corner) and choose File and CSV as format. Next, open Excel and click on the tab 'data', choose 'From Text/CSV' and select comma as the delimiter. When the list is imported, you can choose which columns to keep and will have created an overview of all the identified articles.

To include/exclude articles from your search results efficiently, you can use the Rayyan application (rayyan.qcri.org): collect your search results from all used databases into one citation manager (ie. EndNote or Mendeley), export these into one file (ie RIS file) and upload into the Rayyan app.

STEP 4: DATA EXTRACTION FROM ARTICLES

After completing the complete selection of articles based on both title/abstract and full text, the relevant **data to answer your research questions need to be extracted** from the literature. Three main approaches exist to perform data extraction:

1. **Deductive** approach: dependent on your research questions define several themes you wish to gain information on and specifically search/indicate them in the articles.
2. **Inductive** approach: allow the themes to emerge from the literature itself without previously identifying relevant themes.
3. **Combined** deductive-inductive approach: previously define certain themes you will search for but also allow for inductive addition of new themes dependent on the literature.

Either which approach is chosen, it is important to provide a systematic framework to describe the findings per read article. Therefore, **careful documentation of the themes and the content of the articles describing these themes needs to be foreseen**. This documentation can be supported by either Excel or NVivo. Within **Excel**, it is possible to assign a theme to every column whereas the selected articles constitute the rows. The content of every article that falls under a certain theme can be written down within the corresponding cell. The use of Excel is best fitting when the selected articles are limited. When a large number of full-text articles needs to be analysed, **NVivo** can be a better option. NVivo is a software to analyse text data and allows the creation of categories and subcategories (codes) that may be applied to the literature. After coding all articles, NVivo automatically provides a framework matrix which allows for the comparison of statements between articles within the same theme. The choice

between Excel and NVivo not only depends on the number of selected articles but also on personal preference and standard methods used within the research field.

Step 5: Reporting

When reporting the results of a systematic literature review in a peer-reviewed article, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) are recommended to be present within the submitted paper. This checklist is described as:

> *"PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions."* - http://www.prisma-statement.org/

The following elements need to be completed before publication:

- The PRISMA checklist which can be added in the supplementary material of the article: http://www.prisma-statement.org/PRISMAStatement/Checklist
- The PRISMA flow diagram which can be added as a figure within the method section: http://www.prisma-statement.org/PRISMAStatement/FlowDiagram

USEFUL LINKS & REFERENCES

GUIDELINES AND ARTICLES

Cochrane Handbook for Systematic Reviews of Interventions
https://training.cochrane.org/handbook/current

Systematic Review Tutorial by Yale Medical Library
https://library.medicine.yale.edu/tutorials/subjects/systematic-searches

How to Do a Systematic Review: A Best Practice Guide for Conducting and Reporting Narrative Reviews, Meta-Analyses, and Meta-Syntheses
https://www.annualreviews.org/doi/pdf/10.1146/annurev-psych-010418-102803

Systematic review assistance (Toledo – video + powerpoint slides)
https://p.cygnus.cc.kuleuven.be/webapps/blackboard/content/listContent.jsp?course_id=_471173_1&content_id=_26556466_1&mode=reset

Systematic Reviews & Other Review Types
https://guides.temple.edu/c.php?g=78618&p=3879604

How to write a systematic literature review: a guide for medical students
http://sites.cardiff.ac.uk/curesmed/files/2014/10/NSAMR-Systematic-Review.pdf

Guidance on Conducting a Systematic Literature Review
https://journals.sagepub.com/doi/pdf/10.1177/0739456X17723971

Narrowing a Topic and Developing a Research Question
https://libraries.indiana.edu/sites/default/files/Develop_a_Research_Question.pdf

KU Leuven Bibliotheken - useful links for systematic reviews
https://bib.kuleuven.be/2bergen/mgas/onderzoeksondersteuning/systematic_review/links

PRACTICAL LINKS

How to find MeSH terms:
https://www.ncbi.nlm.nih.gov/mesh/

How to find Emtree terms:
https://www.embase.com/?org.apache.catalina.filters.CSRF_NONCE=5E57F1CEA7B486E72BE7BE15B818E675#emtreeSearch/default

TEMPLATES

TEMPLATE 1 – SEARCH STRATEGY

Search strategy = A AND B AND C OR … OR … NOT …

A: CONCEPT 1			
Concept	MeSH	Emtree	Free text (search in title and abstract)
B: CONCEPT 2			
Concept	MeSH	Emtree	Free text (search in title and abstract)
C: CONCEPT 3			
Concept	MeSH	Emtree	Free text (search in title and abstract)

TEMPLATE 2 – ARTICLE SCREENING & SELECTION

	Reviewer	E. Exclusion criteria (X if present)	E1. Exclusion criterium 1	E2. Exclusion criterium 2	I. Inclusion criteria (X if present)	I1. Inclusion criterium 1	I2. Inclusion criterium 2
Article 1							
Article 2							
Article 3							

Repeat for both title & abstract and full text screening.

Articles only need to comply with one exclusion criterium to be excluded.

Dependent on the inclusion criteria used and the research questions, articles either need to comply with all inclusion criteria or with only one to be included for further screening.

CONCRETE EXAMPLES

EXAMPLE 1

Research question: what are the challenges in regulatory evaluation and market access of gene therapies?

Search strategy: A AND (B OR C)

A: Gene and cell therapies		
Concept	MeSH	Free text (searched in title and abstract)
Gene therapy	"Gene Therapy"	"gene therapy", "gene-therapy", "gene therapies", "genetic therapy", "genetic therapies"
Cell therapy	"Cell Engineering"	"cell therapy", "cell-therapy", "cellular therapy", "cell therapies", "cellular therapies"
B: Regulatory approval		
Concept	MeSH	Free text (searched in title and abstract)
Market authorisation		"market authorisation", "market authorization", "market approval", "regulatory approval", "regulatory evaluation"
Benefit-risk	"Risk Assessment"	"benefit-risk assessment", "benefit risk assessment", "benefit-risk assessments", "benefit risk assessments"
C: Market access		
Concept	MeSH	Free text (searched in title and abstract)
Market access		"market access", "market entry", "patient access", "managed entry agreement", "performance-based", "performance based", "financial-based", "financial based", "coverage with evidence generation", "cost-effectiveness"
Reimbursement		"reimbursement", "economic evaluation", "payer"
Pricing		"price", "prices", "pricing"
HTA	"Technology Assessment, Biomedical"	"health technology assessment", "health technology assessments"

Inclusion criteria:

- Mention of the challenges for the market access OR regulatory approval of gene therapies OR engineered cell therapies
- European, US or Canadian context
- Written in English
- Full text available
- Published 2010-2019

Search results: 590 results

EXAMPLE 2

Research question: which factors and situation influence the value of patient preference studies along the medical product lifecycle?

Search strategy: A AND B AND C AND D NOT E

A: Factors/situations			
Concept	Emtree	MeSH	Free text (searched in title and abstract)
Process			process, processes
Condition			condition, conditions
Factor			factor, factors
Influence			influence, influences, influencer, influencing
Utility			Utility
Weight			Weight
Value			Value
Application			application, applications
Decision making			assessment, assessments, criteria, criterias, "decision making", "decision making", crtertion, "decision point"
B: Patient preferences			
Concept	Emtree	MeSH	Free text (searched in title and abstract)
Patient preferences	"patient preference"	"Patient Preference"	"patients preference", "patients preferences", "preference of patients", "preferences of patients", "patient preference", "patient preferences", "preference of a patient", "preference of the patient", "preferences of a patient", "preferences of the patient"
C: Methods/collection/use			
Concept	Emtree	MeSH	Free text (searched in title and abstract)
Method	"methodology"	"Methods", "Investigative Techniques/ methods"	"elicitation methods", method, methodology, empirical, "qualitative method", qualitative, "quantitative method", quantitative, technique, techniques
Measuring			Measuring
Assessment			measurement, measurements, assessment, assessments
Inclusion			inclusion, including, include, incorporate, incorporating, incorporation, involving, involvement, involve
D: Medical Product LifeCycle			
Concept	Emtree	MeSH	Free text (searched in title and abstract)
Drug life cycle			"life cycle of a drug", "life cycle of a medical device", "medical device life cycle", "lifecycle of a drug", "lifecycle of a medical device", "medical device lifecycle", "drug life cycle" "drug lifecycle"
Development			"drug development", "medical device development", "development of drugs", "development of a drug", "development of medical devices", "development of a medical device"
Benefit and risk	"risk assessment"	"risk assessment"	"benefit and risk" "risk and benefit"
Benefit-risk			"benefit-risk" "risk-benefit"
Reimbursement			"reimbursement"
Research			"drug research", "medical device research", "clinical trials", "clinical trial"

HTA			"health technology assessment", "health technology assessments"
E: NOT terms			
Concept	Emtree	MeSH	Free Text (searched in title and abstract)
NOT terms			"shared decision making", "shared decision making", monitoring, biomarker, biomarkers

Inclusion criteria:

- Mention of factors and situations influencing the value of patient preferences in context of the MPLC;
- OR indication of how patient preferences can be used in processes and decision making along the MPLC
- On European or US context
- Published after 2011
- Written in English
- Full text available (conference abstracts, letters to the editor, book reviews, presentations, conference notes, and workshop presentations were excluded)

Search results: 1033 results

van Overbeeke E, Whichello C, Janssens R, Veldwijk J, Cleemput I, Simoens S, et al. Factors and situations influencing the value of patient preference studies along the medical product lifecycle: a literature review. Drug Discovery Today. 2019;24(1):57–68.

INTERACT PRACTICAL GUIDES[2]

(SEMI-STRUCTURED) INTERVIEWS

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[2] INtroduction To hEalth ReseArCh meThods' (INTERACT) guideline

Step 1: Perform a literature review

Before conducting interviews with stakeholders and experts in the field, it is important to get a better understanding of the context in which your research will take place. To realize this, you will need to **perform a literature review**. Depending on the timing and scope of your project, you can either opt for a systematic literature review (cfr. separate practical guide) or a more limited so-called narrative review (table 1). Regardless of your choice, the literature review is a vital first step in the conduct of interview studies as it will allow you to identify topics that can be addressed during the interviews, which in turn will inspire your interview questions. Additionally, when discussing the results of the interviews, it is important to compare your findings with what has been written by authors in the field.

	Narrative review	Systematic review
Research question	Broadly defined	Highly focused
Inclusion/exclusion criteria	Developed post hoc	Developed at protocol stage
Study types	All study types	Defined study types
Reporting of findings	Simple description of selected findings	Synthesizes and aggregates findings
Replication of review	Impossible, no search strategy published	Possible, search strategy published

Table 1: Overview of the main differences between a narrative and a systematic literature review.

Step 2: Define the target population

A vital question that needs to be addressed early on concerns the experts that you wish to interview for your study. The literature review should have given you an idea of **which stakeholders you should target** to get a comprehensive view of the different perspectives surrounding the research topics you wish to explore. Your target groups can for example be:

- Clinical investigators
- Clinical research associates
- Study nurses

To further specify and narrow down the target population, a **list of inclusion and/or exclusion criteria** can be composed prior to recruitment. Note that you should always be able to justify your choice for a specific criterion. The list of criteria also needs to be disclosed in any publications following from the interviews. Selection criteria can be based on:

- Expertise: e.g. has expertise in the domain of oncology

- Experience: e.g. has been a principal investigator on at least 3 clinical trials before
- Language: e.g. must be able to speak English fluently
- Place of residence/work: e.g. lives or works in a Member State of the European Union
- Affiliation: e.g. must be a member of the European Society for Medical Oncology
- Authority: e.g. must be in a senior or upper management position
- …

Step 3: Formulate the interview questions

Now that you are familiar with the literature available on your research topic and know which stakeholders you want to include in the study, you can begin formulating the interview questions. It is best to **start from a broad perspective** and first write down the general themes that you wish to address during the interviews (table 2). Afterwards, you can think about the specific topics you want to explore per theme. This approach will also make it easier to analyze the interview findings, as you will already have an idea of the overarching themes that can be extracted from the interviews.

Theme	Example of specific interview question
Methodology	What kind of trial designs are used for phase I clinical trials in rare cancers?
Funding	How much does it cost on average to carry out a phase I clinical trial for rare cancers?
Regulatory aspects	How do you experience the regulatory requirements associated with conducting phase I clinical trials for rare cancers?
Patient involvement	According to you, how, if at all, should patient organizations be involved in phase I clinical trials for rare cancers?

Table 2: Example of how questions can be formulated based on the exploration of broader themes

You should try to **avoid yes/no questions** as much as possible, since they do not incite deeper reflection from the interviewees. Instead, you can use the **5W1H method**:

- **W**ho?
- **W**hat?
- **W**hen?
- **W**here?
- **W**hy?
- **H**ow?

If your question starts with one of these 6 words, the interviewee will have to answer in a more specific way, which allows you to get more detailed answers.

Questions should always be formulated in a **neutral tone** to avoid influencing the interviewees' answers. Avoid adjectives unless absolutely necessary, and be mindful of the subjective connotations some words might have. **Do not make any assumptions**:

NOT: How should patient organizations be involved in phase I clinical trials for rare cancers?
BUT: How, if at all, should patient organizations be involved in phase I clinical trials for rare cancers?
NOT: Why do you think phase I clinical trials for rare cancers are so expensive to perform?
BUT: How do you experience the costs associated with phase I clinical trials for rare cancers?

It can also be interesting to ask the interviewees to express their thoughts about a **statement that you extracted from the literature**. This will allow you to make a direct comparison between what is written by authors in the field and what experts with hands-on experience believe. Useful ways to initiate such questions are:

- What is your opinion on the assertion that…
- What do you think of the notion that…
- How do you view the following statement: …

If you are targeting multiple groups of stakeholders, it is possible that you will have to adapt your questions to the different groups you wish to involve in the study. Ideally, each target group should be asked **the same (or similar) questions, in the same order**.

STEP 4: PREPARE THE INTERVIEW GUIDE

The interview guide is a document that describes the interview process in a stepwise fashion. It is used to ensure each interview follows a **standardized procedure**. You can follow it during the interview to make sure that you didn't forget to mention anything. It usually comprises the following parts:

- INTRODUCTION
  - Presentation of interviewer and research team
  - Expression of gratitude to the interviewee for their participation
  - Short explanation of purpose of interview
  - Short explanation of practical details (interview duration, publication of results, explanation of participants' rights, recording of interview)
  - Opportunity for the interviewee to ask any questions they may have
- QUESTIONS
  - Introductory questions
  - Research questions categorized according to the different themes
  - Round-up questions
- CONCLUSION
  - Expression of gratitude for participation
  - Disclosure of interviewer's contact details

A template for the interview guide can be found in the attachments below.

Step 5: Ethical approval

In order to start the focus group discussion, approval is necessary from **ethical committee**.
The data collected during the focus group discussion will always be treated confidentially and never made public. For this, the participants will be given a code (pseudonymised) and only the researchers will be able to identify the participants.
Participants will be informed oral and written about the objectives of the research. All information and **informed consent** will be send in advance and potential participant will have enough time to consider their participation or to ask questions. A template of the informed consent can be found in attachment.

Step 6: Perform pilot interviews

Before any real interviews take place, it is useful to **test your interview guide by conducting several pilot interviews**. Not only will this allow you to get yourself familiarized with the interviewing process, it will also enable you to identify questions that may need to be revised or formulated differently to avoid confusion on the part of the interviewees. Additionally, you can time the pilot interviews and see whether you have allocated enough time for the real interviews. Preferably, pilot interviews are performed with colleagues or friends who have some knowledge of the topics you want to explore in your study, otherwise they will not be reflective of the subsequent research interviews.

Step 7: Find and recruit participants

Recruiting interviewees can be a long and tedious process. In general, there are two different strategies to find potential participants. **Purposive sampling** implies that you actively look for individuals that satisfy a number of subjectively chosen selection criteria which are used to allow you to accomplish the purpose of your study. **Snowball sampling** on the other hand means that you try to include new participants that were suggested to you by previous interviewees. In general, it is a good idea to employ a **combination of these two techniques** to maximize the efficiency of the recruitment process. You will likely also have to complement them with some degree of **quota sampling**, which refers to the act of applying quotas during the selection of potential participants. If you are for example investigating cross-border access to clinical trials in the European Union, it makes sense to limit the number of experts included per country and to ensure that you have at least one interviewee for each Member State. It is again important to note that you should always be able to justify your recruitment method, given that it will have to be disclosed in any papers you publish based on the interview results.

Once you have a list of names of people you are aiming to recruit, you need to send them an invitation to participate in your study by e-mail. This initial **invitation mail** needs to be short enough to not be

ignored by your target audience of busy experts but sufficiently detailed to convince them to take part in an interview. Generally, it should contain the following parts:

- Formal greeting
- Your affiliation (university, research group, principal investigator)
- Name of the study
- Objectives of the study
- Methodology of the study
- Reasons why you think the addressee would be a good interviewee
- Expected duration of interview
- Confidentiality details (recording of interview, pseudonymization of data)
- Availability of addressee for the coming weeks
- Expression of gratitude in advance
- Closing remark

Give the potential participants some time to respond. If you haven't heard anything back from them after a two-week period, you can send a **politely worded reminder**.

If the targeted expert shows interest to participate by responding positively to your mail, you can further arrange the practical details of the interview. At this point, you also send them the **information sheet (IS) and the consent form (CF)**. The IS is a document that contains all of the information the interviewee needs to know before deciding to partake in the interview. It explains to them what the study is about, how it will proceed, what will happen with the collected data and what their rights are as a participant. Although you should allow them some time to read through the document, it is vital that the interviewee signs the CF before the interview takes place. A template of the IS and CF can be found in the attachments of this guide.

TIPS & TRICKS

It may be difficult to find experts that meet all of your inclusion criteria. You can use **LinkedIn** to search for profiles of people affiliated with specific companies or institutions. Although concrete e-mail addresses are usually not openly available, many organizations use a standard e-mail format, and there are websites that allow you to search through databases of professional e-mail addresses (e.g. https://rocketreach.co/).

STEP 8: CONDUCT THE INTERVIEWS

Now that all the preparations have been made, the interview process can start. The **interview guide** serves as the script you need to stick to and follow. While you can read from it during the interview, it is best to **memorize it as much as possible** so that you can engage your interviewee directly.

Depending on the location of the participant, the interview can either take place in person or remotely through the use of appropriate software tools.

In-person interviews

The following considerations have to be taken into account when conducting in-person interviews:

- Make sure that you **arrive at least 30 minutes early**, as it may take some time to find the room and set up the recording equipment
- **Book the room** in which you plan to conduct the interview sufficiently long in advance and for at least 30 minutes longer than you project the interview will take
- Make sure that you sit in such a way that you **face the interviewee** during the interview
- If the **CF** has not been signed yet, bring it with you
- Be mindful of the **acoustics of the room**, since this can interfere with the recording
- Bring a **high-quality recording device** with you
- Make sure that the **recording device has sufficient charge** (bring extra batteries or charge it before the interview)
- **Test the recording function in advance**, if possible in the same room as the one in which the interview will take place
- **Record the interview in duplicate,** for example by also recording the sound with your mobile phone
- **Do not turn on the recorder until the research questions start**
- Always **ask for permission** prior to turning on the recorder
- If necessary, you can bring a laptop with you to **project the questions or statements** that you want the interviewee to share their opinion on
- **Bring pen and paper and make notes** of key concepts addressed by the interviewee
- **Keep eye contact when not making notes**
- **Nod along in agreement and use verbal cues ('Hmm-mm', 'right', 'okay', …)** but not excessively as they will complicate the transcription process
- **Repeating the key words in the interviewee's answer** can help stimulate further elaboration
- Ask **one question at a time**
- Allow the interviewee to **finish their answers without interrupting** them
- **React neutrally to answers** given by interviewees, regardless of whether they confirm or refute your prior ideas
- Do not feel awkward if there is a sudden silence: **let the interviewee break the silence themselves**, even if it takes some time
- Don't be afraid to **ask additional questions**: when the interviewee mentions something interesting, jump on it and ask them for clarification
- **Don't interrupt the interviewee to ask a question**: write it down in your notes and ask it when the opportunity arises
- If you are unsure what the interviewee means with a particular answer, **summarize the key message as you interpreted it in one or two phrases and ask if your interpretation is correct**

('So if I understand you correctly, you believe that…'). This is also useful when the participant gives a long-winded answer or goes off on a tangent as it forces them to get back on topic
- If the participant does not directly address the question in their answer, **don't be afraid to ask the question again**
- After the interview has been concluded, immediately make a **back-up of the audio files** you recorded on a separate thumb drive
- **Reflect** on the interview afterwards: what went well/badly? How can I improve my interviewing technique? Should the interview guide be adapted?

Remote interviews

Many of the abovementioned remarks also apply to remote interviews. Some additional points to bear in mind include the following:

- Make sure that you **enter the virtual conference room at least 15 minutes in advance**
- Ensure that your **internet connection is stable**
- While waiting for the interviewee to arrive, **test your audio and camera**
- Communicate to your interviewee in advance that they should **call in from a quiet room where there is a good internet connection**
- **Book or arrange a quiet room** for yourself so that you don't get interrupted
- **Send a Skype invitation** to the participant in advance instead of calling them up directly, but have their number ready in case something goes wrong and they can't enter the
- **Turn the camera on** during the interview
- **Record the interview in duplicate**: do not only use Skype's built-in recording function but also other software (e.g. MP3 Skype Recorder)
- If the camera cannot be turned on (e.g. due to it slowing down the connection or because the interviewee is calling in on their phone), the **use of verbal cues is essential** to let the interviewee know that you are still on the line
- **Have a back-up system ready**: if Skype doesn't allow for a stable connection, try Zoom or a different program
- If the connection is interrupted, ask the interviewee to **repeat themselves**

When saving the audio files on your computer, **do not mention any identifying information** (e.g. 'Interview Frank Johnson.mp3'), but instead use a coding system (e.g. 'Clinical Investigator 3.mp3'). Make sure to delete the metadata as well, as Skype recordings also document the time and date of the interview and the telephone numbers or e-mail addresses of the participants. Keep track of which codes you used for each interviewee in a separate document (the 'key'). This process is called **pseudonymization**. It differs from anonymization in the sense that the person who has access to the key can still identify the interviewee, which would not be possible if the data were anonymized. Pseudonymization is vital to ensure the confidentiality of the recordings.

Step 9: Transcribe the interviews

In this step, the interview recordings need to be **typed out *ad verbatim***, meaning that everything needs to be written down as it was said literally (including mistakes, stop words, 'uhms', 'hmm-mms', laughter, sighing,…). Note that this is a very **time-consuming** process: experienced transcribers will take about 4 hours to transcribe 1 hour of audio material. It will also require a lot of your energy, as you will often have to replay the same audio fragments dozens of times before understanding a particular word. Make sure to plan ahead and allocate enough time to this step.

If you have a tight schedule and a sufficiently large budget, you can **hire other people to do the transcription** for you. There are companies (e.g. Rev, TodayTranslations, TranscribeMe,…) that you can send the pseudonymized audio recordings to and who will then deliver the transcript to you within a certain timeframe. Depending on the length of the interview, this can quickly get very expensive (+/- 90 dollars/hour). Alternatively, you can set up a contract with one or multiple KU Leuven job students, which is usually a bit cheaper. Note that you will still always need to **check the finished transcript** as the transcriber will not be aware of the context of the interview and will therefore likely not understand certain terms or abbreviations. Additionally, since your interviewees may have distinct accents that the transcribers are not used to, the delivered transcript may contain mistakes. If possible, provide them with feedback before sending in a new audio recording.

TIPS & TRICKS

If you are using job students for the transcription and multiple candidates apply for the position, you can ask them during the hiring process to transcribe a 15-minute fragment of one of your pilot interviews within a one-hour timeframe to see how they perform. This will make it easier to select the best candidate(s) for the job.
If you intend to use the services a transcription company, you can ask for quotes and try to negotiate the price down by playing them against each other (although some companies may apply a standard price). Furthermore, depending on the quantity of the interviews, you may be eligible for a discount.

Step 10: Analyze the data

There are multiple different methods for analyzing qualitative data. For the purpose of this practical guide, two commonly used approaches in health research will be explained in more detail.

Framework analysis method

This method consists of multiple stages which have to be completed in a stepwise fashion.

1. Familiarization with the interviews

   The first stage of the framework analysis method involves **immersing yourself in the collected data**. Before deconstructing and interpreting the interviewees' answers, it is vital to familiarize yourself with the information you have collected. You can do this by carefully reading and re-reading the transcripts, re-listening to the interview recordings and examining your interview notes again. During this stage, you can write down some of your thoughts or impressions about the data in the margins of the transcripts. If you transcribed the interviews yourself, you will probably already be sufficiently familiar with the contents of the interviews.

2. Initial coding of interviews

   In this stage, a number of interview transcripts are analyzed sentence by sentence and descriptive labels are added to excerpts discussing a particular idea or topic (figure 1). These labels are called **codes** and the process of adding them to the transcripts is referred to as **coding**. In general, two types of coding can be distinguished. In **open coding**, the researcher starts from scratch and adds codes in an ad hoc manner. Here, the codes denote a wide range of concept, including concrete things (e.g. 'clinical trials'), values (e.g. 'belief in evidence-based medicine'), emotions (e.g. 'anger') and impressionistic aspects (e.g. 'difficult to explain for interviewee'). Open coding is typical for inductive studies, where you want to use the interviews to build up a broader theory that did not exist prior to your research. In **closed coding**, the codes are pre-defined based on the specific topics you wanted to address in the study. This is typically used in deductive studies, in which you start from a well-defined theory or research concept and subsequently perform interviews to probe the views of individual experts on that theory or concept. Usually in health research, a **combination** of both open and closed coding will be necessary.

   It is best to limit the number of transcripts you code at this stage. **3 to 5 transcripts** should be sufficient. If multiple groups of participants were interviewed, it is best to ensure that you code **at least one transcript per group**. Given the limited number of transcripts to be analyzed at this point, the coding can still be done **by hand**. Using different coloured markers for each text excerpt that you code will make it easier to visualize the various concepts emerging from the transcripts.

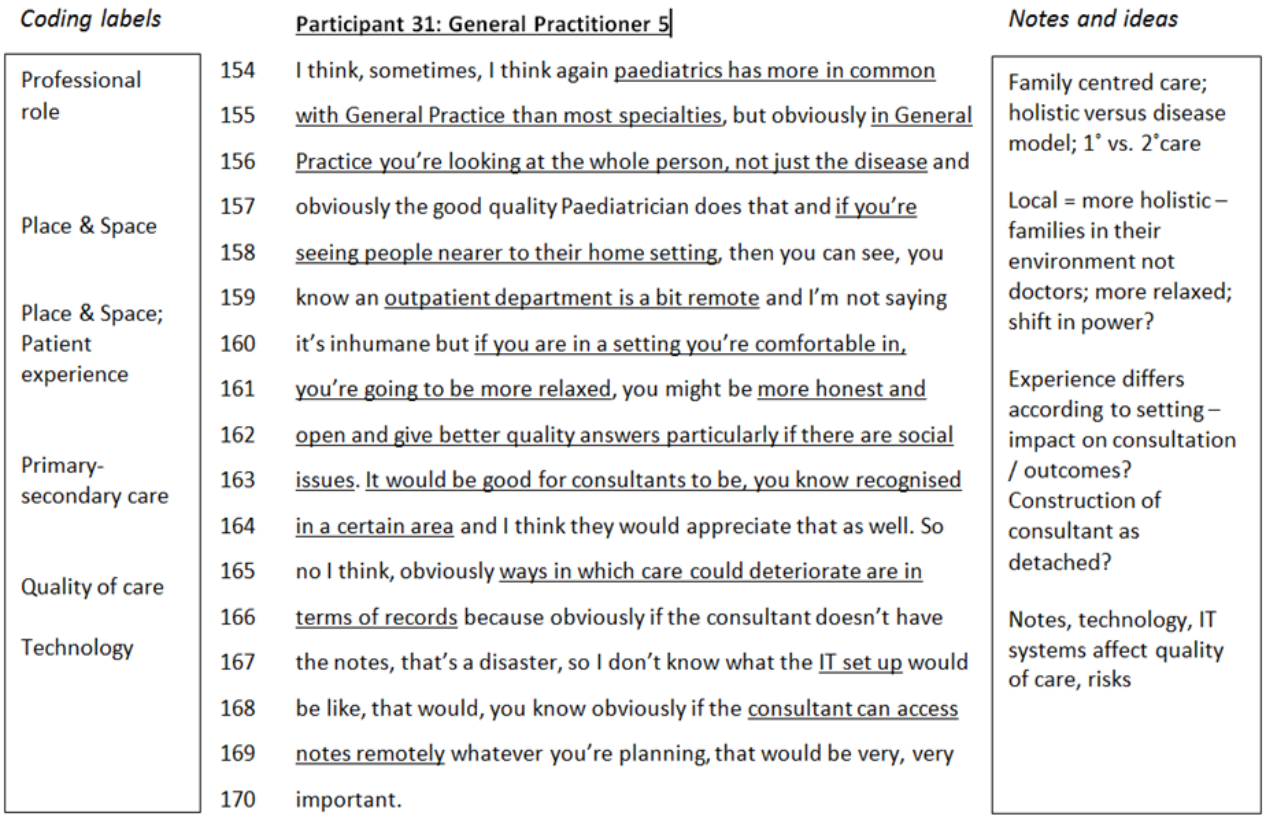


Figure 1: Example of a coded transcript fragment taken from Gale et al. (2013), with room for the codes as well as additional remarks or ideas in the margins of the transcript.

The **length of the text fragments** encompassed by individual codes should **not be too short** (otherwise the coding process takes too long and the interpretation of the data becomes too difficult), **nor too long** (otherwise you will miss out on important ideas or topics). Additionally, the **same excerpt** can be characterized by **multiple different codes**.
Ideally, the initial coding is done by **multiple researchers in parallel**.

3. Developing a working analytical framework

A **working analytical framework** is developed by putting together all the codes from the initial transcripts and coming to a **set of standard codes** that will be used to code subsequent transcripts (e.g. by grouping codes that are very similar together into an overarching code). If multiple researchers performed the initial coding, their results can be compared and a **consensus** can be reached. It is important to note that the working analytical framework is **not final**, as it may be changed when new topics emerge and thus new codes are needed during the coding of the remaining transcripts. The working analytical framework can be visually represented as a tree-like structure, which is often called the **coding tree**.

4. Applying the working analytical framework

   Once the working analytical framework and coding tree have been established, they can be applied to the remaining interview transcripts. This means that these transcripts need to be coded using the set of codes that emerged from the previous stage. This can be done by hand, although this will take a lot of time. Instead, a **CAQDAS** (Computer-Assisted Qualitative Data Analysis Software) tool can be used. An example of such a tool is **NVivo**. You can open your transcript files in NVivo and insert your coding tree. For each transcript, you can then select text excerpts and drag them to the corresponding code in your coding tree. This speeds up the process significantly and allows you to get a better overview of all text fragments grouped together per code. If a particular text fragment cannot be categorized under any of the codes in your coding tree, a new code can be introduced. It can also be useful to have an **'other' code** to group together very specific concepts that only appear once or twice throughout the interviews.

5. Charting data into the framework matrix

   After all transcripts have been coded and the final analytical framework has been constructed, the data need to be charted into a so-called **framework matrix**. This is an Excel spreadsheet in which the columns represent the various codes and the rows depict the different interviewees. The text excerpts categorized under each code are then displayed in the individual cells (table 3). NVivo allows you to automatically export the coded data as an Excel file, so you don't need to do this manually.

6. Interpreting the data

   The final framework matrix is examined in detail and, if applicable, discussed between the different researchers. This allows for patterns to be identified and views to be compared between the various interviewees. Based on the framework matrix, the interview results can be formulated. Be aware that this stage will take some time, so don't try to rush it.

Codes / Participants	Ideology of CCTH	Patient-centred approach	Equity in service provision	Equivalence to hospital care
Manager 1	Gen Paeds doesn't need to be in hospital; with right infrastructure CCTH makes sense *[p1, 24]*.	Need to deliver services based on what families need; at the moment focused on what's easier for us QQQ *[p16, 467]*.	For some people a city centre hospital is CTH than a clinic in the community *[p620, 21]*.	Need to instil confidence that they're getting same level of care, but CTH *[p2, 33]*.

Consultant 7	CCTH is a good recommendation; only patients who need specific investigations should attend hospital for outpatients *[p1, 7]*.	Preservation of the institution (hospital), rather than needs of the population they actually serve, seems to be the predominant interest QQ *[p3, 69]*.		Make it clear to patients it's exactly same service in satellite clinic, they are seeing me (same consultant) *[page 1, 16]*.

Table 3: Example of part of a framework matrix taken from Gale et al. (2013)

QUAGOL METHOD

The **QUAGOL (Qualitative Analysis Guide Of Leuven) method** for analyzing qualitative research data consists of two main parts, each comprising five stages.

1. Preparation of coding process

1.1 *Thorough re-reading of the interviews*

In this stage, the interview **transcripts are read thoroughly and repeatedly** to familiarize yourself with the collected data. Key phrases are underlined and thoughts and reflections that may arise are written down in the margins of the transcript. A **short report** is also made describing the contextual characteristics of the interview. If multiple researchers are involved in the project, they individually read and reflect on the interview transcripts.

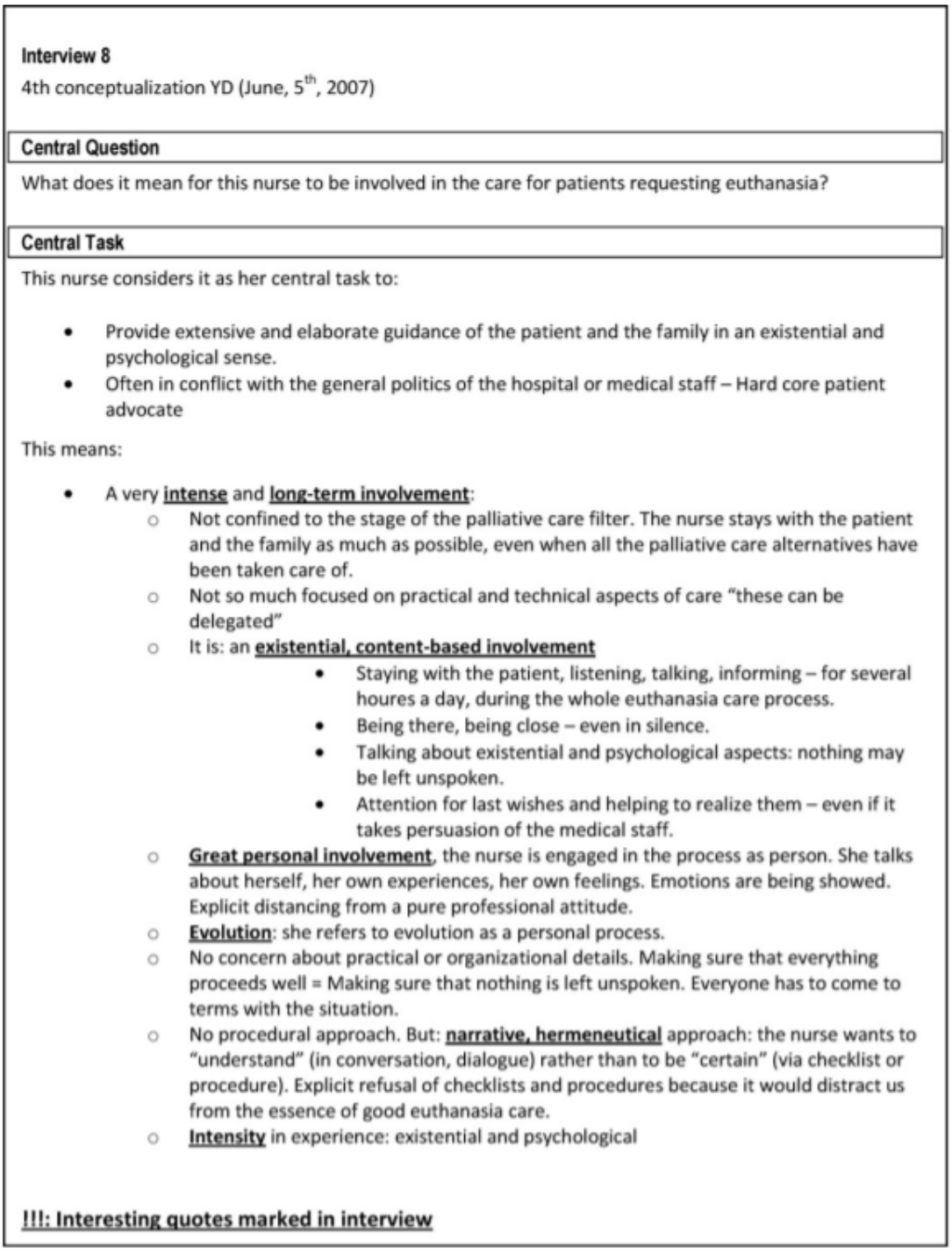
1.2 *Narrative interview report*

The researcher tries to write down the essence of the **interviewee's story in relation to the research question**. Ask yourself the question: what are the essential characteristics of the interviewee's story that may contribute to a better understanding of the research topics? This report, written in a narrative way, can include brief paraphrasings that stays close to data, more abstract renderings of the data and/or comments on the narrative structure or interactional features of the interview event. It is recommended to limit the report to **one page**. Again, each member of the research team individually writes these reports and the results are discussed collectively. It is best to start with the interview(s) that appear to be the richest in information and that provide the most valuable data for the research objective.

1.3 *From narrative report to conceptual interview scheme*

The **conceptual interview scheme** provides concepts that appear relevant to get insight into the research topic. It represents the first move away from the concrete level of experience to the **conceptual level of the story**. The most important data for each interview are filtered and clustered into concepts. These concepts should not be all-encompassing: they need to be

manageable as they will underpin the later coding process. An example of a conceptual interview scheme is given in figure 2.



Interview 8

4th conceptualization YD (June, 5th, 2007)

Central Question

What does it mean for this nurse to be involved in the care for patients requesting euthanasia?

Central Task

This nurse considers it as her central task to:

- Provide extensive and elaborate guidance of the patient and the family in an existential and psychological sense.
- Often in conflict with the general politics of the hospital or medical staff – Hard core patient advocate

This means:

- A very **intense** and **long-term involvement**:
  - Not confined to the stage of the palliative care filter. The nurse stays with the patient and the family as much as possible, even when all the palliative care alternatives have been taken care of.
  - Not so much focused on practical and technical aspects of care "these can be delegated"
  - It is: an **existential, content-based involvement**
    - Staying with the patient, listening, talking, informing – for several houres a day, during the whole euthanasia care process.
    - Being there, being close – even in silence.
    - Talking about existential and psychological aspects: nothing may be left unspoken.
    - Attention for last wishes and helping to realize them – even if it takes persuasion of the medical staff.
  - **Great personal involvement**, the nurse is engaged in the process as person. She talks about herself, her own experiences, her own feelings. Emotions are being showed. Explicit distancing from a pure professional attitude.
  - **Evolution**: she refers to evolution as a personal process.
  - No concern about practical or organizational details. Making sure that everything proceeds well = Making sure that nothing is left unspoken. Everyone has to come to terms with the situation.
  - No procedural approach. But: **narrative, hermeneutical** approach: the nurse wants to "understand" (in conversation, dialogue) rather than to be "certain" (via checklist or procedure). Explicit refusal of checklists and procedures because it would distract us from the essence of good euthanasia care.
  - **Intensity** in experience: existential and psychological

!!!: Interesting quotes marked in interview

Figure 2: Example of a conceptual interview scheme taken from Dierckx de Casterlé et al. (2012)

1.4 *Fitting-test of the conceptual interview scheme*

At this point, the appropriateness of the conceptual interview scheme is verified by **going back to the data**. With the scheme in mind, the researcher re-reads the interview transcripts and asks themselves two questions:

- Does the conceptual interview scheme actually reflect the most important concepts for addressing the research question? Are there any relevant concepts that were overlooked?
- Can the concepts of the conceptual interview scheme be connected to the interview data?

If necessary, the **scheme is adapted, completed or refined** by scrapping, adding or reformulating elements. The scheme can also be optimized through discussions between the members of the research team.

1.5 *Constant comparison process*

This stage is characterized by the **alternating of within-case and across-case analysis**, which will help identify common themes, concepts or hypotheses between the different interviews. The concepts included in the conceptual interview schemes are compared with the schemes and data of other interviews. New themes arising from new interviews are checked for their presence in previous interviews. Gradually, the **common themes and concepts emerge**. The back-and-forth movement is carefully reported using memos that will guide the further analytical process.

2. Actual coding process

2.1 *Draw up a list of concepts*

A **common list of concepts** is composed based on the conceptual interview schemes of the individual interviews. The concepts should not be listed in any hierarchical order. The list is discussed within the research team and subsequently introduced into a CAQDAS program (e.g. NVivo). They are **not yet linked to concrete interview data**.

2.2 *Coding process – back to the 'ground'*

All interviews are read again with the list of concepts at hand and **excerpts from the transcript are linked with one of the concepts** on the list. If a particular fragment cannot be linked to any of the concepts, the list may need to be adapted. Simultaneously, the **quality of the concepts are verified**: codes that are too abstract or too concrete will undermine the efficiency of the coding process and should therefore be revised. Any issues encountered during the coding process are discussed within the research team.

2.3 *Analysis and description of concepts*

In this stage, **all text fragments categorized under a particular concept** are examined in detail. The researcher asks themselves whether excerpts really belong under a specific concept, whether there is **one common message for each concept** or whether the concept should be split into multiple subconcepts or combined with another concept. After that, the **meaning of each concept** can be described based on the empirical data classified under them. This will require a strong collaborative effort from the members of the research team.

2.4 *Extraction of the essential structure*

Using the list of individual concepts and the conceptual interview schemes, the concepts are united into a meaningful **overarching conceptual framework** that is able to tackle the research questions. This framework is then put to the test and cross-checked with each interview transcript and scheme.

2.5 *Description of the results*

With the help of the overarching conceptual framework and the descriptions of the meaning of each concept, the researcher can **write down the interview findings in relation to the research questions**. The core findings should be described first, followed by a characterization of the concepts and how they relate to each other. Where appropriate, **quotes** can be added. Once all the relevant findings have been documented, the researcher again needs to re-read all interviews a final time to ensure that their conclusions are accurate and comprehensive. The results are then ideally discussed in the presence of the members of the research team as well as an interdisciplinary group of external experts.

STEP 11: CONCLUDE THE INTERVIEWS

Steps 6 to 9 can occur in parallel with each other: once an interview has been completed, you can already start transcribing and coding it while waiting for the next interview to take place. New potential participants can be recruited at any time. Try to be as efficient as possible.

Usually, the interviewing process is continued until no more new information emerges from additional interviews. After **data saturation** is achieved, the interviews can be concluded. For confidentiality purposes, the **interview recordings are then deleted** from all of your devices and the **pseudonymized transcripts along with the key are printed and stored in a locked cabinet** at the Faculty until such time as they might be needed for future studies.

STEP 12: REPORTING

When reporting the results of an interview in a peer-reviewed article, it is recommended to be present the results in a systematic manner within the submitted paper.
The following guidelines are useful:

SRQR checklist:
https://journals.lww.com/academicmedicine/fulltext/2014/09000/Standards_for_Reporting_Qualitative_Research__A.21.aspx

USEFUL LINKS & REFERENCES

PRACTICAL LINKS

Analysing your interviews:
https://www.youtube.com/watch?v=59GsjhPolPs

Demonstration qualitative interview – how it should be done:
https://www.youtube.com/watch?v=eNMTJTnrTQQ

How to do a research interview:
https://www.youtube.com/watch?v=9t-_hYjAKww

NVivo 12 tutorial for beginners:
https://www.qsrinternational.com/nvivo/nvivo-12-tutorial-windows/00-let-s-get-started

Qualitative analysis of interview data: A step-by-step guide
https://www.youtube.com/watch?v=DRL4PF2u9XA

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TEMPLATES

Template 1 – Standard email invitation
Template 2 – Informed consent form
Template 3 – Participant information sheet
Template 4 – Participant transparency document
Template 5 – Interview guide
Template 6 – Demographic and clinical information participant sheet
Checklists GDPR compliance
Checklist sequence of events

TEMPLATE 1– STANDARD EMAIL INVITATION

Subject line of the e-mail: Invitation to participate in an interview about […]
Attachments:

1. [Participant Information sheet]
2. [Participant Transparency Information document]
3. [Informed consent form]
4. [Reimbursement guidelines]
5. [UCMU claim form if it is a physical meeting]

Body of the e-mail:

Dear Dr./Mr./Mrs./Miss [+ last name],
I would like to invite you to take part in an interview for a research study that we are conducting about […]. An interview is a one-to-one conversation, guided by the interviewer to learn about your experience in […]. This study is part of a large-scale European project called **Conception** which aims to improve the availability of research evidence regarding the effects of medications used during pregnancy and breastfeeding to improve public health and healthcare. You can find out more about the Conception project here https://www.imi-conception.eu

You are being invited because you are [part of a particular stakeholder group, have had a particular health or pregnancy or baby experience…]. We have identified your name through […]
The interview will be held on [date[3]] and last approximately […] hours. It will take place at [this location OR remotely using this technology]. The interview will take place in the [nationality or region] language.

I am attaching the participant information document that explains more about the research project and the way in which we intend to conduct the interview, including how information will be used. This includes the principles we follow when we run events like this.
I would be happy to answer any questions you have by email or telephone, using my contact details below. If you are willing to participate, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below.

I am attaching the participant information document that explains more about the research project and the way in which we intend to conduct the interview, including how information will be used. This includes the principles we follow when we run events like this.

[3] If the date is not yet known, an approximate date such as the month and year should be given, and an indication of when the final date will be provided. If participants will be consulted about their availability for a set of date options, then the text should indicate when and how this availability will be requested.

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3000 LEUVEN, BELGIUM

I would be happy to answer any questions you have by email or telephone, using my contact details below. If you are willing to participate, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below. Please do not hesitate to ask questions at this stage if anything is unclear.
Thank you in advance for your participation,
Kind regards,

[Signature
Name
Designation
Email
Telephone
Address for correspondence]

TEMPLATE 2 - INFORMED CONSENT FORM

Title of the study: [...]

Contact person: [name and first name]
[email]
[phone]
[department, organisation]
[address]

Filled in by the PARTICIPANT

Please tick the boxes you agree with. You will only be asked to participate in the interview if you are comfortable to agree to all of these points.

- ☐ I have read the information concerning this study and I have had an opportunity to ask questions or discuss any concerns about it;
- ☐ I was given sufficient time to decide whether I am willing to participate in this study;
- ☐ I am aware that participating in this study is completely voluntary;
- ☐ I am aware that I can decide to withdraw at any point, without having to give a reason;
- ☐ I give permission for information about me and the information I provide during and after the interview to be used in the ways described in the participant information document.
- ☐ I have received the information sheet and I hereby confirm my voluntary participation in the study.

Filled in by the PARTICIPANT

_____	_____	_____
Name participant	Signature participant	Date

Filled in by the RESEARCHER

I have discussed the content of the invitation and the information with the above-mentioned person. I have asked for any additional questions and I have answered these.

_____	_____	_____
Name researcher	Signature researcher	Date

TEMPLATE 3– PARTICIPANT INFORMATION SHEET

KU LEUVEN

Title of the study: [...]

Contact person: [Name contact person]
[email]
[department]
[address]
[tel]
[add other contact persons]

Dear,

You are being invited to voluntarily participate in an interview on [...]. An interview is a one-to-one guided discussion, in this case so that we can learn about your experience in [...]. During that interview you will be offered the opportunity to contribute your ideas and opinions relating to [...]. The following topics will be discussed:

[Overview of topics that will be discussed during the interview].

Before you confirm your participation in this study, we ask you to read this information sheet carefully. I would be happy to answer any questions you have by email or telephone, using my contact details below.

If you are willing to participate after any telephone call or email exchange, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below.

Signature
Name
Designation
Email
Telephone
Address for correspondence

What is the purpose of the study?

[…]

Who is conducting the study?

This study is part of a large-scale European project called Conception which aims to improve the availability of research evidence regarding the effects of medications used during pregnancy and breastfeeding to improve public health and healthcare. You can find out more about the Conception project here https://www.imi-conception.eu

Has an Ethics Committee approval been required for this study?

An Ethics Committee is a group of people who are responsible for protecting participants' rights. [Insert text to explain that ethics committee approval has been granted, or why it was not required]

The Conception project has produced a set of ethical principles that all of our meetings adhere to. I am including a copy of these principles, for your information.

[Include a copy of our external stakeholder engagement principles, which are still being refined to be public-friendly.]

Your participation in the interview

The interview will be held on [date] and last approximately […] hours. It will take place at [this location OR remotely using this technology]. The interview will take place in the [nationality or region] language. There is no cost associated with participating in this interview and you will not receive any compensation to take part. However, we are able to reimburse your travel costs for attending the meeting, according to the accompanying reimbursement guidelines. Your contribution will help us explore these issues, meaning that there are no wrong answers; we are interested in everything you have to say.

What is asked of me?

Participation in the interview is entirely voluntary. You do not have to take part and you can decide to withdraw at any point, without having to give a reason. You do not have to answer any questions during

the interview that you do not feel comfortable answering. Your contribution will help us understand the views different people have on our research topics.

The meeting will be run by an expert in the subject being discussed, who also has experience in running meetings. You will be asked to comment on questions within the interview, but only on topics you feel comfortable contributing to. The person running the interview will make sure that the atmosphere is always friendly and that your viewpoints are welcomed. Your ideas, viewpoints and opinions will be taken seriously.

What information will be kept about me, and how will it be protected?

Please see the accompanying transparency information document that explains this in detail.

TEMPLATE 4 – PARTICIPANT TRANSPARENCY INFORMATION DOCUMENT

Title of the study: [...]

Purpose of the study and the legal basis

The personal information that we will hold about you will be for the purpose of conducting an interview as part of a larger research project, ConcePTION, which is described in detail in the attached Patient Information document.

The formal 'controller[4]' of the personal data[5] is: [...] which can be contacted at: [...]

The legal bases for processing this information under the General Data Protection Regulation (GDPR) are:

- Article 6(1)e and Article 9(2)(j) - public interest in scientific research
- Article 6(1)f – legitimate interests in conducting research and Article 9(2)(j) - public interest in scientific research and statistical purposes

Select one of the above bullets, as appropriate: first for academic; second for pharma/commercial, but then need to explain legitimate interests. Check with your Data Protection Officer (DPO).

What information will be kept about me?

1. If you agree to participate, your name, your contact details and a copy of your signed consent form will be kept by the organisation running this interview, [organisation name], as a record that we had your permission to join the interview. Additional information such as your banking details may be required and kept if we arrange to reimburse you for travel costs.
2. If you do not agree to participate, we will delete records of your name once the interview study is complete, and there will be no permanent record that you were invited or that you declined.
3. We normally make an audio recording of interview in order to assist with writing a report of the discussions which took place. The audio recording will later be written out, so we have a written record of the discussions. A few people in our team will also take notes during the discussions. These materials will include your voice or your name, and so this will be identifiable information. This personal information will be kept securely, and only made

[4] A Data Controller is an individual or organisation who determines the purposes for which and the manner in which any personally identifiable data is or will be processed. It is the responsibility of the Data Controller to ensure that any processing of personally identifiable data has an appropriate legal basis.
[5] Personal data is information about an individual which identifies who that person is or could be used to identify who the person is. The personal data about you that will arise through participating in this interview is described in the next section.

available to members of the team running the interview or analysing the data, for the purpose of creating the interview report.

4. The interview report will be a summary of the topics that were discussed and the viewpoints that were raised on each topic. The report will not state who made each comment, and any examples that you mention in your comments that might give a clue about who you are will be changed so that you could not easily be identified from the information in the report.
5. Interview reports normally also describe the kinds of people who were participating in it. This is usually done by including a list only giving the age, gender, and possibly the occupational group or other relevant experience or health background of the participants. Care is taken to make these descriptions non-specific, so that somebody outside the interview reading the report would not be able to tell who had been invited.
6. It is sometimes good to include quotes of what somebody said during the discussions. If any of your remarks are used as quotes, care will be taken to ensure that these quotes don't identify you, by including just a few words or a sentence.
7. Once the interview report is complete, the research team will often create some additional shorter reports, and also probably create a scientific paper that will be published in one of the leading journals. These materials will also avoid using any interview content that could identify a participant.
8. Once all of these materials have been finalised, and scientific papers have been published, the original audio recording, transcription and notes taken during the meeting are no longer accessible to the majority of the research team, but are kept securely in case there is a need to check them again, for [...] years.

The eight points listed above are the usual procedures for handling information relating to an interview.

[Please note if the personal data will be shared with any other parties]

How long will my personal data be stored?

Records containing your personal data such as the audio recording, transcription of the audio and meeting notes, will be retained for a period of maximum [N years] from the end of the study. Audio recordings and computer files will then be deleted, and paper copies will be destroyed. Financial records will only be retained for [7 years].

What rights do I have concerning my personal data?

Under data protection laws you have certain rights that are also respected:

- the right to be informed about the processing of any data about you (as described here);

- the right of access to see or receive a printed copy of any personal data relating to you;
- the right to rectification – to correct any material errors in the personal data we may recorded about you;
- the right to erasure – to ask that all personal data about you is erased if appropriate to do so;
- the right to restrict processing – to ask that we stop processing your data specifically;
- the right to data portability – to have an electronic copy of any data you provided directly;
- the right to object to and not to be subject to automated decision-making, including profiling. There will be no automated decision-making, so this does not apply.

How can I exercise these rights?

Please contact the Data Protection Officer (see below) and this is what will be done in response to your request:

1. If you ask to see what personal information is being held about you, then you will receive a copy of that information, either as an full copy or as a copy with any information about other people removed.
2. If you ask us to correct any errors, then we would usually be happy to do so as we would wish to reflect the views you expressed correctly in our report,
3. If you decide to withdraw before attending the interview, and without having made a claim for travel reimbursement, we can delete all of the information held about you, as if you had never been contacted to participate.
4. If you attend the interview, and if you have claimed any travel reimbursement costs, then the organisation will need to retain a copy of the information they have used for financial audit purposes, even if you withdraw from the interview and the study.
5. If you decide to withdraw from the interview, or if you request that some or all of your comments to the interview be removed, then those remarks that came from you will be deleted from the interview report. Your entry in the list describing the participants can be deleted, before the report is published.
6. It might be difficult, perhaps impossible, to eliminate viewpoints from the report that that summarizes comments made by multiple people including you, but we will try to ensure that your specific points will not be recognizable within the material.

If you would like to review, correct, update, restrict, object to the processing or delete your personal data, or if you would like to receive an electronic copy of the personal data you have provided, you should contact one of the persons mentioned at the top of this form.

Your request for data deletion will be addressed within 30 days after your request has been confirmed. Such request may not be fulfilled in case that deletion renders or seriously impairs the study objectives, or in the case that regulations and laws that apply to this research require this data to be retained, but this will be explained in our response to you.

Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws require your personal data to be retained.

You can request the contact persons mentioned at the top of this form to forward any questions, concerns or complaints you may have to the data protection officer of their institution. You are also welcome to contact the data protection officer directly.

If you would like to receive the results of the research or of the final report, you should contact one of the persons mentioned at the top of this form.

You also have the right to complain to the relevant data protection supervisory authority, which can be contacted at: [...]

Whom do I contact with any questions about my personal data?

For questions about your participation in the interview, please contact:

[...]

For questions about your personal data and your data protection rights, please contact our Data Protection Office/Officer:

[...]

TEMPLATE 5 – INTERVIEW GUIDE

Introduction

- **Present yourself**

  First, allow me to present myself. My name is […] and I am a […] at the KU Leuven working at the Clinical Pharmacology and Pharmacotherapy research unit under the supervision of Professor […]

- **Thank** the interviewee for his/her participation in advance

  I would like to thank you already for taking the time to participate in this interview. Your views are very important to our research.

- Explain **shortly the purpose** of the interview:
  - *With this interview we want to **[insert research objective]*** (keep it brief)
  - *The interview will take about **1 hour.***
  - *Results will **be implemented** in [my Master thesis/my PhD dissertation/a report/publications of the research group supervising this thesis/…]*

- Put the interviewee **at ease**:
  - *I want to emphasize that there are no right or wrong answers, and that it is no problem if you might not know the answer. In that case, it would be great if you could recommend us the name of a contact person who could clarify this aspect.*
  - *This interview will be **digitally recorded**. This makes it easier for us to process all information that is provided in the interviews. Anything you say today will be completely **confidential**, and will be processed **anonymously**, meaning we will not use your name or any personal/company details, unless agreed otherwise. The data collected today will be stored securely and viewed only by approved researchers on this project. Participation is **completely voluntary**, you can **withdraw** at any point (no explanation needed). You **do not have to answer** any questions during the interview if you do **not feel comfortable** answering them.*

- *Do you have any **questions** before we start the interview?*

- *We will start with some warming-up questions. Subsequently, we will turn on the recording function and focus more on the research questions which are organized across [insert number of themes] main themes. The first theme concerns […], the second theme will focus on […], the third theme will deal with […], [insert additional themes]*

Questions

I. Introductory questions

- *Could you please start with introducing yourself?*
- *How long have you been working in your current position?*
- *What are your expectations of this interview?*

- *Let's start with the research questions now. Do I have your permission to turn on the recording function?*

II. Questions about the theme [...]

[Insert questions]

III. Questions about the theme [...]

[Insert questions]

IV. Questions about the theme [...]

[Insert questions]

[add additional themes if necessary]

V. Round-up questions

These were all the questions I had for you. ***Thank you*** *very much for participating.*

- *Do you want to* ***add*** *anything else?*
- *Do you want to* ***emphasize*** *something?*
- *Do you think we* ***forgot*** *something?*
- *Do you think we've* ***overlooked*** *some relevant questions?*
- *Do you have any* ***questions for me****?*
- *Do you have a suggestion for* ***other interesting interviewees concerning this topic****?*

- *I will turn off the recording now.*

Conclusion

Thank you *for your participation.*
If you have any other questions, comments, or want to get in touch with me, please do not hesitate to ***contact me.***

TEMPLATE 6 – DEMOGRAPHIC AND CLINICAL INFORMATION PARTICIPANTS

Characteristics	Stakeholders (n= […])	
	n	%
Sex		
Females		
Males		
Age (years)		
18-24		
25-39		
40-60		
>60		
Country		
[…]		
[…]		
[…]		
[…]		
[…]		
Education		
No diploma		
High school		
Bachelor's degree		
Master's degree		
PhD		
Stakeholder group		
[…]		
[…]		
[…]		
[…]		
Disease area		
[…]		
[…]		
[…]		
Years since diagnosis		
[…]		
[…]		
[…]		

CHECKLIST TABLES

This table can be deleted from the final version, but should be retained and updated until the final version to ensure that the leaflet is GDPR-compliant in all respects

	GDPR Article 13 Checklist	Notes/comments
	Information to be provided where personal data are collected from the data subject	
	1. Where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:	
✓	(a) the identity and the contact details of the controller and, where applicable, of the controller's representative;	Must be added
✓	(b) the contact details of the data protection officer, where applicable;	Must be added
✓	(c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;	The appropriate legal basis must be chosen
✓	(d) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;	If 'legitimate interests' used then an explanation is required
?	(e) the recipients or categories of recipients of the personal data, if any;	Admittedly this is just a template, but should be clearer about participating institutions and any onward sharing of the personal information
?	(f) where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.	
	2. In addition to the information referred to in paragraph 1, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:	
✓	(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;	Give appropriate time periods

	GDPR Article 13 Checklist	Notes/comments
✓	(b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;	
✓	(c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;	
✓	(d) the right to lodge a complaint with a supervisory authority;	Appropriate contact details must be added
✓	(e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;	It is clear that provision is voluntary
✓	(f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.	
✗	3. Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2	It is not clear if the information gathered may be used more widely or is only for this study, so just the single purpose

The intended sequence of events:

This table can be deleted from the final version, but should be retained and updated until the final version to ensure that the leaflet is GDPR-compliant in all respects

	Physical	Electronic	Notes/comments
1.	Amend templates	Amend templates	Arrange to be checked/approved
2.	Generate letters & attachments	Generate emails/ add attachments	& post/send after review
3.	Wait for responses	Wait for responses	
4.	Arrange calls/respond to emails or letters	Arrange calls/ /respond to emails or letters	
5.	Decide best date[6] for meeting & send meeting details with expenses form	Decide best date for meeting & send suitable meeting invitation	
6.	Check logistics - need to make clear how to get to venue	Check logistics - any requirements for online meeting (exactly how to access)	Just so participants are clear as to what to do
7.	Check for signed consent forms	Check for signed consent forms – note: some users may not be able to scan, so may need a suitable online alternative	May need to get REC to approve online 'consent form'
8.	Researcher countersigns forms	Researcher countersigns printed forms or list?	How should researchers countersign electronic forms?
9.	Run meeting	Run online session	Have recording & notes
10.	Type transcript	Type transcript	
11.	Check expense claims	N/A	
12.	Send expenses	Send thank-you letter	
13.	Develop study notes	Develop study notes	Convert transcript to pseudonymised form
14.	Archive original notes/transcripts	Archive original notes/transcripts[7]	Retain only pseudonymised study data
15.	Destroy expense claim forms &	N/A	After 7(?) years
16.	Destroy original notes/transcripts		After 20 years

[6] The 'best date' may already have been decided – so this would occur at or before Step 1; the original proposal had a 'floating date'/location, so form would need to ask about availability, etc.

[7] May need to check what would be held on any online platform, though likely to be retained for only short period, but might include IP Addresses or if requires registration, then more personal data

	Physical	Electronic	Notes/comments
17.	Archive or destroy remaining study files		After 20 years?

INTERACT PRACTICAL GUIDES[8]

FOCUS GROUP DISCUSSION

TABLE OF CONTENTS

[8] INtroduction To hEalth ReseArCh meThods' (INTERACT) guideline

Step 1: Perform a literature review

Before starting a focus group discussion it is important that the moderator is well informed and has enough background information. In order to realize this you can carry out a **literature review**. For this, you can decide to perform for example a systematic literature review (cfr. Separate practical guide). This literature review is of importance in order to get a general idea of the problem and to identify the topics that will be discussed during the focus group discussion. Problems where no answer is found in the literature can be chosen to discuss with a focus group.

Step 2: Define the purpose of the focus group discussion

The modulator of the focus group has gained a wide background after literature reviewing. Whit this in mind you are ready for the next step, which is defining a clear **purpose** of the focus group. Questions that could be asked are for this are:

- What information would you like to obtain ?
- What type of information is important ?
- How would you use the information ?
- For who is the obtained information ?

Step 3: Define and recruit participants

After performing a literature review and formulating the goal that you would like to achieve with the focus group discussion, you should have an idea of the stakeholders that should be included in the focus group discussion. Possible participants of a focus group discussion are:

- Patients with a specific disease
- Healthcare providers
- Clinical investigators
- Clinical research associates
- …

Further specification of the participants can be obtained by applying inclusion and exclusion criteria when recruiting the participant. Possible criteria can be:

- Expertise: *e.g. has expertise in the domain of oncology*
- Experience: *e.g. has been a principal investigator on at least 3 clinical trials before*
- Language: *e.g. must be able to speak English fluently*
- …

A focus group discussion is a planned and well organised discussion between the participants where they share their opinion, experiences, motivation etc. In order to keep this discussion organised it is necessary that the group is of a good size. Generally, a **minimum of 5** participants is necessary in order to have enough interaction between the different participants. On the other hand, more than **10** participants is not desirable as not everyone will be able speak and to fully express them self. Moreover,

for the first discussion it is possible to have a **homogenous group** consisting of participants whit some characteristics in common concerning the topic. In this way they are more comfortable, speak more openly, can share ideas. In later focus group discussions a more **heterogenous group** (e.g. different age, grade of education) can be formed in order to confront different opinions.
Once the participants of the focus group are defined, an **email** will be send with an information sheet in order to get familiarised with the topic that will be discussed. Give the potential participants some time to respond. If you haven't heard anything back from them after a two-week period, you can send a **politely worded reminder**. A template for a standard email can be found in attachment.

STEP 4: FORMULATE QUESTIONS FOR FOCUS GROUP

Literature reviewing gave you broad background information, where after you were able to formulate a well-defined purpose for the focus group discussion. Next, adequate questions need to be prepared in order to get the focus group discussion in the wright direction.
Generally the questions are **not too long** and straightforward in order to create an optimal possibility for interaction between the participants. For this it is first of all important to formulate **open questions** instead of yes/no question. Secondly, these open questions preferably are **no "why" questions**. By transforming a why question into multiple smaller questions, participants will more likely answer from intuition instead of giving a rational answer. Example of how a why questions can be transformed:

Why do you participate ? → ***What*** *made you decide to participate?*

You may start brainstorming for broad questions and ending with more specific questions on the subject. Afterwards similar questions can be grouped and you can bring them to one question. A combination of different types of questions, each with distinct purpose, can be used during the focus group discussion:

- Opening question:
  This is a question for all the participant in order to have characteristics of them in a short time. This is a **general question** without looking for an opinion of the participants.
  e.g.: How did you end up here? What is your job ?
- Introductory question:
  By asking such a question the **subject is introduced**. Stakeholders will be able to reflect on there experiences. An introductory question is not critical for the analysis, but has the purpose to start the discussion.
  e.g.: What do you think of when we say … ?
- Transition questions:
  These questions are a **link** from the introduction **to the key subject** of the focus group discussion. Participants will see the subject wider by responding to these transition questions and will get an idea about how the others think about the subject. These questions are possibly in the form of statement, whereof the participants have to give their opinion.
  e.g.: When you first heard of …. , what was the first thing that came to your mind?

- Key questions:
  The key questions are the most important questions specific about the **subject**. Mostly 5 to maximum 10 questions are asked.
- Ending question:
  This are questions to **complete the discussion** and gives the participants the time to reflect on the given comments. Three different types of ending questions exist:
  1. **All things considered question:** are questions that make the participants to reflect on the discussion and to form their opinion.
     e.g.: What would you say to person X if you had one minute to tell about today's topic?
  2. **Summary question:** is asked after you have summarized the main conclusions of the key questions.
     e.g.: Is this an adequate summary?
  3. Finally, after the summarizing question, you finish the discussion with a **final question**.
     e.g.: Have we missed something?

STEP 5: PREPARE A GUIDE FOR FOCUS GROUP DISCUSSIONS

During the discussion of the different questions, data is collected. In order to collect this data efficient it is desired to have an organised discussion. For this a guide for focus group discussions can be used. This is a **logically structured framework for the modulator** and will make it possible for him to stimulate further discussion without directing it to much as well as give the possibility to discuss unexpected issues that can be relevant. Ideally it will make possible to start the discussion general and end more specific. The different steps that are included in the guide are given below.

- INTRODUCTION
  - Welcoming the participants
  - Present yourself and assistant
  - Thank the participants
  - Short explanation of the goal of the focus group and mention that all ideas are welcome. There are no wrong answers to the questions.
  - Short explanation of practical details (interview duration, publication of results, explanation of participants' rights, recording of the session)
- QUESTIONS
  - Opening question
  - Introductory question
  - Transition question
  - Key question
  - Ending question
- CONCLUSION

- Final word
- Thank to participants

A template guide for a focus group discussion can be found in attachment.

Step 6: Preparation of moderator and assistant

To make a session run smoothly it is necessary to be two persons to guide the session, being the moderator and assistant. Both need to be well prepared for the focus group discussion, which can be done by going over the guide and make the tasks clear.
The **moderator** needs to know how to handle each type of group ,which can vary between two extremities of a silent as well as a very enthusiast group. Therefore the moderators tasks are:

- Fluent passage from one question to another
- Adequate knowledge of the topic
- Exercise mild unobtrusive control
- Appears like the participants
- Use purposeful small talk
- Alert and free from distractions (put sound of phone off and do not have your phone on you)
- Have the discipline of listening and apply active listening
- Familiar with questioning route
- Take into account the different types of participants (dominant talkers, shy participants, etc.) and try to balance the conversation while addressing the obligatory topics

It is the moderators role to get deeper in the discussion of the questions. This can be done by asking questions such as "*Can you explain further?* " or *"Can you give an example?* " .
The moderator is assisted by an **assistant** who has the following tasks:

- Handles logistics (location of refreshments, bathrooms, emergency exits)
- Take additional notes and observations of the verbal and nonverbal reactions, the seating of the participants
- Make sure that all participants are participating equally. Otherwise this is communicated to the moderator.
- Monitoring the recording
- Time management and communicating this to the modulator.
- Gives a summary at the end of the focus group
- Collects consent forms and surveys

Step 7: Practical preparations before start

Before the start of the focus group discussion several practical things have to be arranged. First of all a venue/room needs to be booked. Make sure to book the room 30 minutes longer than the expected

duration of the focus group discussion. Preferably the sessions take place in a **neutral environment** which is accessible for all participants, has absent of background noice that could disturb the recording and which is provided with a **table**. Ideally instructions to get to the venue and room are provided for the participants.

- NEUTRAL: *e.g. hotel, university*
- NOT NEUTRAL: *e.g. government, company*

Finally, if possible, the information sheet could be provided to all participants in advance via email as well as your/assistants' phone number(s). In this way all the participants will be able to optimal participate to focus group discussion.

TIPS & TRICKS

To make sure that the booked room is free of background noise and contains a table which make it possible to sit in a circle with all the participants, it is always a good idea to visit the venue before booking.

STEP 8: ETHICAL APPROVAL

In order to start the focus group discussion, approval is necessary from **ethical committee**.
The data collected during the focus group discussion will always be treated confidentially and never made public. For this, the participants will be given a code (pseudonymised) and only the researchers will be able to identify the participants.
Participants will be informed oral and written about the objectives of the research. All information and **informed consent** will be send in advance and potential participant will have enough time to consider their participation or to ask questions. A template of the informed consent can be found in attachment.

STEP 9: CONDUCT A PILOT DISCUSSION

Once the moderator and assistant have overseen the guide for the focus discussion and are familiar with their tasks, a pilot discussion can be organised. In this way both moderator and the assistant can see of they are well prepared and they can test if the questions are good or need to be revised. For this, only one participant is necessary.

STEP 10: CONDUCT THE FOCUS GROUP DISCUSSION

Now that all the preparations have been made, the focus group discussion can start. During this approximately 2-hours discussion, the moderator should try to follow the guide, but is not obligated to finish all the topics. It is better to go in depth on some topic in stead of rushing over all the topics. It is best if the moderator is familiar with the questioning route.
The focus group will generally take place **three times**. Most information is collected during the first and second session. In a third session you can balance if a fourth session is necessary.

Depending on the location of the participants, it is possible to have a face-to-face discussion or to conduct the focus group discussion by teleconference. If all participants have the same native language, the discussion can be conducted in this language. Otherwise it is possible to conduct the focus group discussion in English.

FACE-TO-FACE FOCUS GROUP DISCUSSION

Some considerations have to be taken into account when conducting a face-to-face focus group discussion:

- **Test** the recording devices in advance, if possible in the same room as where the discussion will take place
- Be **30 minutes in advance**, in this way you have enough time to find the room and do some preparations
- Take **two audio records** (+ extra batteries) with you and place these on the table at the opposite side
- Have enough information sheets, consent forms and surveys with you
- Provide enough **writing material and paper**
- Bring a **laptop** and set up the PowerPoint presentation
- Provide **name cards** (only first name of the participants) and put these on the table
- Provide drinks (water/coffee/tea) and something to eat
- Make sure that all participants are seated in a **circle around a table**
- Always **ask for permission** prior to turning on the recorder
- **Do not turn on the recorder until the research questions start**
- After the focus group discussion has been concluded, immediately make a **back-up of the audio files** you recorded on a separate thumb drive

REMOTE FOCUS GROUP DISCUSSION

Most of the earlier mentioned considerations also apply to remote focus group discussions , but some additional considerations should be kept in mind.

- Ensure that your **internet connection is stable**
- Make sure that you enter the virtual conference room **at least 15 minutes in advance**
- While waiting for the participants of the focus group discussion to arrive, **test your audio and camera**
- **Communicate in advance** that they should call in from a quiet room where there is a good internet connection
- **Book** or arrange a **quiet room** for yourself so that you don't get interrupted
- Send a Skype invitation to the participant in advance instead of calling them up directly, but have their number ready in case something goes wrong
- Turn the **camera on** during the discussion
- **Record** the focus group discussion **in duplicate**: do not only use Skype's built-in recording function but also other software (e.g. MP3 Skype Recorder)

- If the camera cannot be turned on (e.g. due to it slowing down the connection or because the participant is calling in on their phone), the use of **verbal cues** is essential to let the interviewee know that you are still on the line
- Have a **back-up system ready**: if Skype doesn't allow for a stable connection, try Zoom or a different program
- If the connection is interrupted, ask the participant to repeat themselves

When the focus group discussions are closed, make sure you save the audio records on our computer by using a clear but anonymous name for your file.

STEP 11: TRANSCRIBE THE FOCUS GROUP DISCUSSION

Once the focus group discussions are finished and the audio files are correctly saved on your computer, it is time to **type** them **out *ad verbatim***. This means that the audio records need to be typed out literally (including mistakes, stop words, 'uhms', laughter , …). However, note that this is a **very time-consuming** process: generally experienced transcribers need 8 hours to transcribe an audio of 2 hours. The audio fragments will be played of several times before every single word will be well understood and typed out. It is important to **plan enough time** for this step.

If you have a lack of time, it is possible to **hand over** the transcription to a specialised company or job student. Companies that you could contact are Rev, TodayTranslation, TranscribeMe etc. You must keep in mind that for long audio records this can quickly get quite expensive (+/- 90 dollars/hour). Secondly, a cheaper alternative, is to appeal to job students from KU Leuven. Herby you have to keep in mind that these persons are not known with the context, which make it possible that they do not understand specific terms. Additionally, a job student may not have experience in transcribing and have difficulties in understanding the accent of the participants. So, be aware of possible mistakes in the finished transcript and always **check** the final work. In order to improve next transcripts, it could help to give feedback to the job student.

TIPS & TRICKS

If you intend to use the services of a transcription company, you can ask for quotes and try to negotiate the price down by playing them against each other (although some companies may apply a standard price). Furthermore, depending on the quantity of discussions, you may be eligible for a discount.

When you rely on job students, you can let them take a test in order to see if they are a good candidate for this work. For example they got 1 hour to transcribe a 15 minutes audio-fragment.

STEP 12: ANALYSING, INTERPRETING AND REPORTING OF THE DATA

Thematic analysis is a common used method to analyze quantitative data and consists of the following steps.

1. DATA FAMILIARIZATION

The first step of the thematic analysis is getting **familiar with the collected data**. Firstly, you can do this by being **present at the focus group discussion**, either as moderator or assistant. The transcript will be

literal since a thematic analysis is about what is said and less about how it is said. It is the role of the moderator and/or assistant to check in this stage if the **literal transcript** is complete and accurate. If there are difficulties in understanding the transcript, there will be discussed in order to agree together about what is said in the focus group discussion. Once the transcript is complete, it is good to **thoroughly read it several times**. This will help you in getting familiar with the collected data.

2. Initial coding generation

In this stage you are not identifying themes yet, but you place **labels** that will describe the content of 1, 2 or 3 lines. These codes are preferably based on an **abstraction**. The more abstract they are, the better the final themes will be. When making codes, you can choose between a theory-led or a **data-led approach**. In the last case, the codes are primarily guides by careful analysis of what is in the data. Sometimes it is necessary to rename codes that are covering the same meaning so they have the same wording. If several focus group discussions are hold, the coding can be done by multiple analysers. If this is the case, then they have to convene and review all the coded text after they have independently coded the entirety of the data. Reviewing all the coded text can reveal that:

- A coding label is not accurate/precise enough. In this case the code needs to be renamed
- Sometimes some data in a certain code does not match and a new code will be formed
- When the coded text below two codes is too similar, the codes need to be combined to one

A final list of initial codes is obtained after the review of the different codes.

3. Search of themes

Next, the initial codes are turned into themes. This requires of lot of analytic work and involves searching for patterns among the initial codes. By grouping and categorizing the codes, the themes can be formed. In some cases the themes are obvious , but in other cases it might be useful to use methods of sorting. This can be for example by writing down all the initial codes on a separate slip of paper and creating piles if related codes. The themes can be searched independently upon the initial codes, and later on discussed and agree in order to find themes upon the initial codes.

4. Review themes

At this stage you have a set of tentative themes, which help you to understand the data. As the data was organised around the codes previously, so is with the reviewing of themes the **data organized around the set of themes**. During this stage there is a critical revise whether the theme should be:

- Abandoned or modified, when there is very little in the data supporting the theme
- Divided or subdivided when the data in one theme imply two different themes or sub-themes
- Replaced by a new theme if some of the data that you originally believed to be part of the theme, does not fit in the theme.

5. Theme definition and labelling

In this final stage the **final list of themes and sub-themes** is made. This is done by **discussing** as well as **defining exactly** the different themes. Herby it is important that you can **distinguish** the different themes from each other. Additionally it is good to talk to other people and to allow them to question you. Finally after discussion, you agree upon the final list of themes.

6. Report writing

In the final report you **explain and describe the themes** you have identified. Different criteria can be applied to select an **appropriate excerpts to illustrate** your final themes. These criteria are:

- How "typical" the material is of the data which belong to particular theme
- How "fit" the material is in relation to the theme

When reporting the results of an interview in a peer-reviewed article, it is recommended to be present the results in a systematic manner within the submitted paper.
The following guidelines are useful:

SRQR checklist:
https://journals.lww.com/academicmedicine/fulltext/2014/09000/Standards_for_Reporting_Qualitative_Research__A.21.aspx

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TEMPLATES

Template 1 – Standard email invitation
Template 2 – Informed consent form
Template 3 – Participant information sheet
Template 4 – Participant transparency document
Template 5 – Interview guide
Template 6 – Demographic and clinical information participant sheet
Checklists GDPR compliance
Checklist sequence of events

TEMPLATE 1– STANDARD EMAIL INVITATION

Subject line of the e-mail: Invitation to participate in a focus group study about […]
Attachments:

6. [Participant Information sheet]
7. [Participant Transparency Information document]
8. [Informed consent form]
9. [Reimbursement guidelines]
10. [UCMU claim form if it is a physical meeting]

Body of the e-mail:
Dear Dr./Mr./Mrs./Miss [+ last name],
I would like to invite you to take part in a focus group discussion for a research study that we are conducting about […]. A focus group is a diverse group of people assembled to participate in a guided discussion, in this case so that we can learn about their experience in […]. This study is part of a large-scale European project called **ConcePTION** which aims to improve the availability of research evidence regarding the effects of medications used during pregnancy and breastfeeding to improve public health and healthcare. You can find out more about the Conception project here https://www.imi-conception.eu
You are being invited because you are [part of a particular stakeholder group, have had a particular health or pregnancy or baby experience…]. We have identified your name through […]
The focus group discussion will be held on [date[9]] and last approximately […] hours. It will take place at [this location OR remotely using this technology]. The discussion will take place in the [nationality or region] language.
I am attaching the participant information document that explains more about the research project and the way in which we intend to conduct the focus group session, including how information will be used. This includes the principles we follow when we run events like this.
I would be happy to answer any questions you have by email or telephone, using my contact details below. If you are willing to participate, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below.
I am attaching the participant information document that explains more about the research project and the way in which we intend to conduct the focus group session, including how information will be used. This includes the principles we follow when we run events like this.
I would be happy to answer any questions you have by email or telephone, using my contact details below. If you are willing to participate, I would be grateful if you would email me a scanned signed copy

[9] If the date is not yet known, an approximate date such as the month and year should be given, and an indication of when the final date will be provided. If participants will be consulted about their availability for a set of date options, then the text should indicate when and how this availability will be requested.

of the accompanying consent form or post it to me at the address given below. Please do not hesitate to ask questions at this stage if anything is unclear.

Thank you in advance for your participation,

Kind regards,

[Signature
Name
Designation
Email
Telephone
Address for correspondence]

TEMPLATE 2 - INFORMED CONSENT FORM

Title of the study: [...]

Contact persons: [name and first name]
[email]
[phone]
[department, organisation]
[address]

Filled in by the PARTICIPANT

Please tick the boxes you agree with. You will only be asked to participate in the focus group if you are comfortable to agree to all of these points.

- ☐ I have read the information concerning this study and I have had an opportunity to ask questions or discuss any concerns about it;
- ☐ I was given sufficient time to decide whether I am willing to participate in this study;
- ☐ I am aware that participating in this study is completely voluntary;
- ☐ I am aware that I can decide to withdraw at any point, without having to give a reason;
- ☐ I give permission for information about me and the information I provide during and after the focus group session to be used in the ways described in the participant information document.
- ☐ I have received the information sheet and I hereby confirm my voluntary participation in the study.

Filled in by the PARTICIPANT

_____	_____	_____
Name participant	Signature participant	Date

Filled in by the RESEARCHER

I have discussed the content of the invitation and the information with the above-mentioned person. I have asked for any additional questions and I have answered these.

_____	_____	_____
Name researcher	Signature researcher	Date

TEMPLATE 3– PARTICIPANT INFORMATION SHEET

Title of the study: [...]

Contact persons: [Name contact person]
[email]
[department]
[address]
[tel]
[add other contact persons]

Dear,

You are being invited to voluntarily participate in a focus group discussion on [...]. A focus group is a diverse group of people assembled to participate in a guided discussion, in this case so that we can learn about their experience in [...]. During that discussion you will be offered the opportunity to contribute your ideas and opinions relating to [...]. The following topics will be discussed:
[Overview of topics that will be discussed during the focus group discussion].
Before you confirm your participation in this study, we ask you to read this information sheet carefully. I would be happy to answer any questions you have by email or telephone, using my contact details below.
[Explain the subject/problem that will be discussed during the focus group discussion].
If you are willing to participate after any telephone call or email exchange, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below.
Signature
Name
Designation
Email
Telephone
Address for correspondence

What is the purpose of the study?
[...]
Who is conducting the study?
This study is part of a large-scale European project called Conception which aims to improve the availability of research evidence regarding the effects of medications used during pregnancy and breastfeeding to improve public health and healthcare. You can find out more about the Conception project here https://www.imi-conception.eu

Has an Ethics Committee approval been required for this study?

An Ethics Committee is a group of people who are responsible for protecting participants' rights. [Insert text to explain that ethics committee approval has been granted, or why it was not required]

The Conception project has produced a set of ethical principles that all of our meetings adhere to. I am including a copy of these principles, for your information.

[Include a copy of our external stakeholder engagement principles, which are still being refined to be public-friendly.]

Your participation in a focus group discussion

The focus group discussion will be held on [date] and last approximately [...] hours. It will take place at [this location OR remotely using this technology]. The discussion will take place in the [nationality or region] language.

There is no cost associated with participating in this focus group discussion and you will not receive any compensation to take part. However, we are able to reimburse your travel costs for attending the meeting, according to the accompanying reimbursement guidelines. Your contribution will help us explore these issues, meaning that there are no wrong answers; we are interested in everything you have to say.

What is asked of me?

Participation in a focus group discussion is entirely voluntary. You do not have to take part and you can decide to withdraw at any point, without having to give a reason. You do not have to answer any questions during the focus group discussion that you do not feel comfortable answering. Your contribution will help us understand the views different people have on our research topics.

The meeting will be run by an expert in the subject being discussed, who also has experience in running meetings. You will be asked to comment on questions and to contribute within group discussions, but only on topics you feel comfortable contributing to. The person running the event will make sure that the atmosphere is always friendly and that all viewpoints are welcomed. Your ideas, viewpoints and opinions will be taken seriously and equally alongside the other focus group participants.

What information will be kept about me, and how will it be protected?

Please see the accompanying transparency information document that explains this in detail.

TEMPLATE 4 – PARTICIPANT TRANSPARENCY INFORMATION DOCUMENT

Title of the study: [...]

Purpose of the study and the legal basis

The personal information that we will hold about you will be for the purpose of conducting a focus group as part of a larger research project, ConcePTION, which is described in detail in the attached Patient Information document.

The formal 'controller[10]' of the personal data[11] is: [...] which can be contacted at: [...]
The legal bases for processing this information under the General Data Protection Regulation (GDPR) are:

- Article 6(1)e and Article 9(2)(j) - public interest in scientific research
- Article 6(1)f – legitimate interests in conducting research and Article 9(2)(j) - public interest in scientific research and statistical purposes

Select one of the above bullets, as appropriate: first for academic; second for pharma/commercial, but then need to explain legitimate interests. Check with your Data Protection Officer (DPO).

What information will be kept about me?

9. If you agree to participate, your name, your contact details and a copy of your signed consent form will be kept by the organisation running this focus group, [organisation name], as a record that we had your permission to join the focus group. Additional information such as your banking details may be required and kept if we arrange to reimburse you for travel costs.
10. If you do not agree to participate, we will delete records of your name once the focus group study is complete, and there will be no permanent record that you were invited or that you declined.
11. We normally make an audio recording of focus group sessions in order to assist with writing a report of the discussions which took place. The audio recording will later be written out, so we have a written record of the discussions. A few people in our team will also take notes during the discussions. These materials will include your voice or your name, and so this will be identifiable information. This personal information will be kept securely, and only made available to members of the team running the focus group or analysing the data, for the purpose of creating the focus group report.
12. The focus group report will be a summary of the topics that were discussed and the viewpoints that were raised on each topic. The report will not state who made each comment, and any examples that you mention in your comments that might give a clue about who you are will be changed so that you could not easily be identified from the information in the report.

[10] A Data Controller is an individual or organisation who determines the purposes for which and the manner in which any personally identifiable data is or will be processed. It is the responsibility of the Data Controller to ensure that any processing of personally identifiable data has an appropriate legal basis.
[11] Personal data is information about an individual which identifies who that person is or could be used to identify who the person is. The personal data about you that will arise through participating in this focus group is described in the next section.

13. Focus group reports normally also describe the kinds of people who were participating in it. This is usually done by including a list only giving the age, gender, and possibly the occupational group or other relevant experience or health background of the participants. Care is taken to make these descriptions non-specific, so that somebody outside the focus group reading the report would not be able to tell who had been invited.
14. It is sometimes good to include quotes of what somebody said during the discussions. If any of your remarks are used as quotes, care will be taken to ensure that these quotes don't identify you, by including just a few words or a sentence.
15. Once the focus group report is complete, the research team will often create some additional shorter reports, and also probably create a scientific paper that will be published in one of the leading journals. These materials will also avoid using any focus group content that could identify a participant.
16. Once all of these materials have been finalised, and scientific papers have been published, the original audio recording, transcription and notes taken during the meeting are no longer accessible to the majority of the research team, but are kept securely in case there is a need to check them again, for [...] years.

The eight points listed above are the usual procedures for handling information relating to a focus group.

[Please note if the personal data will be shared with any other parties]

How long will my personal data be stored?

Records containing your personal data such as the audio recording, transcription of the audio and meeting notes, will be retained for a period of maximum [N years] from the end of the study. Audio recordings and computer files will then be deleted, and paper copies will be destroyed. Financial records will only be retained for [7 years].

What rights do I have concerning my personal data?

Under data protection laws you have certain rights that are also respected:

- the right to be informed about the processing of any data about you (as described here);
- the right of access to see or receive a printed copy of any personal data relating to you;
- the right to rectification – to correct any material errors in the personal data we may recorded about you;
- the right to erasure – to ask that all personal data about you is erased if appropriate to do so;
- the right to restrict processing – to ask that we stop processing your data specifically;
- the right to data portability – to have an electronic copy of any data you provided directly;

- the right to object to and not to be subject to automated decision-making, including profiling. There will be no automated decision-making, so this does not apply.

How can I exercise these rights?

Please contact the Data Protection Officer (see below) and this is what will be done in response to your request:

7. If you ask to see what personal information is being held about you, then you will receive a copy of that information, either as an full copy or as a copy with any information about other people removed.
8. If you ask us to correct any errors, then we would usually be happy to do so as we would wish to reflect the views you expressed correctly in our report,
9. If you decide to withdraw before attending the focus group, and without having made a claim for travel reimbursement, we can delete all of the information held about you, as if you had never been contacted to participate.
10. If you attend the focus group, and if you have claimed any travel reimbursement costs, then the organisation will need to retain a copy of the information they have used for financial audit purposes, even if you withdraw from the focus group and the study.
11. If you decide to withdraw from the focus group, or if you request that some or all of your comments to the focus group be removed, then those remarks that came from you will be deleted from the focus group report. Your entry in the list describing the participants can be deleted, before the report is published.
12. It might be difficult, perhaps impossible, to eliminate viewpoints from the report that that summarizes comments made by multiple people including you, but we will try to ensure that your specific points will not be recognizable within the material.

If you would like to review, correct, update, restrict, object to the processing or delete your personal data, or if you would like to receive an electronic copy of the personal data you have provided, you should contact one of the persons mentioned at the top of this form.
Your request for data deletion will be addressed within 30 days after your request has been confirmed. Such request may not be fulfilled in case that deletion renders or seriously impairs the study objectives, or in the case that regulations and laws that apply to this research require this data to be retained, but this will be explained in our response to you.
Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws require your personal data to be retained.

You can request the contact persons mentioned at the top of this form to forward any questions, concerns or complaints you may have to the data protection officer of their institution. You are also welcome to contact the data protection officer directly.
If you would like to receive the results of the research or of the final report, you should contact one of the persons mentioned at the top of this form.
You also have the right to complain to the relevant data protection supervisory authority, which can be contacted at: [...]

Whom do I contact with any questions about my personal data?

For questions about your participation in the focus group, please contact:
[...]
For questions about your personal data and your data protection rights, please contact our Data Protection Office/Officer:
[...]

TEMPLATE 5– FOCUS GROUP DISCUSSION : GUIDE

Welcome the participants

Make a warm welcome, provide some drinks or food and make circular arrangements. Interact with the participants and try to stimulate interaction between the participants. At this point you check of participants have filled in the consent form. Wait for 5 minutes to give time to all participants to join.

Introduction

- Welcome the participants and p*resent yourself*
  Welcome, my name is […], *working as [….] at* [name institute] *and I will be your moderator today. In addition, also* [first name of assistants] *called in to help me with the focus group. My role as moderator will be to guide the discussion.*
- **Thank the participants**
  I would like to thank you all for taking time to be part of this focus group discussion.
- **General introduction**
  The discussion that we will have today is on [subject].We want to have this discussion with you as [name stakeholder], since we think it is important to know how you feel about […]. The opinions collected today will be used to write reports and publications to inform […].The focus group will take about […] hours.
- **Explain the rules**
  - *I want to emphasize that there are no right or wrong answers, there are only differing points of view.*
  - *We are looking for your opinions and hope for a good discussion*
  - *It is possible that you do not agree with all opinions, but may I ask to listen to each other's points of view. Each view is important and counts. Afterwards you are welcome to provide your view.*
  - *We're audio recording, so it would be very helpful for the analysis if only one person is speaking at a time.*
  - *Since this is an informal discussion, we will address each other only by their first name*
  - *If there are any questions or terms that are used during the focus groups that are not clear to you, please let us know*
  - *So, we will now start the recording. Is that OK for everybody?*

Questions

- Opening question
  First, to get to know each other, could everybody state their name and job title?
- Introduction to the topic
  [explanation topic]
  [explain on the basis of an example]
  - *If there are any questions or terms that are used during the focus groups that are not clear to you, please let us know.*

- **Introductory question**
- Questions about the topics

I. Questions about the topic […]

[Insert questions]

II. Questions about the topic […]

[Insert questions]

III. Questions about the topic […]

[Insert questions]

IV. Questions about the topic […]

[Insert questions]

[add additional themes if necessary]

V. Questions about the topic […]

[Insert questions]

[add additional themes if necessary]

Conclusion

- **Final summary by assistant**
  - *Has anything been missed, or would somebody like to add anything?*
- **Thank all participants**
  - *Thank you all for participating to this focus group discussion.*

TEMPLATE 6 – DEMOGRAPHIC AND CLINICAL INFORMATION PARTICIPANTS

Characteristics	Stakeholders (n= […])	
	n	%
Sex		
Females		
Males		
Age (years)		
18-24		
25-39		
40-60		
>60		
Country		
[…]		
[…]		
[…]		
[…]		
[…]		
Education		
No diploma		
High school		
Bachelor's degree		
Master's degree		
PhD		
Stakeholder group		
[…]		
[…]		
[…]		
[…]		
Disease area		
[…]		
[…]		
[…]		
Years since diagnosis		
[…]		
[…]		
[…]		

CHECKLIST TABLES

This table can be deleted from the final version, but should be retained and updated until the final version to ensure that the leaflet is GDPR-compliant in all respects

	GDPR Article 13 Checklist	Notes/comments
	Information to be provided where personal data are collected from the data subject	
	1. Where personal data relating to a data subject are collected from the data subject, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:	
✓	(a) the identity and the contact details of the controller and, where applicable, of the controller's representative;	Must be added
✓	(b) the contact details of the data protection officer, where applicable;	Must be added
✓	(c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;	The appropriate legal basis must be chosen
✓	(d) where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;	If 'legitimate interests' used then an explanation is required
?	(e) the recipients or categories of recipients of the personal data, if any;	Admittedly this is just a template, but should be clearer about participating institutions and any onward sharing of the personal information
?	(f) where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or in the case of transfers referred to in Article 46 or 47, or the second subparagraph of Article 49(1), reference to the appropriate or suitable safeguards and the means by which to obtain a copy of them or where they have been made available.	
	2. In addition to the information referred to in paragraph 1, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:	
✓	(a) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;	Give appropriate time periods

	GDPR Article 13 Checklist	Notes/comments
✓	(b) the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;	
✓	(c) where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;	
✓	(d) the right to lodge a complaint with a supervisory authority;	Appropriate contact details must be added
✓	(e) whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;	It is clear that provision is voluntary
✓	(f) the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.	
✗	3. Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2	It is not clear if the information gathered may be used more widely or is only for this study, so just the single purpose

The intended sequence of events:

This table can be deleted from the final version, but should be retained and updated until the final version to ensure that the leaflet is GDPR-compliant in all respects

	Physical	Electronic	Notes/comments
18.	Amend templates	Amend templates	Arrange to be checked/approved
19.	Generate letters & attachments	Generate emails/ add attachments	& post/send after review
20.	Wait for responses	Wait for responses	

	Physical	Electronic	Notes/comments
21.	Arrange calls/respond to emails or letters	Arrange calls/ /respond to emails or letters	
22.	Decide best date[12] for meeting & send meeting details with expenses form	Decide best date for meeting & send suitable meeting invitation	
23.	Check logistics - need to make clear how to get to venue	Check logistics - any requirements for online meeting (exactly how to access)	Just so participants are clear as to what to do
24.	Check for signed consent forms	Check for signed consent forms – note: some users may not be able to scan, so may need a suitable online alternative	May need to get REC to approve online 'consent form'
25.	Researcher countersigns forms	Researcher countersigns printed forms or list?	How should researchers countersign electronic forms?
26.	Run meeting	Run online session	Have recording & notes
27.	Type transcript	Type transcript	
28.	Check expense claims	N/A	
29.	Send expenses	Send thank-you letter	
30.	Develop study notes	Develop study notes	Convert transcript to pseudonymised form
31.	Archive original notes/transcripts	Archive original notes/transcripts[13]	Retain only pseudonymised study data
32.	Destroy expense claim forms &	N/A	After 7(?) years
33.	Destroy original notes/transcripts		After 20 years
34.	Archive or destroy remaining study files		After 20 years?

[12] The 'best date' may already have been decided – so this would occur at or before Step 1; the original proposal had a 'floating date'/location, so form would need to ask about availability, etc.

[13] May need to check what would be held on any online platform, though likely to be retained for only short period, but might include IP Addresses or if requires registration, then more personal data

INTERACT PRACTICAL GUIDES

NOMINAL GROUP DISCUSSION

TABLE OF CONTENTS

Step 1: Define the research question

A nominal group technique (NGT) is a consensus method used in research that is directed at problem solving, idea-generation or determining priorities. How consensus is defined and operationalised will vary from study to study, depending on the research objectives. Consensus methods raise potential solutions or answers to a question, which can then be prioritised or agreed upon.

Step 2: Perform a literature review

Before conducting nominal group technique (NGT) with stakeholders and experts in the field, it is important to get a better understanding of the context in which your research will take place. To realize this, you will need to **perform a literature review**. Depending on the timing and scope of your project, you can either opt for a systematic literature review (cfr. separate practical guide) or a more limited so-called narrative review (table 1). Regardless of your choice, the literature review is a vital first step in the conduct of NGT studies as it will allow you to identify topics that can be addressed during the nominal group discussion (NGD), which in turn will inspire your NGD questions. Additionally, when discussing the results of the NGD, it is important to compare your findings with what has been written by authors in the field.

	Narrative review	Systematic review
Research question	Broadly defined	Highly focused
Inclusion/exclusion criteria	Developed post hoc	Developed at protocol stage
Study types	All study types	Defined study types
Reporting of findings	Simple description of selected findings	Synthesizes and aggregates findings
Replication of review	Impossible, no search strategy published	Possible, search strategy published

Table 1: Overview of the main differences between a narrative and a systematic literature review.

Step 2: Define the target population

A vital question that needs to be addressed early on concerns the experts that you wish to include for your study. The literature review should have given you an idea of **which stakeholders you should target** to get a comprehensive view of the different perspectives surrounding the research topics you wish to explore. Experts, in the context of consensus methods, are those who have knowledge about the topic of concern which is dependent upon the research aims and objectives.

To further specify and narrow down the target population, a **list of inclusion and/or exclusion criteria** can be composed prior to recruitment. Note that you should always be able to justify your choice for a specific criterion. The list of criteria also needs to be disclosed in any publications following from the NGT. Selection criteria can be based on:

- Expertise: e.g. has expertise in the domain of oncology
- Experience: e.g. has been a principal investigator on at least 3 clinical trials before
- Language: e.g. must be able to speak English fluently
- Place of residence/work: e.g. lives or works in a Member State of the European Union
- Affiliation: e.g. must be a member of the European Society for Medical Oncology
- Authority: e.g. must be in a senior or upper management position
- …

The **composition** of a NGT should consist of participants who are relatively homogeneous in status. Power differentials between participants may mean that people with less power may feel unable to contribute their own views or contradict the views of someone more powerful. A NGT should not be conducted with a large number of participants. A maximum of seven participants has been recommended.

Step 3: Formulate the NGT stages

Now that you are familiar with the literature available on your research topic and know which stakeholders you want to include in the study, you can begin formulating the NGT questions.
A NGT comprises four key stages that are briefly explained below.

First stage: Silent generation

In advance of the NGT, one to two questions are sent to the participants. In the first stage the participants are given up to 20 minutes to silently reflect or record their individual ideas/solutions in response to a question.

Second stage: Round robin

During the round robin one participant at a time is asked to **state a single idea** to the group. Participants are able to think of new ideas/solutions during this process, but must wait their turn before they can share with the group. This second stage takes as much time as needed until no new ideas are forthcoming. It is recommended that there be no discussion at this stage.

Third stage: clarification

The clarification of ideas stage also provides the opportunity for a grouping step, where **similar ideas are grouped together** with agreement from all participants. Participants may also exclude, include or alter ideas, as well as generate grouping themes. All ideas should be discussed to ensure participant understanding. This enables the participants to make an informed decision when they come to voting on ideas. Participants do not have to agree with all ideas listed as, at the end of the clarification stage participants are able to ignore ideas by voting on personal preferences. This stage can take up to 30 minutes.

FOURTH STAGE: VOTING (RANKING OR RATING)

In the final stage participants are provided with a **ranking sheet**, where they are asked to select their **top preferences from the generated ideas**. The number of items chosen by participants depends on the topic, but the **ranking of five ideas** is common in the literature. A number should be allocated to each selected item, with larger numbers reflecting greater importance. Although there is no anonymity for participants during nominal group discussions (NGD), individual scoring on a ranking sheet is confidential. Finally the **scores for each idea are summed and presented** to the group for discussion. The timing of this stage is likely to depend on a number of factors, including the complexity of the topic and how many items need to be prioritised (the more items to rank, the harder the process and more time consuming it can become). The timing to complete one NGD is variable, and depends on group size, how many questions are asked, and the type of participants involved.

VARIATION ON THE NGT

The NGT is a highly adaptable method and the four stages can vary among different studies. An example of a variation is briefly explained below.

FIRST STAGE: SILENT GENERATION AND FIRST GRADING

Instead of generating the ideas during the NGT by the participants, the **ideas can also be obtained from the literature and grouped in advance**. Following a brief explanation of the ideas, participants have first the opportunity to state any additional ideas. Then participans are able to **silently reflect** and **individually grade** all ideas according to how important they find them.

SECOND STAGE: ROUND ROBIN

One by one, participants state the **issues they graded most highly** while the assistant writes them on a slide. Participants will be able to explain **why** they graded a certain issue highly. It is recommended that there is no discussion at this stage and ideas are merely recorded. During a break, the **mean grades** of the group for each of the issues are calculated by the assistant and presented on a slide.

THIRD STAGE: CLARIFICATION OF IDEAS

After the break, **participants discuss** the list, mean grades and the potential additional issues mentioned at the beginning of the first stage. All potential issues will be discussed to ensure participant understanding.

FOURTH STAGE: SECOND GRADING

Participants **silently reflect about the first grading they gave** to the issues and are able to **change** their grading based on the discussion. Participants will come to consensus about the grades for each of the issues.

Step 4: Prepare the NGT guide

The NGT guide is a document that describes the NGT process in a stepwise fashion. You can follow it during the NGD to make sure that you didn't forget to mention anything. It usually comprises the following parts:

- ANSWER FORM
  - An answer form is sent to the participants prior to the NGD
  - Questions about the participants characteristics
- INTRODUCTION
  - Short personal introduction of the research team
  - Short explanation of the study and the purpose of the NGT
  - Explanation of practical details and the rules
- STAGES
  - Reaching a consensus
- CONCLUSION
  - Expression of gratitude for participation
  - Disclosure of participants contact details

A template for the NGD guide can be found in the attachments below.

Step 5: Ethical approval

In order to start the focus group discussion, approval is necessary from **ethical committee**.
The data collected during the focus group discussion will always be treated confidentially and never made public. For this, the participants will be given a code (pseudonymised) and only the researchers will be able to identify the participants.
Participants will be informed oral and written about the objectives of the research. All information and **informed consent** will be send in advance and potential participant will have enough time to consider their participation or to ask questions. A template of the informed consent can be found in attachment.

Step 6: Perform pilot study

Before the NGD can take place, it is useful to **test your NGD guide by conducting a pilot study** with one expert. Not only will this allow you to get yourself familiarized with the NGT process, it will also enable you to identify questions that may need to be revised or formulated differently to avoid confusion on the part of the participants. Preferably, pilot studies are performed with an expert who does not participate in the NGD.

STEP 7: FIND AND RECRUIT PARTICIPANTS

Recruiting participants can be a long and tedious process. **Purposive sampling** implies that you actively look for individuals that satisfy a number of subjectively chosen selection criteria which are used to allow you to accomplish the purpose of your study. **Snowball sampling** on the other hand means that you try to include new participants that were suggested to you by other potential participants. **Convenience sampling** is also a method for finding participants for a NGD. The NGD requires face-to-face meetings, however it may be difficult to organise a nominal group discussion for a time that suits every participant.

In general, it is a good idea to employ a **combination of these three techniques** to maximize the efficiency of the recruitment process.

You will likely also have to complement them with some degree of **quota sampling**, which refers to the act of applying quotas during the selection of potential participants. If you are for example investigating cross-border access to clinical trials in the European Union, it makes sense to limit the number of experts included per country and to ensure that you have at least one participant for each Member State. It is again important to note that you should always be able to justify your recruitment method, given that it will have to be disclosed in any papers you publish based on the NGD results.

Once you have a list of names of people you are aiming to recruit, you need to send them an invitation to participate in your study by e-mail. This initial **invitation mail** needs to be short enough to not be ignored by your target audience of busy experts but sufficiently detailed to convince them to take part in the NGD. Generally, it should contain the following parts:

- Formal greeting
- Your affiliation (university, research group, principal investigator)
- Name of the study
- Objectives of the study
- Methodology of the study
- Reasons why you think the addressee would be a good participant
- Expected duration of NGD
- Confidentiality details (recording of NGD, pseudonymization of data)
- Expression of gratitude in advance
- Closing remark

Give the potential participants some time to respond. If you haven't heard anything back from them after a two-week period, you can send a **politely worded reminder**.

If the targeted expert shows interest to participate by responding positively to your mail, you can further arrange the practical details of the NGD. At this point, you also send them the **information sheet (IS) and the consent form (CF)**. The IS is a document that contains all of the information the participant

needs to know before deciding to partake in the NGD. It explains to them what the study is about, how it will proceed, what will happen with the collected data and what their rights are as a participant. Although you should allow them some time to read through the document, it is vital that the participant signs the CF before the NGD takes place. A template of the IS and CF can be found in the attachments of this guide.

TIPS & TRICKS

It may be difficult to find experts that meet all of your inclusion criteria. You can use **LinkedIn** to search for profiles of people affiliated with specific companies or institutions. Although concrete e-mail addresses are usually not openly available, many organizations use a standard e-mail format, and there are websites that allow you to search through databases of professional e-mail addresses (e.g. https://rocketreach.co/).

STEP 8: CONDUCT THE NGD

Now that all the preparations have been made, the NGD process can start. The **NGD guide** serves as the script you need to stick to and follow. While you can read from it during the NGD, it is best to **memorize it as much as possible**.

The NGD will be organized at a location convenient for participants.

FACE-TO-FACE NGD

1. NGD

- Book a meeting room that is easily accessible and allows for a circle seating around a table
- Provide the participants with instructions to get to the room
- If the **CF** has not been signed yet, bring it with you
- Print the information sheet, informed consents and answer forms
- Provide your and your assistants' phone number(s) to the participants
- **Book the room** in which you plan to conduct the NGD sufficiently long in advance and for at least 30 minutes longer than you project the NGD will take
- Make sure that you **arrive at least 30 minutes early**, as it may take some time to find the room and set up the slideshow, recording devices, seating arrangements…
- Dress code for moderator and assistant: business, not too formal
- Be mindful of the **acoustics of the room**, since this can interfere with the recording
- Bring a **high-quality recording device** with you
- Make sure that the **recording device has sufficient charge** (bring extra batteries or charge it before the NGD)

- **Test the recording function in advance**, if possible in the same room as the one in which the NGD will take place
- **Record the NGD in duplicate,** for example by also recording the sound with your mobile phone and place them at the opposite sides of the room
- **Do not turn on the recorder until the research questions start**
- Always **ask for permission** prior to turning on the recorder
- **Make notes** of key concepts addressed by the participants
- **Provide name cards** (mentioning the first name of the participants), to put on the table
- **Provide water/coffee/tea + something to eat**
- **Nod along in agreement and use verbal cues ('Hmm-mm', 'right', 'okay', …)** but not excessively as they will complicate the transcription process
- Ask **one question at a time**
- Ask the participants to **speak one at a time**
- Allow the participants to **finish their answers without interrupting** them
- **React neutrally to answers** given by participants, regardless of whether they confirm or refute your prior ideas
- Do not feel awkward if there is a sudden silence: **let the participants break the silence themselves**, even if it takes some time
- **Don't interrupt the participants to ask a question**: write it down in your notes and ask it when the opportunity arises
- If the participant does not directly address the question in their answer, **don't be afraid to ask the question again**
- After the NGD has been concluded, immediately make a **back-up of the audio files** you recorded on a separate thumb drive
- **Reflect** on the NGD afterwards: what went well/badly? Should the NGD guide be adapted? Are there still topics unclear?

2. Moderator and assistant team

- A meeting between moderator and assistant should be planned before the focus group to go over the guide and discuss the moderator and assistant's tasks.

2.1. Attitude of moderator

- Exercise mild unobtrusive control (moderate the discussion but do not interrupt)
- Steering the focus group where needed
- Adequate knowledge of topic
- Appears like the participants
- Use purposeful small talk
- Do not complement or discourage stakeholders on the points they make

- Alert and free from distractions (put sound of cell phone off and do not have your cell phone on you)
- Have the discipline of listening and apply active listening
- Familiar with questioning route (know this protocol very well)
- Take into account the different types of participants and try to balance the conversation while addressing the obligatory topics: dominant talkers, shy participants, etc.

2.2. Tasks of the assistant

- Handles logistics (location of refreshments, bathrooms, emergency exits)
- Collects consent forms and answer forms
- Takes careful notes (bring laptop/paper)
    - Verbal reactions (Audio: Discussion, change in attitude (voice))
    - Nonverbal reactions (Video: movements, attitudes, emotions)
- Controls for equal participation by all participants and informs the moderator if some participants are not getting the chance to participate
- Monitors audio recording equipment
- Time management via discrete signs or verbal communication to the moderator
- Gives a general summary of what has been said at the end of the focus group

REMOTE NGD

https://www.sciencedirect.com/science/article/abs/pii/S0360835206001963

Many of the abovementioned remarks also apply to remote NGD. Some additional points to bear in mind include the following:

- Make sure that you **enter the virtual conference room at least 15 minutes in advance**
- Ensure that your **internet connection is stable**
- While waiting for the participants to arrive, **test your audio and camera**
- Communicate to the participants in advance that they should **call in from a quiet room where there is a good internet connection**
- **Book or arrange a quiet room** for yourself so that you don't get interrupted
- **Send a Skype invitation** to the participants in advance instead of calling them up directly, but have their number ready in case something goes wrong and they can't enter the virtual conference room
- **Turn the camera on** during the NGD
- **Record the NGD in duplicate**: do not only use Skype's built-in recording function but also other software (e.g. MP3 Skype Recorder)
- If the camera cannot be turned on (e.g. due to it slowing down the connection or because the participant is calling in on their phone), the **use of verbal cues is essential** to let the participant know that you are still on the line

- **Have a back-up system ready**: if Skype doesn't allow for a stable connection, try Zoom or a different program
- If the connection is interrupted, ask the participant to **repeat themselves**

When saving the audio files on your computer, **do not mention any identifying information** but instead use a coding system (e.g. 'NGD.mp3'). Make sure to delete the metadata as well, as Skype recordings also document the time and date of the NGD and the telephone numbers or e-mail addresses of the participants. Keep track of which codes you used for each participant in a separate document (the 'key'). This process is called **pseudonymization**. It differs from anonymization in the sense that the person who has access to the key can still identify the participant, which would not be possible if the data were anonymized. Pseudonymization is vital to ensure the confidentiality of the recordings.

STEP 9: TRANSCRIBE THE NGD

In this step, the NGD recording need to be **typed out *ad verbatim***, meaning that everything needs to be written down as it was said literally (including mistakes, stop words, 'uhms', 'hmm-mms', laughter, sighing,…). Note that this is a very **time-consuming** process: experienced transcribers will take about 4 hours to transcribe 1 hour of audio material. It will also require a lot of your energy, as you will often have to replay the same audio fragments dozens of times before understanding a particular word. Make sure to plan ahead and allocate enough time to this step.

If you have a tight schedule and a sufficiently large budget, you can **hire other people to do the transcription** for you. There are companies (e.g. Rev, TodayTranslations, TranscribeMe,…) that you can send the pseudonymized audio recordings to and who will then deliver the transcript to you within a certain timeframe. Depending on the length of the NGD, this can quickly get very expensive (+/- 90 dollars/hour). Alternatively, you can set up a contract with one or multiple KU Leuven job students, which is usually a bit cheaper. Note that you will still always need to **check the finished transcript** as the transcriber will not be aware of the context of the NGD and will therefore likely not understand certain terms or abbreviations. Additionally, since your participants may have distinct accents that the transcribers are not used to, the delivered transcript may contain mistakes. If possible, provide them with feedback before sending in a new audio recording. Finally, another difficulty in transcribing a NGD is when the participants talk at the same time.

TIPS & TRICKS

If you are using job students for the transcription and multiple candidates apply for the position, you can ask them during the hiring process to transcribe a 15-minute fragment of one of your pilot study within a one-hour timeframe to see how they perform. This will make it easier to select the best candidate(s) for the job.

If you intend to use the services a transcription company, you can ask for quotes and try to negotiate the price down by playing them against each other (although some companies may apply a standard price). Furthermore, depending on the quantity of the NGDs, you may be eligible for a discount.

Step 10: Analyze the data

Following the nature of the collected data, the results will be analyzed descriptively or qualitatively.

Descriptive analysis

The information captured through the **grading exercise** is quantitative data and is analysed **descriptively** using Microsoft Excel. Other information gathered, namely participant characteristics, will be tabulated for all participants together and for each of the questions asked.
For the grading exercise, participants' final individual grading scores will be combined to produce a list of the NGD's cumulative scores for each of the issues. This will be done both for the first grading (during the NGD) and for the second grading (after the NGD). The outcome of this analysis will be a table listing the issues, their explanations and two lists of the mean grades for each of the issues. A higher grade will mean a higher importance for the issue.

Qualitative analysis

The answers to the open questions, the focus group transcripts of the NGD, notes and potential additional interview transcripts will be together analyzed thematically using a mainly deductive approach. The choice for a mainly deductive analysis is based upon its ability to code the data with the pre-established list of codes, allowing for slight modification based on what participants said during the NGD. The framework method as explained by Lacey and Luff will be used (Table 1). The audio-recordings will be transcribed verbatim. The NGD will be transcribed by researchers involved in the study and in English. The rationale behind the choice of the analysis method '**thematic analysis'**:

- Thematic analysis focusses on what has been said rather than how it was said;
- Thematic analysis is accessible to novice researchers, as it is less demanding than other methods (e.g. thematic analysis does not involve the same level of sophistication in data collection and theory building as grounded theory);
- Useful technique when:
    - Data collection has finished; thematic analysis, as opposed to grounded theory, does not have the requirement that the data being collected are reviewed part-way through the analysis and new approaches to data collection are initiated;
    - Data consists of detailed textual material (e.g. focus group transcripts);
    - A broad-brush approach to analysis is desired (as opposed to some fine-grained approaches which characterize some qualitative methods).

1.	Familiarization	Moderator and assistent will thoroughly read and re-read each document and discuss or listen back to the audio-recorded NGD whenever a certain part is unclear. The margins of the documents will be used to write down analytical notes, thoughts or impressions (e.g. when NGD participants expressed exceptionally strong or contrasting views).
2.	Identifying a thematic framework	The deductive thematic framework will be developed starting from the list of potential issues and explanations. This list will be transported to NVivo (11th edition, QSR International).
3.	Coding	Moderator and assistent will attach text in the documents describing what participants stated about these issues to the corresponding issue (coding). During coding, moderator and assistent will assess whether the issues cover what participants said during the focus group. If not, they will modify the name of the code and/or explanation accordingly. The final framework will consist of the final list of all issues, each with a brief explanatory description of their meaning and examples of what ideas or elements could be summarized under that code.
4.	Charting	Excel will be used for charting (summarizing) the data. The coded text will be exported per code from the final list of codes, from NVivo to Excel. In Excel, a separate tab sheet will be created per code (issue). Each tab sheet will be comprised of one row per participant of the NGD. To retain links to the transcripts, verbatim text will be indicated by underlining it.
5.	Mapping and interpretation	The framework matrix in Excel will be analyzed qualitatively. Moderator and assistent will write down independently, their interpretations for each issue. Afterwards, a meeting will be organized among the moderator and assistent and following this with the entire study team to discuss these interpretations together with the scorings of the quantitative analysis.

Table 1: Steps of the framework method

Lacey and luff:
https://www.rds-yh.nihr.ac.uk/wp-content/uploads/2013/05/9_Qualitative_Data_Analysis_Revision_2009.pdf

Step 11: Conclude the NGD

For confidentiality purposes, the **NGD recordings are deleted** from all of your devices and the **pseudonymized transcripts along with the key are printed and stored in a locked cabinet** at the Faculty until such time as they might be needed for future studies.

Useful links & references

Practical links

NVivo 12 tutorial for beginners:
https://www.qsrinternational.com/nvivo/nvivo-12-tutorial-windows/00-let-s-get-started

Qualitative analysis of interview data: A step-by-step guide
https://www.youtube.com/watch?v=DRL4PF2u9XA

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TEMPLATES

TEMPLATE 2 - INFORMED CONSENT FORM

Title of the study: [...]

Contact persons: [name and first name]
[email]
[phone]
[department, organisation]
[address]

Filled in by the PARTICIPANT

Please tick the boxes you agree with. You will only be asked to participate in the focus group if you are comfortable to agree to all of these points.

- ☐ I have read the information concerning this study and I have had an opportunity to ask questions or discuss any concerns about it;
- ☐ I was given sufficient time to decide whether I am willing to participate in this study;
- ☐ I am aware that participating in this study is completely voluntary;
- ☐ I am aware that I can decide to withdraw at any point, without having to give a reason;
- ☐ I give permission for information about me and the information I provide during and after the focus group session to be used in the ways described in the participant information document.
- ☐ I have received the information sheet and I hereby confirm my voluntary participation in the study.

Filled in by the PARTICIPANT

_____	_____	_____
Name participant	Signature participant	Date

Filled in by the RESEARCHER

I have discussed the content of the invitation and the information with the above-mentioned person. I have asked for any additional questions and I have answered these.

_____	_____	_____
Name researcher	Signature researcher	Date

KU LEUVEN
FACULTY OF PHARMACEUTICAL SCIENCES
CLINICAL PHARMACOLOGY AND PHARMACOTHERAPY
HERESTRAAT 49, O&N2 BOX 521
3000 LEUVEN, BELGIUM

TEMPLATE 3– PARTICIPANT INFORMATION SHEET

Title of the study: [...]

Contact persons: [Name contact person]
[email]
[department]
[address]
[tel]
[add other contact persons]

Dear,

You are being invited to voluntarily participate in a focus group discussion on [...]. A focus group is a diverse group of people assembled to participate in a guided discussion, in this case so that we can learn about their experience in [...]. During that discussion you will be offered the opportunity to contribute your ideas and opinions relating to [...]. The following topics will be discussed:
[Overview of topics that will be discussed during the focus group discussion].
Before you confirm your participation in this study, we ask you to read this information sheet carefully. I would be happy to answer any questions you have by email or telephone, using my contact details below.
[Explain the subject/problem that will be discussed during the focus group discussion].
If you are willing to participate after any telephone call or email exchange, I would be grateful if you would email me a scanned signed copy of the accompanying consent form or post it to me at the address given below.
Signature
Name
Designation
Email
Telephone
Address for correspondence

What is the purpose of the study?

[...]

Who is conducting the study?

This study is part of a large-scale European project called Conception which aims to improve the availability of research evidence regarding the effects of medications used during pregnancy and breastfeeding to improve public health and healthcare. You can find out more about the Conception project here https://www.imi-conception.eu

Has an Ethics Committee approval been required for this study?

An Ethics Committee is a group of people who are responsible for protecting participants' rights. [Insert text to explain that ethics committee approval has been granted, or why it was not required]

The Conception project has produced a set of ethical principles that all of our meetings adhere to. I am including a copy of these principles, for your information.

[Include a copy of our external stakeholder engagement principles, which are still being refined to be public-friendly.]

Your participation in a focus group discussion

The focus group discussion will be held on [date] and last approximately [...] hours. It will take place at [this location OR remotely using this technology]. The discussion will take place in the [nationality or region] language.

There is no cost associated with participating in this focus group discussion and you will not receive any compensation to take part. However, we are able to reimburse your travel costs for attending the meeting, according to the accompanying reimbursement guidelines. Your contribution will help us explore these issues, meaning that there are no wrong answers; we are interested in everything you have to say.

What is asked of me?

Participation in a focus group discussion is entirely voluntary. You do not have to take part and you can decide to withdraw at any point, without having to give a reason. You do not have to answer any questions during the focus group discussion that you do not feel comfortable answering. Your contribution will help us understand the views different people have on our research topics.

The meeting will be run by an expert in the subject being discussed, who also has experience in running meetings. You will be asked to comment on questions and to contribute within group discussions, but only on topics you feel comfortable contributing to. The person running the event will make sure that the atmosphere is always friendly and that all viewpoints are welcomed. Your ideas, viewpoints and opinions will be taken seriously and equally alongside the other focus group participants.

What information will be kept about me, and how will it be protected?

Please see the accompanying transparency information document that explains this in detail.

Title of the study: [...]

Purpose of the study and the legal basis

The personal information that we will hold about you will be for the purpose of conducting a focus group as part of a larger research project, ConcePTION, which is described in detail in the attached Patient Information document.

The formal 'controller[14]' of the personal data[15] is: [...] which can be contacted at: [...]

The legal bases for processing this information under the General Data Protection Regulation (GDPR) are:

- Article 6(1)e and Article 9(2)(j) - public interest in scientific research
- Article 6(1)f – legitimate interests in conducting research and Article 9(2)(j) - public interest in scientific research and statistical purposes

Select one of the above bullets, as appropriate: first for academic; second for pharma/commercial, but then need to explain legitimate interests. Check with your Data Protection Officer (DPO).

What information will be kept about me?

17. If you agree to participate, your name, your contact details and a copy of your signed consent form will be kept by the organisation running this focus group, [organisation name], as a record that we had your permission to join the focus group. Additional information such as your banking details may be required and kept if we arrange to reimburse you for travel costs.
18. If you do not agree to participate, we will delete records of your name once the focus group study is complete, and there will be no permanent record that you were invited or that you declined.
19. We normally make an audio recording of focus group sessions in order to assist with writing a report of the discussions which took place. The audio recording will later be written out, so we have a written record of the discussions. A few people in our team will also take notes during the discussions. These materials will include your voice or your name, and so this will be identifiable information. This personal information will be kept securely, and only made

[14] A Data Controller is an individual or organisation who determines the purposes for which and the manner in which any personally identifiable data is or will be processed. It is the responsibility of the Data Controller to ensure that any processing of personally identifiable data has an appropriate legal basis.

[15] Personal data is information about an individual which identifies who that person is or could be used to identify who the person is. The personal data about you that will arise through participating in this focus group is described in the next section.

available to members of the team running the focus group or analysing the data, for the purpose of creating the focus group report.

20. The focus group report will be a summary of the topics that were discussed and the viewpoints that were raised on each topic. The report will not state who made each comment, and any examples that you mention in your comments that might give a clue about who you are will be changed so that you could not easily be identified from the information in the report.

21. Focus group reports normally also describe the kinds of people who were participating in it. This is usually done by including a list only giving the age, gender, and possibly the occupational group or other relevant experience or health background of the participants. Care is taken to make these descriptions non-specific, so that somebody outside the focus group reading the report would not be able to tell who had been invited.

22. It is sometimes good to include quotes of what somebody said during the discussions. If any of your remarks are used as quotes, care will be taken to ensure that these quotes don't identify you, by including just a few words or a sentence.

23. Once the focus group report is complete, the research team will often create some additional shorter reports, and also probably create a scientific paper that will be published in one of the leading journals. These materials will also avoid using any focus group content that could identify a participant.

24. Once all of these materials have been finalised, and scientific papers have been published, the original audio recording, transcription and notes taken during the meeting are no longer accessible to the majority of the research team, but are kept securely in case there is a need to check them again, for […] years.

The eight points listed above are the usual procedures for handling information relating to a focus group.

[Please note if the personal data will be shared with any other parties]

How long will my personal data be stored?

Records containing your personal data such as the audio recording, transcription of the audio and meeting notes, will be retained for a period of maximum [N years] from the end of the study. Audio recordings and computer files will then be deleted, and paper copies will be destroyed. Financial records will only be retained for [7 years].

What rights do I have concerning my personal data?

Under data protection laws you have certain rights that are also respected:

- the right to be informed about the processing of any data about you (as described here);
- the right of access to see or receive a printed copy of any personal data relating to you;

- the right to rectification – to correct any material errors in the personal data we may recorded about you;
- the right to erasure – to ask that all personal data about you is erased if appropriate to do so;
- the right to restrict processing – to ask that we stop processing your data specifically;
- the right to data portability – to have an electronic copy of any data you provided directly;
- the right to object to and not to be subject to automated decision-making, including profiling. There will be no automated decision-making, so this does not apply.

How can I exercise these rights?

Please contact the Data Protection Officer (see below) and this is what will be done in response to your request:

13. If you ask to see what personal information is being held about you, then you will receive a copy of that information, either as an full copy or as a copy with any information about other people removed.
14. If you ask us to correct any errors, then we would usually be happy to do so as we would wish to reflect the views you expressed correctly in our report,
15. If you decide to withdraw before attending the focus group, and without having made a claim for travel reimbursement, we can delete all of the information held about you, as if you had never been contacted to participate.
16. If you attend the focus group, and if you have claimed any travel reimbursement costs, then the organisation will need to retain a copy of the information they have used for financial audit purposes, even if you withdraw from the focus group and the study.
17. If you decide to withdraw from the focus group, or if you request that some or all of your comments to the focus group be removed, then those remarks that came from you will be deleted from the focus group report. Your entry in the list describing the participants can be deleted, before the report is published.
18. It might be difficult, perhaps impossible, to eliminate viewpoints from the report that that summarizes comments made by multiple people including you, but we will try to ensure that your specific points will not be recognizable within the material.

If you would like to review, correct, update, restrict, object to the processing or delete your personal data, or if you would like to receive an electronic copy of the personal data you have provided, you should contact one of the persons mentioned at the top of this form.

Your request for data deletion will be addressed within 30 days after your request has been confirmed. Such request may not be fulfilled in case that deletion renders or seriously impairs the study objectives, or in the case that regulations and laws that apply to this research require this data to be retained, but this will be explained in our response to you.

Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws require your personal data to be retained.

You can request the contact persons mentioned at the top of this form to forward any questions, concerns or complaints you may have to the data protection officer of their institution. You are also welcome to contact the data protection officer directly.

If you would like to receive the results of the research or of the final report, you should contact one of the persons mentioned at the top of this form.

You also have the right to complain to the relevant data protection supervisory authority, which can be contacted at: [...]

Whom do I contact with any questions about my personal data?

For questions about your participation in the focus group, please contact:

[...]

For questions about your personal data and your data protection rights, please contact our Data Protection Office/Officer:

[...]

TEMPLATE 4 – NGD GUIDE

Everything below in *Italic* is to be said to the participants; everything in black is guidance and if applicable can be told to the participants in your own words. In **bold** the timing of actions is given.

00:00 Welcome

- Create a warm and friendly environment; try to get every participant's name directly and welcome them
- Provide coffee/tea/water, make circular seating arrangements
- Interact with participants and stimulate interaction between participants
- Check whether participants have filled in the consent form, brought with them the answer form with section 1 completed. If not, provide them with the consent form and answer form and have them fill it in on site
- Wait until all participants have joined for 5 minutes

00:05 Check whether all participants have arrived. If not, the assistant will try to reach these persons via telephone, in a separate room. If the missing participants cannot be reached, the focus group will start without these persons

- *Welcome, my name is Rosanne Janssens and I will be your moderator today. I am a PhD researcher working at the EMA where I study the topic of patient preference studies in regulatory decision-making. In addition, also Julie Pinoy will help me. She is a masters` thesis student Pharmacy who is doing this study as her masters` thesis*
- *My role as moderator will be to guide the discussion*
- *We want to have this discussion with you as regulators, since you would be the ones potentially confronted with preference study results during the assessment and we think it is important to know how you feel about using patient preference studies in the regulatory context. With this study we want to seek consensus on the issues affecting the use of patient preference studies in regulatory decisions. The broader objective of this research is to set an agenda formulating the key regulatory issues affecting the use of patient preference studies in regulatory decision-making. We regard you as a critical EMA-member that can provide valuable insights to reach these research objectives, which is why you were invited to participate.*
- *First of all, has anyone been already involved in a group discussion, also known as a focus group, for research previously?*
    - *If so: this focus group may be different to your previous experience as this is a more structured focus group with 4 different stages.*
- *The purpose of a focus group is to generate ideas at a group level, rather than personal detailed experiences. As I stated earlier, today's discussion is going to be a structured 4 stage process so keeping to time will be really important. So please forgive us if we have to cut anything short to stay on time, we will be happy to continue further discussions on an individual basis after the formal group session has ended. We should not take longer than 2 hours.*

00:07 Explain the rules:

- *There are no right or wrong answers, only differing points of view*
- *We are looking for your opinions and hope for a good discussion*
- *It is possible that you do not agree with all opinions, listen to each other's points of view; each view is important and counts. Afterwards you are welcome to provide your view.*
- *We're audio recording, so it would be very helpful for the analysis if only one person is speaking at a time*
- *Since this is an informal discussion, we will address each other only by their first name*
- *We ask you to turn off the sound of your phones*
- *If there are any questions or terms that are used during the focus groups that are not clear to you, please let us know*
- *So, we will now start the recording. Is that OK for everybody?*

- *First, to get to know each other, could everybody introduce themselves in 1 minute (name, background, function/role at EMA)?*

00:15 Introduce the topic of patient preference studies:

- A slideshow will be used to support the FGD. In this slideshow all concepts and definitions used throughout the FGD will be clearly and visually explained.
- Explain the definition of the FDA for patient preference information: *"qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions"*
- *In other words, patient preferences are the basis of how patients choose a particular treatment over others. To make a choice, patients make trade-offs between a treatment's characteristics, weighing its advantages and disadvantages collectively.*
- *Different preference methods enable to investigate patient preferences. One categorization of preference methods is the difference between qualitative (or direct) method and quantitative (or indirect) methods. Qualitative methods aim at gaining in-depth knowledge about the value of a specific drug. Examples of qualitative input are oral or written feedback from patients or patient representatives on specific questions during the decision-making process.*
- *Today we are focusing on quantitative preference methods, used in patient preference studies. Preference studies allow eliciting and quantifying preferences from a group of patients. In this study, we will use preference methods to refer to methods requiring patients to choose between hypothetical treatments or their characteristics (or attributes). Preference methods can be used to quantify the relevance of treatment outcomes (e.g. their benefits and risks) to patients and understand how patients trade-off between them. Preference methods can also identify whether there are subgroups of patients with different preferences.*
- *Despite interest, preference studies are currently not systematically conducted and used to inform regulatory decisions and no European (regulatory) guiding principles or framework is in place for their conduct and use.*
- Ask if this is understandable to all
- *If there are any questions or terms that are used during the focus groups that are not clear to you, please let us know*

PHASE 1: SILENT GENERATION AND FIRST GRADING

00:17 *As I mentioned earlier, today we want to seek consensus on the issues affecting the use of patient preference studies in regulatory decisions that you, both individually and as a group, consider to be most important. Remember there are no right or wrong answers, it is about what is important to you, as regulators. We will now hand out a list containing potential issues, which you also received by email prior to the focus group discussion. These potential issues were identified through previous research that*

investigated stakeholders` views (academics, Health Technology Assessment (HTA)/payer representatives, industry, patients, physicians and regulators) regarding patient preference studies to inform decision-making throughout the medical product life cycle.
Hand out answer form (assistant). The moderator now goes through all issues and explains them briefly. *I want you to take section 2 of the answer form, entitled 'Grading' and take 10 minutes to fill it in. If you think that there are issues missing from the list, please add them below in the form. Please fill in the form in silence, and do not discuss your opinion with others. Please raise your hand if you have any questions.*
PHASE 2: ROUND ROBIN
00:30 *Now we are going to go around the room and one-by-one each state one issue that you have given a high grade and the assistant will write it up here on the slide. We will go around until we run out of issues. Please also state those issues you wrote down that you feel were not captured in the list. Please do not forget to mention why you considered the issue important; and remember that there are no wrong answers, each response is very valuable to us.*

While participants are stating their answers, the assistant writes down the issues provided by the participants on a slide so everyone can see them.

1:00 Break. *We will now have a break of 10 minutes. Please hand in your form when you leave the room. Feel free to use the restroom, take water/ coffee/tea/something to eat.*

During break, the assistant calculates the mean grade per issue in Excel and puts them on a slide
PHASE 3: CLARIFICATION OF IDEAS
1:10 When participants enter the room they will be given back their answer form. *Here on the slide you can see the mean grade for each of the issues. A big score means that on average, the issue is very important to all of you. A small score means that it is not so important.*

- *What do you think about these grades?*

The group will discuss each of the issues, their grades and seek consensus on their grade
PHASE 4: SECOND GRADING
1:40 Did the round of the table discussion and this discussion make you want to change your grade? Please take 2 minutes to change your grades if you changed your mind.
1:45 Do you have any proposals or suggestions for addressing the most pressing issues?
WRAP-UP
02:00 Hand in answer forms. *The focus group discussion is now finished*

- Summarize the lessons learnt of today's discussion – by assistant
- Ask if the summary is correct, or if you have forgotten something
- Ask if there are any questions
- Inform the participants that they will receive a copy of their signed informed consent via mail after the FGD.

- Inform the participants that if certain aspects mentioned during the focus group discussion remained unclear with the researchers, additional individual interviews will be carried out.
- Thank all participants for their participation

Collect the following materials:

- Consent forms
- Answer forms
- Recordings
- Notes

ANSWER FORM

Dear participant,

Please fill out the information below. We would like to collect your answers on the questions below to learn more about you as a focus group participant. The answers of all participants on these questions (excluding the names of participants) will be summarized as group characteristics in reports and publications on this focus group. All information provided by you will be pseudonymized during the analysis, meaning the results of this study will never be linked to your name and identity. If a question is not clear to you, please ask the focus group moderator or an assistant for more information.

Section 1: Personal characteristics

1. What is your name (first name and family name)?

2. What is your age?

3. What is you gender?
    a. Female
    b. Male

4. How long have you been working at/for the EMA?

5. Which country or countries are you a citizen of?

6. What is your highest degree of education?

7. To which EMA committee(s) do you belong?

8. What is your role in this/these committees?

9. Do you have expertise within a specific disease area? If yes, please describe which disease area below

10. Before this study, had you already heard about patient preference studies (*)?

11. How familiar would you say you are with patient preference studies (*):
    a. Very familiar
    b. Somewhat familiar
    c. Not at all familiar

12. Before this study, had you already come into contact with patient preference studies (*)?
    a. Yes, please explain:
    b. No, please explain:

13. If you already had come into contact with patient preference studies, which patient preferences methods (*) do you know to investigate patient preferences?

Please continue to the next section only when the moderator says so.

(*) Background information about patient preferences patient preference studies

Patient preference studies are currently not systematically conducted and used to inform regulatory decisions and no European (regulatory) guiding principles or framework is in place for their conduct and use. With this study we want to seek consensus on most important issues for regulators affecting the use of patient preference studies in regulatory decisions.

Patient preference information has been defined as: *"qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions"*. In other words, patient preferences are the basis of how patients choose a particular treatment over others. To make a choice, patients make trade-offs between a treatment's characteristics, weighing its advantages and disadvantages collectively. To make a choice, patients make trade-offs between a treatment's characteristics, weighing its advantages and disadvantages collectively.

Different preference methods enable to investigate patient preferences. One categorization of preference methods is the difference between qualitative (or direct) methods and quantitative (or indirect) methods. Qualitative methods aim at gaining in-depth knowledge about the value of a specific drug. Examples of qualitative input in the regulatory context are oral or written feedback from patients or patient representatives on specific questions during the decision-making process.

Today we are focusing on quantitative preference methods, used in patient preference studies. Preference studies allow eliciting and quantifying preferences from a group of patients. In this study, we will use preference methods to refer to methods requiring patients to choose between hypothetical treatments or their characteristics (or attributes). Preference methods can be used to quantify the relevance of treatment outcomes (e.g. their benefits and risks) to patients and understand how patients trade-off between them. Preference methods can also identify whether there are subgroups of patients with different preferences.

INTERACT PRACTICAL GUIDES[16]

DELPHI METHOD

STEP 1: REFINE STUDY QUESTION FOR DELPHI STUDY

The delphi method is an iterative, multistage and structured process where the purpose is to obtain a consensus among a panel of experts. This is achieved by a series of questionnaires interspersed with feedback. First of all, it is necessary to form a well-defined research question. **Experience** can bring you to a possible research question, but this needs to be further refined. Through a systematic **literature review** (cfr. Separate practical guide) you can see if and where a gap exists wherefore you wish to find a consensus.

[16] INtroduction To hEalth ReseArCh meThods' (INTERACT) guideline

Step 2: Recruit participants for delphi study

Recruiting the participants is a crucial step in the delphi study since the quality of the study will depend on them. Typically, a delphi method involves an **expert panel** that will come to a consensus. These experts generally consist of a group with a **homogenous background**. When you are selecting the experts that will contacted, the list of experts can be specified by using some **inclusion criteria** such as:

- Experts are willing to complete multiple surveys
- Expertise: e.g. Has expertise in the domain of oncology
- Experience: e.g. Has been principal investigator
- Educational degree: e.g. Has a doctoral degree
- ….

The chosen experts depend on the research question, but could be for example:

- Academics
- Members of a pharmaceutical industry
- People who have a regulatory background

In theory there are no fixed numbers of experts needed to have a successful study. In fact, the expert panel can range from 10 to 1.000. In practice generally **12-15 experts** are participating in the study. In this way there are enough participant to pool the judgment concerning the topic and the response rate should be fine.

Once you have an idea of which experts are eligible for the delphi study, all of them are contacted by **email** (a template can be found in attachment). In this way you invite them to participate to the study, starting with informing them about the **purpose of the study**. Also will they be informed about the **time** they will have to spend on the different surveys as well as the fact that their impute in the study will always be **quasi-anonymous.** This means that only the investigator will know them, but their opinion remains anonymous to the other experts. Moreover, participants will never meet face-to-face. Depending on their **willingness** to participate, they are free to decide whether they participate in the study or not. It can be challenging to find enough experts, since on the one hand the process can be time consuming and on the other hand experts are often busy.

TIPS & TRICKS

In your search to experts concerning your research question, you can use **LinkedIn.** Herby you can search for profiles of people affiliated with specific companies or institutions. In this way you got rarely access to their email address, but you can make a first contact by LinkedIn. Otherwise you can search through **databases of professional email addresses** (e.g. https://rocketreach.co).

Step 3: Make a first round questionnaire for delphi study

Now that a specific research question has been formed, the first questionnaire (a template can be found in attachment) concerning this subject can be made. Do **not underestimate** this step! Generally, around a month is necessary to make the first questionnaire.

When making the questionnaire, it is important to formulate the questions carefully in order to make sure that all participants understand the questions. Otherwise you will receive inappropriate answers. Generally, questionnaires used in delphi studies are well **structured** and contain **open-ended questions**, which are not too long or too short, as well as **statements**. Generally, these questions start wide and gradually they focus more and more on the research question. Examples of questions/statements are:

- *Describe the training and support you were given to teach in clinical settings (e.g. types of training, length of training)*
- *List three concerns you have with teaching in the clinical setting*
- *How do you provide constructive feedback to students regarding their progress? Describe specific strategies or techniques you use*

The participants will be asked to **fill in** the questions **and motivate** their answer where possible.

Step 4: Pilot first round questionnaire

Before sending the first questionnaire to the expert panel, it is recommended to pilot the questionnaire. By sending the questionnaire to co-workers that are not included in the expert panel, you can pilot the phrasing of the statements and you will get an idea of how long it takes to fill in the questionnaire. At the end of the pilot you can **improve the first questionnaire** based on the received comments and suggestions.

Step 5: Perform and analyse first round questionnaire for delphi study

In this first round, the panel of experts is given the optimized first questionnaire by email (a template can be found in attachment). If necessary, after two weeks a polite reminder can be sent to the experts in order to get an answer from as much experts as possible. For this first round, the panel of experts is asked to fill in the questionnaire from their **own point of view**, **motivate** their opinion if possible and to **rate** their degree of agreement. This last one is done on a **5-point Likert scale**, where numbers 1 to 5 stands for:

1. Strongly disagree
2. Disagree
3. Neither agree nor disagree
4. Agree
5. Strongly agree

The data that you obtain in this first round, is being anonymized and a **descriptive analysis** is done. The mean, median, mode as well as the standard deviation (SD) of the panel are obtained. This first **data** will be **summarized** and themes will be formed**.** This will group similar information together and data will be reduced. This all will form the **core** for the **second round** in this delphi study.

TIPS & TRICKS

As it is only the first round, a lot of data on the research question will be generated. To process and analyse all of this easily it can be useful to use an **electronic questionnaire** such as *SurveyMonkey, Qualtrics, Survio, Survicate* etc. The link to the electronic survey can be added in the email send to the expert panel. However, be aware that is might be possible that emails with online questionnaires can arrive in the "**spam**" of the participants. If you do not get any answer it might be a good idea to send them an email without the questionnaire where you mention that previous mails with the questionnaire are possible marked as spam.

STEP 6: PERFORM AND ANALYSE SECOND ROUND QUESTIONNAIRE FOR DELPHI STUDY

After the data of the first round has been analysed, the expert panel is recontacted by email and invited to fill in the second questionnaire.
In this second round, the panel of experts must fill in the questionnaire for a second time. Here for they receive a summarized feedback report of the answers that they gave in the first round and **descriptive data** obtained after the **first round.** These statistical results (table 1) are added, both graphical (histogram) and in text, to the questionnaire to make sure everyone interpret them correct. In this way the experts can see if and how much their opinion differs from the other ones. The experts are invited to **reconsider** their first answer and can **adapt** their answer and/or motivation. This form of **feedback or reflection** is an essential key element in the delphi method in order to come to a consensus. As in the first round, the experts are also asked to rate with a 5-point Likert scale. At the end of this step, areas of agreement and disagreement can be identified, and a **consensus starts** to be formed. A delphi study has a **minimum of two rounds.**

	Panel rating		
	mean	SD	Your previous rating
Theme 1			
Question/Statement 1.1	…	…	…
Question/Statement 1.2	…	…	…
…			

TABEL 1 VISUALISATION STATISTICAL DATA

Again, the obtained data is analysed using descriptive statistics (mean, median, mode and standard deviation). Compared to the first round, the **range of responses will be reduced** because of the starting consensus.

STEP 7: PERFORM AND ANALYSE QUESTIONNAIRE ROUNDS UNTIL CONSENSUS

The analysed data of the second round of questionnaire will again be used as a core for a next round. Just like in the second round, also now the descriptive data of the previous rounds will be added to the questionnaire. Once more the experts will have the opportunity to **reflect** on their answer, motivate

and will be able to adjust this. They also get the opportunity to **specify the reason they stay outside** the consensus that is starting to form. After the questionnaire has been filled in by the expert panel, the data is analysed as in the previous rounds and will from the core for the next questionnaire. This step is **repeated until** a **consensus** is achieved. Generally, a consensus is achieved when **80% of the answers** fall within **three categories of the 5-point Likert scale**.

Step 8: Summarize answers into a consensus

Finally, when it looks like you achieved a consensus on the initial research question, you can summarize the answers of the questionnaire into a **final consensus** among the expert panel. This can take the form of a **list** with priorities. This list can later be used for other cases within the research subject.

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TEMPLATE 1: INVITATION EMAIL

Subject line of the e-mail: Invitation to participate in a Delphi study about […]

Body of the e-mail:

Dear Dr./Mr./Mrs. [name],

We would like to invite you as an expert in […] to participate in a Delphi study that aims to […]. We realize that as a professional you are extremely busy, but we are convinced that you are good candidate for this delphi study.

The Delphi study will consist of [expected number of rounds] rounds in which you will be asked to fill in a [(online)] questionnaire of [number of questions] questions and statements. We estimate that every round will take approximately [expected time] of your time. By rating the multiple questions and statements and revising your opinion in each round a final consensus we hope to reach a consensus in the last round. During the entire study your opinion and answers will stay anonymous to the other participants.

We hope you are willing to participate to this study and help us in this way to come to a consensus concerning [subject of the study].

If you have questions or wish to have more information, you can always contact us by email [email address] or phone [number].

Tank you in advance for your time,

Kind regards,

[E-mail signature of the person who sent the invitation]

TEMPLATE 2: EMAIL FIRST QUESTIONNAIRE

Subject line of the e-mail: First questionnaire of the Delphi study about […]

Body of the e-mail:

Dear Dr./Mr./Mrs. [name],

We thank you for your willingness to participate to this study which aims to […]. During the entire study your answers will be anonymous to other participants. In this way you can answer the questions honestly.

In this first round we would like to ask you to fill in the first questionnaire [through the following link (….) (in case of an online questionnaire)]. In this questionnaire we have [number of questions] open-ended questions whereof you can give your opinion in the provided box. We would also like to ask you to rate your agreement to the given statements on a scale of 1 to 5. Herby the numbers stand for:

1. Strongly disagree
2. Disagree
3. Neither agree nor disagree
4. Agree
5. Strongly agree

In the next weeks we will recontact you for the next questionnaire where you will be able to reflect on your first answers.

Tank you in advance for your time,

Kind regards,

[E-mail signature of the person who sent the invitation]

TEMPLATE 3: EXAMPLE QUESTIONNAIRE

Welcome to the first questionnaire of the delphi study. We ask you to answer the questions from your opinion and to rate your agreement on a scale of 1 to 5 by filling the circle. Herby the numbers stand for:

1. Strongly disagree, 2. Disagree, 3. Neither agree nor disagree, 4. Agree, 5. Strongly agree

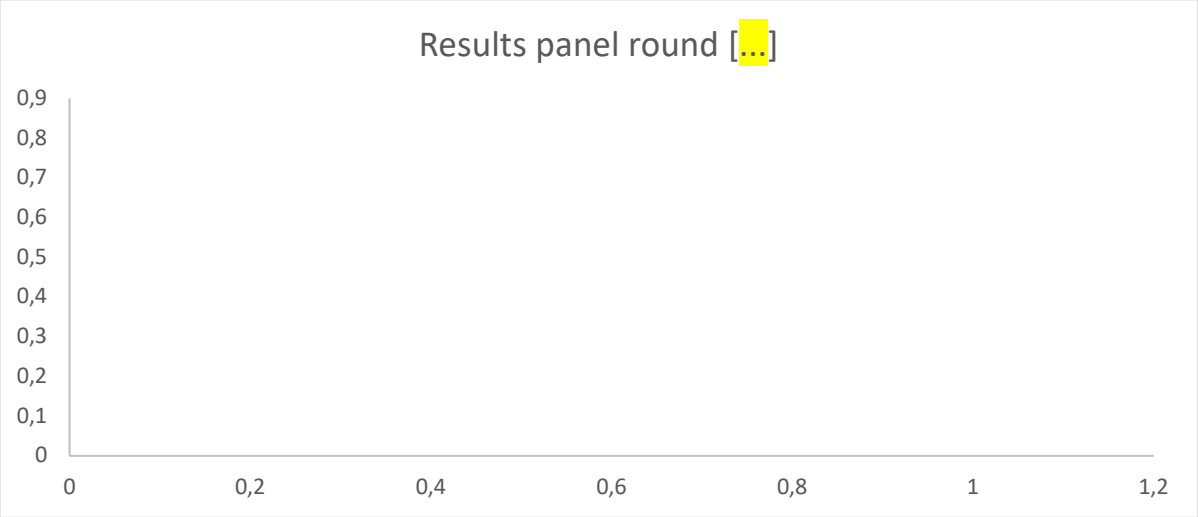
No.	Statement/question				
1	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					
2	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					
3	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					
[...]	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					

General notes:

TEMPLATE 4: EXAMPLE QUESTIONNAIRE ROUND 2 OR MORE

Welcome to the [...] questionnaire of the delphi study. In this round you can compare your previous answer to the answers of the other experts through the descriptive data. You may adapt your opinion or explain why you don't follow the forming consensus. Finally, we ask you to rate your agreement on a Likert scale of 1 to 5. Herby the numbers stand for: 1. Strongly disagree, 2. Disagree, 3. Neither agree nor disagree, 4. Agree, 5. Strongly agree

	Panel rating		
	mean	SD	Your previous rating
[Theme 1]			
[Question/Statement 1.1]	...	...	...
[Question/Statement 1.2]	...	...	...
[...]			



[Researcher can add data (by double clicking on the graph area) of the results to obtain a visual view]

No.	Statement/question				
1	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					
2	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯

Note/motivation					
3	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					
[...]	[...]				
Likert scale:	1 ◯	2 ◯	3 ◯	4 ◯	5 ◯
Note/motivation					

General notes: