

ConcePTION

WP5 – Dissemination and education

for HCPs, pregnant and breastfeeding women,

and general public

D5.2: Report describing communication plan and governance for Work Package 5, Subtask 5.3

Lead contributors	Alison Oliver, Sally Stephens, Agnes Kant, Josepine Fernow
Other contributors	Stéphanie Tcherny-Lessenot, Annlouise Assaf, Ida, Niklson, Hildrun Sunseth, Roxana Radu, Laura Yates, Jennifer Drevin
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Contents

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1 Table of Contents

2	Introduction and statement of purpose10		.10
3	Pho	armacovigilance	.12
	3.1	Adverse Event Reports (retrospective reports)	. 12
	3.2	Prospective data collection	. 13
	3.3	Challenges for promotion of PV and pregnancy research	.14
4	Ove	erarching principles for communication	.15
	4.1	Guiding principles	.15
	4.2	Branding	.16
	4.3	Creating inclusive promotional materials	.16



	4.3.1	Communication responsibilities across work packages	16
5	Aim	s of communication in task 5.3	18
6	Gove	ernance for Task 5.3 activities	19
7	Aud	ience and development of strategy for external communication	20
7	7.1	Audience	20
7	7.2	Approach to developing tools and tactics for HCP, patients and general population	
	7.2.1	Development of a strategy to communicate to HCPs and women	23
	7.2.2	Sending and multiplying messages	23
	7.2.3	Building/engaging the audience	24
	7.2.4	Objectives and key messages	25
	7.2.5	Tools and tactics for campaigns	26
	7.2.6	Toolkit development	28
8 wa		eton action Plan for communication to HCPs, pregnant and breastfeeding	28
	men.		
wa 9	omen. Mea		29
w o 9	Mea 0.1 (surement of impact through pilot studies	29 29
wo 9 ي 10	0 men. Mea 0.1 (0 0.2) Ge	surement of impact through pilot studies	29 29 29 PV
wo 9 9 10 sys	Mea. 0.1 0.2 Ge stems	surement of impact through pilot studies Overview of pilot studies Key Performance indicators eneral tactics communications and social media campaigning to promote .	29 29 29 PV 30
wo 9 9 10 sys	Mea. 0.1 (0 0.2 1 Ge stems	surement of impact through pilot studies Overview of pilot studies Key Performance indicators eneral tactics communications and social media campaigning to promote a and prime audiences for ConcePTION outputs	29 29 29 PV 30 35
wo 9 9 10 sys 11	0.1 (0.1) 0.1 (0.1) 0.2) 0.2) Ge stems (0.1) Ta	surement of impact through pilot studies Overview of pilot studies Key Performance indicators eneral tactics communications and social media campaigning to promote a and prime audiences for ConcePTION outputs Participation in recurring Twitter campaigns	29 29 PV 30 35 37
wo 9 10 5ys 11	0.1 (0.2) 0.2) 5tems 10.1) 1.1)	surement of impact through pilot studies Overview of pilot studies Key Performance indicators eneral tactics communications and social media campaigning to promote a and prime audiences for ConcePTION outputs Participation in recurring Twitter campaigns urgeted pilot campaign 1: Promotion of PV reporting via UKTIS BUMPS	29 29 PV 30 35 37
wo 9 10 5ys 11	Mea. 0.1 (0.2) Ge stems 10.1) 1.1 1 1.2 (1.2 (1.2)	surement of impact through pilot studies Overview of pilot studies Key Performance indicators eneral tactics communications and social media campaigning to promote a and prime audiences for ConcePTION outputs Participation in recurring Twitter campaigns Introduction to UKTIS and BUMPS	29 29 PV 30 35 37 37 37



-	2 Tailored objectives, messages and tools and tactics for stimulating participation in EGNANT	41
13	Action Plan	.42
14	Summary	.45
15	References	.45
16	Annexes	.46
C	nex 1. ConcePTION WP5.3 communications SWOT analysis SWOT analysis to inform mmunications plan for 5.3 (PV reporting and participation in research, in the context of the ncePTION project).	46
ŀ	nex 2. Social media and events calendar	55
	nex 3. Inventory of third-party social media and communication channels for amplification of essages	
4	3.3.1 Communication responsibilities across work packages Aims of communication in task 5.3	
5	Governance for Task 5.3 activities	
6	Audience and development of strategy for external communication	
ť	1 Audience	20
e	2 Approach to developing tools and tactics for HCP, patients and general population	22
	6.2.1 Development of a strategy to communicate to HCPs and women	23
	6.2.2 Sending and multiplying messages	23
	6.2.3 Building/engaging the audience	24
	6.2.4 Objectives and key messages	25
	6.2.5 Tools and tactics for campaigns	26
	6.2.6 Toolkit development	28
7 wa	Skeleton action Plan for communication to HCPs, pregnant and breastfeeding nen	.28



8	Measurement of impact through pilot studies	.29
8	3.1 Overview of pilot studies	.29
8	3.2 Key Performance indicators	.29
9	General tactics communications and social media campaigning to promote PV	
sys	stems and prime audiences for ConcePTION outputs	.30
Ç	9.1 Participation in recurring Twitter campaigns	.35
10	Targeted pilot campaign 1: Promotion of PV reporting via UKTIS BUMPS	.37
ĺ	10.1 Introduction to UKTIS and BUMPS	.37
ĺ	10.2 Tailored tools, tactics and messaging for stimulating PV reporting through BUMPS	.38
11	Targeted pilot campaign 2: Promotion of PV reporting through pREGnant	.40
ĺ	11.1 Introduction to pREGnant	. 40
	11.2 Tailored objectives, messages and tools and tactics for stimulating participation in pREGNANT	. 41
12	Action Plan	.42
13	Summary	.45
14	References	.45
15	Annexes	.46
C	Annex 1. ConcePTION WP5.3 communications SWOT analysis SWOT analysis to inform communications plan for 5.3 (PV reporting and participation in research, in the context of the ConcePTION project)	. 46
ŀ	Annex 2. Social media and events calendar	. 55
	Annex 3. Inventory of third-party social media and communication channels for amplification of nessages	. 57



List of figures

Figure 1: Overview of PV reporting and information sharing in Europe	13
Figure 2: Expected content in communications in ConcePTION channels and clarification of role of Task 5.3.	
Figure 3: Schematic of proposed strategy for Task 5.3	24
Figure 4: Skeleton plan for task 5.3 communications	29

List of tables

Table 1: Task 5.3 governance	19
Table 2: Characteristics of different HCPs in the audience.	21
Table 3: Key objectives and messages for Task 5.3 communications.	25
Table 4: Different audiences targeted by communication activities.	27
Table 5: KPIs for monitoring impact of promotional campaigns.	30
Table 6: Objectives, key messages and tools for general communication activities for general pilo campaigning to increase PV reporting and awareness of biobank	
Table 7: KPIs to monitor engagement rates and reach for task 5.3 communications campaigns	37
Table 8: Examples of objectives, key messages and tolls for targeted pilot campaign 1	38
Table 9: Objectives, key messages and tools for targeted pilot campaign 2	41

Executive Summary

Most external communication to HCPs, patients and the general public in the IMI ConcePTION project is divided over two Work Packages (WPs). WP5 has the responsibility for communicating to healthcare professionals (HCPs), patients, and the general public the



importance of pregnancy exposures reporting and outcome follow-up. They are also tasked with communicating to breastfeeding women the importance of donating blood and milk samples for the biobank. WP8 is responsible for communicating project results as well as general communication on the IMI ConcePTION project, why it is important, and how the project fills the information gap.

Raising awareness about the lack of reliable evidence (as well as the need for broader communication) on the issue of knowledge gaps on medication use during pregnancy and breastfeeding is a common theme within the communication activities on the ConcePTION project in WP5 and WP8. Therefore, it is important that those activities are synchronized and communicate similar messages. In order to achieve this goal, the communication plan below describes these activities as a shared responsibility between these two WPs. The communication on the results and outputs of the ConcePTION project are the responsibility of WP8 and will not be described in this deliverable.

This report will focus on deliverables of WP5, including the communication to key stakeholders and audiences, key objectives and messages for external communication, and an initial plan for two pilot campaigns (Q4 2020 until Q2 2022) and one general campaign (Q4 2020). The document outlines a general messaging approach through ConcePTION channels (amplified by partner local channels) to promote pharmacovigilance (PV) systems and the breastmilk biobank (developed in WP4), and to raise awareness of ConcePTION resources that are in development (Knowledge Bank). This will be paired with two pilot campaigns with targeted messaging to run in parallel using local channels to promote two specific systems which are participating in WP2 of ConcePTION (UKTIS BUMPS, Lareb pREGnant). The first three months of the action plan are devoted to preparation of initial promotional materials for the pilot campaigns. A plan for targeted messages via social media designed to correspond to key dates in the healthcare/women's health social media calendar is included. We will, however, take advantage of opportunities for ad hoc messaging based on current news and 'hot topics' when possible. Key performance indicators will be measured before and following the initial 12-month pilot campaigns. Insights will be used to produce a communications toolkit, which will provide a lasting legacy and contribute to overall sustainability of the ConcePTION ecosystem. The strategies, activities, tool and tactics outlined in this document build on a Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis for external communications.



List of acronyms/abbreviations

Abbreviation	Explanation
ADR	Adverse drug reaction
EMA	European Medicines Agency
MHRA	Medicine and Healthcare Products Regulatory Agency
EFPIA	European Federation of Pharmaceutical Industries and Associations
ENTIS	European Network of Teratology Information Services
EU	European Union
GDPR	General Data Protection Regulation
GVP	Good pharmacovigilance practices
НСР	Healthcare Professional
KPI	Key Performance Indicator
МАН	Marketing Authorisation Holders
NCA	National Competent Authority
PV	Pharmacovigilance
SWOT	Strengths, Weaknesses, Opportunities, Threats
TIS	Teratology Information Service



WP	Work package
отс	Over the counter
NCA	National competent authority

Glossary of terms

Term	Explanation
Audiences	Groups for which the communication or dissemination is targeted.
Communication objective	Goals for 5.3 communication that can be used to identify audiences, develop messaging strategies and evaluate the effectiveness of communications.
Consortium	Collectively, all organisations that have signed the ConcePTION consortium agreement.
Consortium member	Individual involved in the ConcePTION project.
Consortium partners	All participants of the IMI ConcePTION project- full or associate.
Plain language	Communicating in a clear, concise and structured way, avoiding jargon or convoluted language.
Stakeholder	Any individual or organisation with an interest or concern related to the ConcePTION project.
Content owner	Person with responsibility for accuracy of information in a specified channel.



Teratology	Also designated as developmental toxicology.
	Developmental toxicity is defined as any structural or functional alteration caused by environmental insult that interferes with normal growth, differentiation, development, and/or behaviour. ¹
Pharmacovigilance	Pharmacovigilance is the practice of detecting, assessing, understanding and preventing the adverse effects of medicines. Pharmacovigilance enhances patient safety and public health by providing reliable information on the risks and benefits of medicines. ²
Adverse Drug Reaction	A response to a medicinal product which is harmful and unintended. ²
Serious Adverse Event	An adverse event (AE) is called serious if it: results in death, is life- threatening (at risk of death at the time of the adverse event, not an event which 'could' hypothetically have caused death if it were more severe), requires hospitalisation or extension of existing inpatients' hospitalisation, results in a persistent or significate disability or incapacity, or is a congenital anomaly or birth defect. ²

¹ Encyclopedia of toxicology (3rd Edition), 2014

² EUPATI and WP6 glossary

2 Introduction and statement of purpose

The overarching purpose of this communication plan is to:

- Define the communication strategy for healthcare professionals (HCPs), pregnant and breastfeeding women and the general public
- Generate awareness that they can play an active role in increasing the general knowledge about the safety of medicines used during pregnancy and breastfeeding in the post-authorisation phase
- To support the ConcePTION project by engaging with HCPs and women to encourage PV reporting and participation in research.



Pregnant and breastfeeding women are not generally included in clinical trials, and therefore, most safety information is collected **after** the drug has been approved for use, following intentional or unintentional use¹. Data collection is currently fragmented throughout Europe and based on voluntary reporting systems. Consequently, there are often insufficient data from these channels to draw conclusions on the safety of drug use during pregnancy and breastfeeding. However, pregnancy drug safety information is vital to the discovery of emerging teratogens, reducing the number of preventable adverse fetal and neonatal effects, and the prevention of unnecessary termination of otherwise wanted pregnancies. Equally, given the well-established health benefits of breastfeeding for both mother and child², and that concern that lack of medicine safety information may constitute a barrier to breastfeeding³, it is vital that more research is established in this area.

The ConcePTION project aims to fill the knowledge gaps in these areas of pregnancy and breastfeeding medicines safety information. Work package 2 of the ConcePTION project aims to improve pregnancy medicines data collection and analysis by developing a common data model for harmonised data collection. This may lead to the potential for combining of data from multiple sources (TIS, academia and EFPIA partners), enabling sufficient numbers of exposed pregnancies and hence statistical power for signal detection to be achieved more rapidly. This would enable conclusions on the safety of medicines use during pregnancy to be made earlier. The teratology information services in the UK (UKTIS) and in the Netherlands (Lareb) will contribute data to demonstration projects in WP2.

In WP4 of ConcePTION, a milk biobank is being developed to collect samples of blood and breast milk from breastfeeding women taking medicines. The samples collected will enable the study of medicines transferred from the mother through milk to the baby. The samples will be collected in several demonstration studies for specific drugs, in Sweden, France and Switzerland. Samples will be stored in facilities provided by Uppsala Biobank, Sweden (https://www.uppsalabiobank.uu.se/en/), with the potential for more sites to be added as the project progresses.

11



Downstream of knowledge generation is knowledge dissemination, and the Knowledge Bank (Task 5.2) will aim to present current knowledge on the safety of medicines in pregnancy and breastfeeding in a website that is accessible to both women and HCPs.

Communications as part of WP5 will aim to support the success of these ConcePTION research initiatives, through promotion of reporting into PV systems in general, as well as a focus on UKTIS and Lareb TIS systems which are contributing to WP2. The plan will also support recruitment of participants to the WP4 breastmilk biobank and prime audiences for the emergence of the Knowledge Bank.

3 Pharmacovigilance

Pharmacovigilance (PV) surveillance in the context of pregnancy is performed by marketing authorisation holders (MAHs), academic and pharmacovigilance centre systems, or national healthcare registries, which collect spontaneous reports of pregnancy exposures and outcomes during post-authorisation surveillance or as part of research studies. Post-authorisation PV monitoring and prospective observational cohort collection databases are a valuable tool in teratogenic signal detection. These sources are equally important for establishing the lack of a teratogenic signal- enabling patients and HCPs to make informed decisions about the treatment of medical conditions during pregnancy.

3.1 Adverse Event Reports (retrospective reports)

Adverse event reporting during the post-authorisation phase is one primary source of information on adverse events occurring following exposure *in utero* or during breastfeeding⁴. In spontaneous adverse event reporting, all birth defects are Serious Adverse Events⁴. The EMA guidance to patients⁵ encourages the reporting of side effects (i.e., suspected adverse reactions) by both healthcare professionals and patients. However, in some countries there is no legal requirement for HCPs to report adverse events and time constraints often mean that they don't.^{6,7}

Pregnant women or HCPs may contact the marketing authorisation holder (MAHs) or their local teratology information service to request information on the teratogenic potential of a drug following an adverse event. Teratology information services (TISs) are funded and operated by



academic, public health or regional PV centres. In some countries, regional PV centres are in place under the coordination of the national competent authority (NCA).

Therefore, spontaneous reports from HCPs or women may be received by either the MAH, the NCA, including PV regional centre, or TIS (see Figure 1). It is possible that the HCP or woman may be in contact with more than one entity.

There is no EMA guidance on spontaneous reporting by health care professionals or consumers of drug exposure during pregnancy or lactation without suspected adverse reactions. Therefore, reports of normal outcomes are not considered alongside those documenting suspected adverse effects.



Figure 1: Overview of PV reporting and information sharing in Europe. Arrows indicate direction of the flow of information with a dotted line representing a situation that occurs 'sometimes', MAH may collect data in prospective registries as well as PV systems for spontaneous reports.

3.2 Prospective data collection

Adverse event reporting is inadequate to provide routine signal detection on medicine induced fetal effects, or lack of effects. Therefore, when new medicines are launched, the creation of pregnancy exposure registries may be requested by the regulatory authorities, and together with Teratology Information Services will collect information about ongoing drug exposed pregnancies, following up until pregnancy outcome. Disease specific registries also exist to proactively monitor for adverse pregnancy outcomes following *in utero* exposure to a drug or group of drugs using similar methodology. Successful monitoring requires the reporting of an



adequate number of exposed pregnancies, motivated women and clinicians to provide follow up data, and accurate and detailed information about the pregnancy and the exposure.

Teratology Information Services (TISs) collect valuable prospective data (but on all medicinal products, as opposed to a specific product), as well as retrospective observational pregnancy data at a national level from HCPs and women who contact their services for advice. The European Network of Teratology Information Services (<u>www.entis-org.eu</u>) is a global collaborative network of 30 TISs, 18 of which are in the European Union, covering the population of 11 countries. Most TISs are funded by teaching hospitals or government health agencies with additional support from research and charitable organisations. To mitigate small sample sizes, TISs (as part of ENTIS collaborations), pool their pregnancy outcome data and publish their findings in the peer reviewed literature, but the problem of low ascertainment of pregnancy outcomes remains when relying on busy clinicians for information. One other often overlooked aspect of teratogen surveillance is the high cost and time to collect data regarding effects of *in utero* medicine exposure and the subsequent longer-term health and neurodevelopment effects on the offspring.

To address some of these issues the TIS of the PV Centre Lareb in the Netherlands and the TIS commissioned by Public Health England in the UK have developed Pregnancy Drug Registries. These web based registries are population based systems for proactive monitoring of medication use during pregnancy and breastfeeding where pregnancies can be self-reported by pregnant women, creating an opportunity to provide ongoing information about their medicines, pregnancies and children's long term health and neurodevelopment. However, these are relatively new systems where resources for promotion are limited, making it difficult to highlight their existence to an ever changing audience of childbearing age women.

3.3 Challenges for promotion of PV and pregnancy research

There is a clear need to encourage PV reporting; however, there are a number of challenges for promotion of reporting of drug exposure during pregnancy. As already alluded to, there are a number of ways that a woman or HCP can report a pregnancy exposure and therefore there is a need to channel reporting to the most appropriate system for the situation (which may depend on the country that the patient resides and the drug that they are taking). Promotion at a



national level in local language is key to effectively stimulating reporting. In addition, TIS and NCA systems collect data on all medicines and therefore communications need to target a wide range of patients' groups and cover a broad range of medicinal products. From the perspective of international MAH PV reporting systems, including drug and disease pregnancy registries, communications need to target specific patient groups and mention specific medicines. Where pregnancies are reported prospectively, encouraging women and healthcare providers to remain engaged with information exchange through to pregnancy outcome and beyond into childhood is a challenge.

This document will outline an approach to try to effectively overcome some of these challenges through targeted messaging and parallel campaigns to raise awareness and stimulate reporting by both HCPs and pregnant women.

4 Overarching principles for communication

4.1 Guiding principles

Guiding principles for stakeholder engagement have been created by WP6 as part of D6.1. Briefly, communications in this plan will adhere to the following key guiding principles, which require that communications are:

- 1. Responsive and reciprocal
- 2. Inclusive
- 3. Conscious of the need for clear communication, used with discretion
- 4. Neutral, objective and free of conflict of interest:
- 5. Open, transparent, accountable and trustworthy
- 6. Respectful
- 7. Purposeful and well-prepared



- 9. Non-interfering
- 10. Impactful and sustainable

4.2 Branding

All promotional materials including videos, infographics, slide decks, posters and promotional graphics will acknowledge IMI ConcePTION as specified in the publication policy and will display the IMI ConcePTION logo with accompanying IMI and EFPIA logos. Logos of individual organisations will be used in addition, where appropriate.

4.3 Creating inclusive promotional materials

Materials developed for all audiences will be inclusive; taking into consideration the wide range of socioeconomic and cultural backgrounds from which women and HCPs come. Where promotional materials feature photographs of women, inclusive imagery will be used. Plain language will be used in all tools developed for women and non-specialist language used for HCPs. Where infographics are developed to explain concepts (such as PV, teratology), they will be written in plain language, so they are accessible to the general public as well as HCPs. Overall campaigns promoting PV reporting through ConcePTION channels will be carried out in English, using video and graphics that are easily translated to partner's languages when using their own channels. Materials developed for campaigns related to specific TIS's or registries on the national level will be developed in the national language and translated to minority languages to include women from ethnic minorities and large immigrant communities, where feasible.

4.3.1 Communication responsibilities across work packages

The ConcePTION project is structured such that the communication activities are divided between WP8 and WP5. The tasks of WP8 are communication around raising awareness of the ConcePTION project and communication of project deliverables and results through different channels. The communication activities around raising awareness of the ConcePTION project and the need for more data concerning safety of medicines use during pregnancy and lactation to a great extent overlap with raising awareness of the need for reporting exposed pregnancies to different pregnancy reporting systems. Both target the same audience and stakeholders with



the same or similar messaging contents. This requires that 5.3 communications are in alignment with overall messaging from the project.



Figure 2: Expected content in communications in ConcePTION channels and clarification of role of Task 5.3.

Communication about the problem is achieved through a stepwise approach, where communications through project channels are designed to; 1) explain and frame the project, 2) support project needs (for example recruitment in WP's 2, 7, 5 & 4) and mitigate risks (e.g. addressing concerns surround data governance and security), and 3) ensure timely and impactful communication of ConcePTION results. In addition, we will design communications to raise awareness about the lack of knowledge/information, how the ConcePTION project responds to this, placing us (project, partner organisations, individuals) as experts and explaining the ecosystem, which includes the 5.3 goal of stimulating pharmacovigilance reporting. On an operational level, this will involve developing content for website and print materials, agreed messaging, slide decks, video and print leaflets about the project, developing content for ConcePTION channels and third party channels, designing social media campaigns, and developing bespoke video and print materials for different activities. This needs to be



complemented by publicity activities, including publicity for results in ConcePTION channels, multiplied through third-party channels, assessment of news value for publicity activities beyond the project's channels, press activities, and ensuring all outputs are published open access. In addition to results, publicity activities and strategy are also needed for supporting activities developing content for ConcePTION channels to be multiplied; encouraging project members to give expert interviews in media outlets and write editorial text, blogs and newsletters; and developing social media campaigns to place the project in the same domains as our audiences, It is also important to show that we are relevant as a consortium, as partners, and as individual experts in different fields and contexts.

5 Aims of communication in task 5.3

The aim of our communications developed in Task 5.3 is to stimulate PV reporting by raising awareness via social media and other digital channels. Using resource-effective promotional materials we will pay attention to continuous audience building at a national and European level throughout the lifespan of ConcePTION to bring about sustained behavioural change towards PV reporting and participation in research. These methods will be tested in two pilots for specific systems, namely, pREGnant (operated by Lareb) and *BUMPS* (operated by UKTIS). In addition, a general pilot campaign mirroring these campaigns will promote awareness of relevant PV systems at the European level through IMI ConcePTION channels and of breastmilk biobanks developed by WP4. Reporting for a wide range of product exposures for prescription and over the counter (OTC) medicines will be encouraged through general awareness building activities. PV participatory rates and change in behaviour will be measured via online channels. The lessons learned from the targeted pilot campaigns of pREGnant and *BUMPS* described in this communication plan will create a legacy promotional toolkit (examples of successful materials and messaging with detailed guidance) for use by other pregnancy PV systems with the aim to stimulate a shift in paradigm that sees PV reporting as a societal responsibility for all.

ConcePTION outputs such as the Knowledge Bank will be available towards the end of the ConcePTION project. A detailed plan for promoting this output is therefore not presented within this communications plan. However, there will be a need to prime audiences for the emergence



of the Knowledge Bank. It represents an important incentive to encourage participation of women and HCPs in PV and research, as a downstream 'consequence' of improved data collection. Thus, pregnancy outcome data can be utilised to provide information on the use of medicines during pregnancy and breastfeeding.

6 Governance for Task 5.3 activities

The procedures for Task 5.3 communications are outlined below.

Table 1: Task 5.3 governance.

Activity	Responsible persons
Approval of 5.3 communication plan	Management Board
Messages from ConcePTION channels regard	ing PV and milk biobank
Development of specific messages	Project members (WP2, WP5, WP4)
Approval of ad hoc messages	Sally Stephens and Annlouise Assaf Jennifer Drevin (WP4)
Planning and coordinating use of ConcePTION channels for 5.3 communications	Josepine Fernow (liaison between WP8 and 5.3)
KPI collection from ConcePTION analytics	WP8
Operational responsibility	Josepine Fernow
Spokesperson for media engagement	Relevant WP leaders



Coordination of communication efforts with WP2	Alison Oliver
Messages from local pilot campaign channels	(pREGNnant and BUMPS)
Approval of ad hoc messages	Sally Stephens, Agnes Kant
Approval of ad hoc communications	Local ENTIS leads (Lareb, Agnes Kant, UKTIS, Sally Stephens)
Spokesperson for media engagement	Local pilot campaign leads (Director of Lareb and UKTIS)
Operational responsibility	Local pilot campaign leads (Lareb, UKTIS)
KPI collection	Lareb and UKTIS
Coordination of communication efforts with WP2	Alison Oliver
General	
Tracking and storing consent to use photos and video material on members area	WP5 lead

7 Audience and development of strategy for external communication

7.1 Audience

- 1) ConcePTION audiences and potential tactics were identified during a messaging workshop with ConcePTION partners. The key stakeholders for communications in Task 5.3 are:
 - Women of childbearing age: specifically, women who are pregnant, breastfeeding or planning a pregnancy and/or living with a chronic disease. Women represent a major



stakeholder in the promotion of reporting systems and, providing prospective health data.

We aim to speak to women across Europe (different languages, ethnicities and nationalities), from all socio-economic backgrounds.

Healthcare professionals (HCPs): A person who provides medical care or medical advice to women before, during or after pregnancy. This person can be handling the management of the pregnancy, disease, or be someone with a clinical background (i.e. people in an advisory role or writing and publishing local or national pregnancy guidelines). Healthcare professionals are invaluable to providing high quality data on drug exposures and maternal outcomes. They may also play a role in disseminating information about research projects and trustworthy information resources for women. HCPs, especially physicians, are the ones who provide spontaneous reports to pharmacovigilance systems of MAHs and enable prospective follow up according to defined schemes. We divide HCPs into three groups:

Table 2: Characteristics of different HCPs in the audience.

Prescribers	HCPs who have medication related conversations	HCPs who tend not to have medicines related conversations (but meet patients)
Medical doctors (includes all: specialists for specific disease management, OBGyn for pregnancy related issues, geneticists, GP's to treat temporary or chronic conditions, or	Midwives, nurses, pharmacists	Sonographers, physiotherapists, clinical geneticists, doulas
manage pregnancy-related issues) Note: in some countries, this group includes pharmacists, nurses and midwives who can prescribe predefined medicines	Note: in some countries, this group can also prescribe medicines	This group could get questions and then direct patients to online knowledge databases, TIS's, or other health-care professionals for advice



7.2 Approach to developing tools and tactics for HCP, patients and general population

In order to gain an understanding of the challenges associated with communicating to women and HCPs in this task, a series of SWOT analyses were performed (Annex 1). The results of survey 5.1.3 (for HCPs and women) were considered during this process.

Several challenges were identified, such as; the lack of awareness of PV reporting and lack of understanding of the need and purpose for such reporting, the low visibility of teratology services and lack of awareness of what teratology is. This highlighted the need to use informative graphics to explain pharmacovigilance in the process of building the audience.

Several barriers to stakeholder 'buy-in' (reporting of exposures) were also identified which need to be addressed in any communication strategy. These barriers included:

- No legal obligation for HCPs to report pregnancy exposures and may not see the full picture when it comes to pregnancy outcomes.
- Failure of regulatory agencies to have addressed this issue
- Lack of awareness that women can be part of the solution by participating in PV reporting
- Perception of pregnant women as 'vulnerable' and to be protected from research.
- No direct benefits of participation in research for women compounded by lack of feedback from organisations.
- Public perception/distrust of the pharmaceutical industry
- Data security concerns and GDPR
- Culture and language (SWOT and results from the 5.3.1. survey points to the need to communicate to women in their native language)



7.2.1 Development of a strategy to communicate to HCPs and women

General messaging about the project, specific messaging to reach women, and a blueprint strategy to communicate with women were developed for the purpose of recruiting respondents for the 5.1.3 survey. This strategy was evaluated and is described in a document along with a Twitter campaign (to be used as a template for social media strategy) and social media toolkits for Twitter, Facebook and Instagram. This work was followed by communications task force workshops to develop messaging for a number of audiences, including women, patients and health care professionals. This work has informed the development of this strategy.

7.2.2 Sending and multiplying messages

Partners in the ConcePTION project have access to a wide range of relevant networks and channels (websites, newsletters, social media). These networks will be leveraged to multiply messages from 5.3, in general campaigns, and pilot campaigns, using channels that are linked to the participating PV systems. The aim is to engage with people and organisations working in a relevant field.

In liaison with ConcePTION partners, (pilot) PV systems, patient organisations and other actors, we will develop campaign-specific channel strategies to raise awareness about the current lack of safety evidence and information gap. We will make the audience aware that their participation is essential to allow generation of better data to improve safety information. We will leverage existing channels and networks, and develop a social media strategy to engage with patient organisations and advocacy groups to call women and HCP's to main actions:

- 1. encouraging pregnant women and their healthcare providers to take part in reporting ongoing pregnancies to pregnancy reporting systems
- 2. reporting cases in spontaneous adverse event reporting systems



These calls to action will be packaged together with general messaging about the existing knowledge gap, stressing the importance of pharmacovigilance reporting, as well as targeted information about how to report exposure. In parallel to this, communications and awareness building will be piloted in selected organisations (UKTIS and Lareb TIS) where pregnancy data is collected. The sender of the message will depend on the specific system and organization that collect the data in the country. A toolkit, based on the outcomes of the campaigns, will be developed and disseminated.



Figure 3: Schematic of proposed strategy for Task 5.3.

7.2.3 Building/engaging the audience

ConcePTION social media toolkits and social media strategy blueprints will be used as a basis to develop general audience engagement, specifically women and HCPs, throughout the lifespan of the project. Building an audience of (pregnant and breastfeeding) women presents some challenges to be considered as pregnancy is a temporary state, but one which may be



relevant later in their lives as they have further pregnancies. This requires recurring campaigns to reach women through different stages of their lives.

7.2.4 Objectives and key messages

Specific messaging with accompanying calls to action will be used in a targeted way to allow impact to be quantified (see section 9 on key performance indicators). Key objectives and messages for WP5.3 communications are presented in the table below. These messages are further tailored in subsequent sections for specific campaigns and sub-populations (see sections 10, 11 and 12).

Table 3: Key objectives and messages for Task 5.3 communications.

Objectives for external communications (ECO)	Key messages for external communications (ECM) to be refined based on audience
ECO1 Increase awareness of the issue	ECM1 Women should have information about the safety of drugs that they take in pregnancy, but information is lacking. ConcePTION aims to fill that knowledge gap
ECO2 Increase women's feeling of empowerment about the issue to be able to do something about it (whether it be reporting, asking for a second opinion if	ECM2 Know that ConcePTION is building a pregnancy safety ecosystem
a doctor says they can't take medications and get pregnant, searching for information)	ECM3 Know that ConcePTION will have outputs that are useful to women and HCPs
	ECM4 Instead of considering pregnant and breastfeeding women as vulnerable, they will be empowered, through the opportunity to contribute to data collection and improve the current lack of safety knowledge, thus contributing to PV systems
ECO3 Increase HCP reporting to PV systems /teratology services	ECM5 Be aware of PV, what it is and why it is important
	ECM6 Know that if a woman has been exposed to a medicine during pregnancy, this can be reported to PV systems/TIS to help build knowledge on safety of medicine in pregnancy
ECO4 Increase patient reporting to PV systems/teratology services	ECM5 Be aware of PV what it is and why it is important
	ECM7 Knowledge on safety of medicines during pregnancy is lacking. In order to know more about the safety of medicines in pregnancy, we need your help. If you are pregnant, tell us



	about the medicines you use. If you don't use any medicines, this gives us useful information too
	ECM8 Know that there are services available in some countries to help women make informed choices about medicine use in pregnancy
ECO5 Increase use of TIS resources/KB	ECM8 Know that there are services available in some countries to help women make informed choices about medicine use in pregnancy
	ECM9 ConcePTION is working with TISs to create a Knowledge Bank
ECO6 Increase the number of lactating/breastfeeding/nursing women to donate breastmilk to the biobank	ECM10 Equity in care: There is a knowledge gap and we need to fill it with evidence
ECO7 Getting buy-in and help to recruit women to the biobank from health care professionals	ECM11 HCPs/You need this •to be able to give pregnant and nursing women the care they need •to feel safe giving treatment and advice based on sound research
	ECM12 HCPs, we need your support and active collaboration to be able to recruit donors, without your help, there will be no evidence

7.2.5 Tools and tactics for campaigns

In addition to short-form content in social media, we will develop long-form content in formats that are easy to adapt and translate to other languages and channels. Using the same messaging and calls to action, long form content can take the form of editorial text, infographics (e.g. explaining PV in pregnancy), video posted on the ConcePTION YouTube channel, print or pdf flyers, slide sets for HCPs and ConcePTION partners to embed into talks and lectures, posters (designed in PowerPoint to allow adaptation and translation). We will also develop news releases for the ConcePTION website, that can be mirrored on partner websites and shared through newsletters that reach audiences interested in midwifery/obstetrics.

Using images and graphic representations: All images will be used in accordance with GDPR. We will collect and store consent to use video and images that can identify an individual, and as far as possible, use images that are under creative commons licences (e.g. from Otck, Unsplash or Pixabay). Images will be in line with the strategy to communicate with women,



aiming to be inclusive and using a range of pictures of women of different shapes, ages, skin colours and abilities. More details of the tools and tactics and the channels which will be explored for use for different audiences are presented in .

Table 4.

Table 4: Different audiences targeted by communication activities.

Audience	Desired behavioural changes	Channel mix	Tools and materials
Women planning pregnancy	 use local pregnancy information resources use ENTIS resources/KB to inform best use of medicines in pregnancy 	GENERAL MEDIA - Pregnancy website - Breastfeeding websites - Blogs	 Communicating to women toolkit Flyers Example articles Infographics Video Example social media posts editorial text
Pregnant women	 use ENTIS resources/KB to inform best use of medicines in pregnancy report pregnancy exposure/non- exposure to ENTIS centre/pregnancy registry/ ask your HCP to report to MAH PV spontaneous reporting systems 	SOCIAL MEDIA - Patient organisation channels - Facebook - Twitter - Influencers - Patient organisations - Pregnancy chat groups - Breastfeeding support groups	
Breastfeeding Women	 participate in the milk biobank report medicine use in any future pregnancies use ENTIS resources/KB to inform best use of medicines in breastfeeding 	INTERPERSONAL - HCPs - Patient advocates (both disease specific and general)	
HCP: Prescribers	 use local information resources/ report pregnancy 	SOCIAL MEDIA - Twitter - Linked in	 Flyers Advertisements Example articles



HCP: having medication related conversations	 exposures guide women to appropriate resource use local pregnancy information resources/ direct women to these resources encourage women to report pregnancy exposures report patient medication exposures to appropriate PV system use ENTIS resources/KB to inform best use of medicines in pregnancy/breastfee ding 	PROFESSIONAL ORGANISATIONS - national midwifery and obstetric organisations - national pharmacy organisations - national GP and nursing organisations	 Infographics Video Example social media posts slide set for conferences
HCP: seeing patients but not having medication related conversations	 direct women to local information resources use ENTIS resources/KB to inform best use of medicines in pregnancy/breastfee ding 		

7.2.6 Toolkit development

There is an opportunity to provide a legacy from the project. Ongoing promotion of pregnancy reporting will be important to optimise this work. Results from the pilot will inform which materials and messaging had the greatest impact, as well as which platforms were the most successful at reaching HCPs, women and the general public. A toolkit will be developed based on the outcomes of the campaign and disseminated via a publication.



8 Skeleton action Plan for communication to HCPs, pregnant and breastfeeding women

A skeleton action plan for the lifespan of the project is presented here. A detailed action plan spanning 18 months is presented for the two pilot campaigns in subsequent sections.





9 Measurement of impact through pilot studies

9.1 Overview of pilot studies

Tools and tactics will be piloted as part of campaigns to encourage reporting of exposures to systems that are involved in WP2 of ConcePTION (and thus play an integral part of the ConcePTION ecosystem by contributing data). We also have access to KPI data for these systems. These systems will be pREGnant (a patient reported prospective registry of pregnancy drug exposures in the Netherlands https://www.pregnant.nl/) and UKTIS *BUMPS* (a patient reported prospective data collection of pregnancy drug exposures in the UK bumps - best use of medicine in pregnancy).

Where required/requested, targeted campaigning for medicines of interest will be supported, for example when there are new suspected teratogens or new vaccines. The action plan will therefore be a living document which will be developed throughout the course of the project.



9.2 Key Performance indicators

The effectiveness of campaigns will be assessed by collecting baseline reporting data (before the promotion begins) from those ConcePTION partners who have systems that are taking part in the campaign pilots (UKTIS and LAREB). Reporting will be assessed midway through the campaign and again at the end. Where materials are produced with links to reporting systems, hits to the material and 'click throughs' to the reporting systems will be monitored and calculated to determine visibility and effectiveness to stimulate interest in reporting systems. Where available, time spent on each page will be measured.

Impact will also be measured more directly by examining rates of pregnancy exposure reporting to TISs before and after the initiation of the campaign. Internet searches will be used to determine if there have been other notable events or campaigns which could account for any changes seen in levels of reporting. Learnings from this pilot study support the development of a communications toolkit that can be used by other PV reporting systems who wish to replicate our efforts.

Table 5: KPIs for monitoring impact of promotional campaigns.

Activity	ΤοοΙ	Responsible
Website traffic to TIS websites	Google analytics	Participating TISs
Pregnancy exposures	Data Report	Participating TISs

10 General tactics communications and social media campaigning to promote PV systems and prime audiences for ConcePTION outputs

Task 5.3 will develop communication activities, materials and campaigns to support the needs of other parts of the project (e.g. milk biobank recruitment, priming audiences to use the Knowledge Bank, and driving reporting to support WP2 demonstration studies), as well as promoting PV systems. This includes a set of general tactics, supported by the participation in a number of Twitter campaigns to: 1) gain visibility for the ConcePTION project, 2) deliver key



messages for HCP, women, and patient audiences, 3) place ConcePTION as a relevant and credible actor in this field, 4) promote the milk biobank, 5) promote the knowledge bank, 6) raising awareness of the importance of pharmacovigilance reporting, 7) provide an information resource for women and HCP's who wish to know where to report (landing page on the ConcePTION website), and 8) encourage PV reporting.

By participating in on-going events, we will share our research results, connect with other initiatives and reach out to a wider audience to help multiply our messages. This more general visibility in social media and other media will help support the targeted pilot campaigns, as well as overall project communication goals. General messaging to raise awareness about the importance of PV reporting and prime audiences for ConcePTION outputs will be shared through ConcePTION channels and multiplied by partner organisations and networks.

ConcePTION will raise awareness about the project, highlight the lack of knowledge in this area, and raise the importance of pharmacovigilance reporting. This will be done by participating in existing social media and conducting awareness raising activities on a recurring basis (see Annex 4 for an inventory of such events). Participation in these types of activities will increase visibility, support the mission of the ConcePTION project, and place us as a strong actor in the context of medicine safety during pregnancy and breastfeeding. This in turn will help us build an informed audience to multiply our messages and encourage activities that happen at later stages in the project (such as promotion of the milk biobank and the Knowledge Bank). We have identified a number of recurring events and actors with which we want to connect: the October Safe Motherhood Week, the November #MedSafetyWeek, the May Maternal Mental Health Month and Maternal Mental Health Awareness Week (where we did a mini-campaign in May 2020) and World Breastfeeding Week. We will participate, using ConcePTION messaging relevant to the campaign, and calling different audiences to action, for example by encouraging women and health care professionals to report exposure.



Providing resources: Raising awareness of the need for women to report medicines exposures during pregnancy requires tools to enable and empower them. ConcePTION will provide a web resource (dedicated page on the project website), listing how women (and health care professionals) can report exposure. This list will include links to European registries, PV systems, teratology services and other existing resources. The landing page will also allow us to promote other outputs from the ConcePTION project in a timely fashion.

General social media campaign tactics include, but are not limited to:

- Main campaign landing page: General PV reporting resource on ConcePTION website with links to national registries
- Editorial text on ConcePTION website, multiplied through social media and in project's and partners' newsletters.
- Editorial text on blogs and in journals, multiplied through the project's and partner's channels.
- Connecting with patient organisations (e.g. general national, European and international groups such as the European Patients Forum and other members of the EMA Patient and Consumer Working Party, European Organisation for Rare Diseases (Eurordis), European Cancer Patient Coalition), the World Health Organisation (WHO) and other disease specific organisations (national and international), working with issues related to women's health, pregnancy and breastfeeding (e.g. La Leche League).

Objectives for external communications (ECO)	Key messages for external communications (ECM)	Tools and tactics
ECO1 Increase awareness of the issue	ECM1 Women should have evidence-based	Publicity (blogs, editorial text)
	information about the	Social media
ECO2 Strengthen women's	safety of medicines	
feeling of empowerment that they can play an active (whether	that they take in pregnancy, but	Branding for ConcePTION
it be reporting, or asking for a	information is lacking.	Joining existing campaigns Visibility with
second opinion if their health	ConcePTION aims to	other relevant actors (e.g. Uppsala
professional cannot advise them)	fill that knowledge gap	Monitoring Centre through
		#MedSafetyWeek, #SafeMotherhoodWeek,
	ECM2 Know that	#MaternalMentalHealthAwarenessWeek)

Table 6: Objectives, key messages and tools for general communication activities for general pilot campaigning to increase PV reporting and awareness of biobank.



	O DTION!	
	ConcePTION is building a pregnancy safety ecosystem	Webinars (organised in collaboration with other WP's)
	ECM3 Know that ConcePTION will have outputs that are useful to women and HCPs	Newsletters
	ECM4 Instead of considering pregnant and breastfeeding women as vulnerable, they are empowered. Instead there is an opportunity for them to contribute to research and be actors of their own health	
ECO3 Increase HCP reporting to	ECM5 Be aware of	Infographics
PV systems /teratology services	pharmacovigilance, what it is and why it is important	Slide set
	ECM6 Know that if a woman has been exposed to a medicine during pregnancy, this can be reported to PV systems/TIS to help build knowledge on the safety of medicine in pregnancy	
ECO4 Increase patient reporting to PV systems/teratology services	ECM5 Be aware that you can help to increase information on the safe use of medicines through pharmacovigilance reporting. ECM7 Knowledge on the safety of medicines during pregnancy is often lacking. In order to improve this information safety gap, we need your help. If you are pregnant, tell us about the medicines you use. If you don't use any medicines, this gives us useful information too.	Joining existing campaigns Visibility with other relevant actors (e.g. Uppsala Monitoring Centre through #MedSafetyWeek, #SafeMotherhoodWeek, #MaternalMentalHealthAwarenessWeek)



ECM8 know that in there are services available in some countries to help women make informed choices about medicine use in pregnancy Providing a web resource guide to national TIS reporting an exposure ECO5 Increase use of TIS resources/Knowledge Bank ECM8 know that in some countries there are services available to help women make informed choices about medicine use in pregnancy Providing a web resource guide to national TIS reporting an exposure ECO6 Increase the number of lactating/breastleeding/nursing women who will donate breastmilk to the biobank ECM10 Equity in care: There is a knowledge gap and we need to fill it with evidence Supporting WP4 recruitment with tailored communication materials in national languages ECO6 Greese the number of lactating/breastleeding/nursing women who will donate breastmilk to the biobank ECM10 Equity in care: There is a knowledge gap and we need to fill it with evidence Supporting WP4 recruitment with tailored communication materials in national languages Identify access points – often individuals to clinical sites who are involved in patient care who can help identify the women, building knowledge for the future -Maternal care is important! Supporting WP4 recruitment with tailored care who can help identify the women, building knowledge for the future Identify access points – often individuals on clinical sites who are involved in patient care who can help identify the women, building knowledge for the future -Oncone should be context to make and nursing women have an ingit to information -Lack of evidence: we are filling a gap, based on sound research evident memory explore web children, and get pregnant (reproductive autonomy) - Access to sound a	F		[
working with TISs to create a Knowledge BankSupporting WP4 recruitment with tailored communication materials in national languagesECO6 Increase the number of lactating/breastfeeding/nursing women who will donate breastmilk to the biobankECM10 Equity in care: There is a knowledge gap and we need to fill it with evidenceSupporting WP4 recruitment with tailored communication materials in national languagesECO7 Getting support from healthcare professional to recruit women to the biobank-Maternal care is important! -We need your help! -Why should I bother? Solidarity with other women, building knowledge for the future -No-one should be forgotten, pregnant and nursing women have a right to information -Lack of evidence: we are filling a gap, based on sound research -Women with chronic diseases want to have children, and get pregnant (reproductiva autonomy) -Access to sound and trustworthy data on the consequences of taking medicines -90% of pregnantEngage with patient associations - Invite them to include their logo, social media campaign, editorial text for newsletters, video for web		there are services available in some countries to help women make informed choices about medicine use in pregnancy ECM8 Know that in some countries there are services available to help women make informed choices about medicine use in	
lactating/breastfeeding/nursing women who will donate breastmilk to the biobankCount of Legury in care. There is a knowledge gap and we need to fill it with evidenceOutpotning with a redunitient with ratioled communication materials in national languagesECO7 Getting support from healthcare professional to recruit women to the biobank-Maternal care is important! -We need your help! -Why should I bother? Solidarity with other women, building knowledge for the future -No-one should be forgotten, pregnant and nursing women have a right to information -Lack of evidence: we are filling a gap, based on sound research -Women with chronic diseases want to have children, and get pregnant (reproductiva autonomy) -Access to sound and trustworthy data on the consequences of taking medicines -90% of pregnantIdentify access points – often individuals on clinical sites who are involved in patient care who can help identify the women, recruit them and potentially also support 		working with TISs to create a Knowledge	
ECO7 Getting support from healthcare professional to recruit women to the biobank•Maternal care is important! •We need your help! •Why should I bother? Solidarity with other women, building knowledge for the future •No-one should be for gotten, pregnant and nursing women have a right to information -Lack of evidence: we are filling a gap, based on sound research •Women with chronic diseases want to have children, and get pregnant (reproductive autonomy) •Access to sound and trustworthy data on the consequences of taking medicines •90% of pregnantIdentify access points – often individuals on clinical sites who are involved in patient care who can help identify the women, recruit them and potentially also support sample collection (see below for HCP) ·Contacts with patients organisations to promote the study in social media and newsletters ·Publicity tool: writing editorial text to raise awareness in the country/region/disease area (e.g. Jennifer's blog post on Baking Babies, Sweden). Posting in Facebook groups (requires access). Approach influencers (Instagram)Engage with patient associations · Invite them to include their logo, social media campaign, editorial text for newsletters, video for web	lactating/breastfeeding/nursing women who will donate	ECM10 Equity in care: There is a knowledge gap and we need to fill	communication materials in national
I WOMEN TAKE AL LEAST I DEVELOP TO TESEATCH DUISES ARE KEV DEODIE	healthcare professional to recruit	-Maternal care is important! -We need your help! -Why should I bother? Solidarity with other women, building knowledge for the future -No-one should be forgotten, pregnant and nursing women have a right to information -Lack of evidence: we are filling a gap, based on sound research -Women with chronic diseases want to have children, and get pregnant (reproductive autonomy) -Access to sound and trustworthy data on the consequences of taking medicines	on clinical sites who are involved in patient care who can help identify the women, recruit them and potentially also support sample collection (see below for HCP) -Contacts with patients organisations to promote the study in social media and newsletters -Publicity tool: writing editorial text to raise awareness in the country/region/disease area (e.g. Jennifer's blog post on Baking Babies, Sweden). Posting in Facebook groups (requires access). Approach influencers (Instagram) Engage with patient associations - Invite them to include their logo, social media campaign, editorial text for newsletters, video for web Get acceptance from all staff in the clinic as the study relies on one-on-one contacts,



 medicine This is a stressful time in women lives, with lots of information on how she should eat, exercise, and take care of herself: This should be true also if she is sick and needs medical treatment. All information should be trustworthy. ECM11 HCPs/You need this to be able to give pregnant and nursing women the care they need to feel safe giving treatment and advice based on sound research ECM12 HCPs, we need your support and active collaboration to be able to recruit donors, without you, there will be no evidence 	Provide supporting materials: Study- specific printed material about the study supported by - branded generic material (pens, notepads etc). -Templates – slide deck about the project. - Agreed-on oral and written information about the specific study (patient information and consent to the study, ethics review). -" crib sheet" or note with plain language bullet points about study and consent in addition to legal information for use in social media campaign and video. -Use trusted trademarks
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10.1 Participation in recurring Twitter campaigns

General PV reporting social media campaigns will use popular hashtags related to maternal health, disease awareness, or medicine safety. Campaigns will call women and HCP's to action to report exposures to medicines during pregnancy to TIS and/or industry and NCA PV systems. In 2020, we participated in the #MaternalMentalHealthAwarenessWeek, testing the project's social media toolkit and messaging to develop a blueprint for awareness raising campaigns. We are also committed to engage with the World Breastfeeding Week and to provide timely support for WP4 with disease-area specific awareness raising activities related to ongoing demonstration studies and national recruitments of donors for the blood and milk biobank. We



have established relationships with the organisers of two recurring events: the #SafeMotherhoodWeek through the Synergist, and the #MedSafetyWeek, through the Uppsala Monitoring Centre, offering ConcePTION branded graphics from their 2018 pregnancy theme that we can reuse on an annual basis. These two campaigns are described in more detail below.

During the annual **#SafeMotherhoodWeek** various channels will be used to raise awareness about the importance of pharmacovigilance for the general public (women of childbearing age) and specialised audiences (healthcare professionals), developing a committed audience and educating the hard-to-reach publics on the topic at hand. Beyond awareness, this initiative's objective is to identify what women and HCPs think and want with regards to care during pregnancy - including prenatal care, family planning, and medication use - in the post COVID-19 era. The results would be able to inform future campaigns and initiatives of ConcePTION.

#SafeMotherhoodWeek is a yearly initiative - ConcePTION has already been an active partner in its first year, within an effective collaborative structure that has the potential to continue for the entire project lengths, as well as beyond in its sustainability phase.

During the annual **#MedSafetyWeek**, the Uppsala Monitoring Centre teams up with medicine regulatory authorities around the world, to launch a social media campaign that raises awareness of side effects of medicines. The 2020 campaign ran on 2–6 November. This was an opportunity for ConcePTION, and its partners, to join in an existing effort to increase reporting on medicines exposure during pregnancy and breastfeeding (with or without side effects). The Uppsala Monitoring Centre also offers support by providing tailored campaign materials to pharmacovigilance centres in:

- Becoming visible in an already existing context (showing that we are a relevant player in this field)
- Increasing networks, building audiences
- Getting out messages from ConcePTION through pre-existing channels

This campaign can be repeated annually, and elements of it can be used in relation to specific diseases, or disease areas (e.g. Covid-19, #MaternalMentalHealthAwarenessWeek).


Days for raising awareness for specific diseases or disease areas can be used to raise awareness about ConcePTION, our outputs and the importance of PV reporting, i.e. a specific disease with specific drugs, directing women to a web resource (landing page on ConcePTION website already described) where they can find out how to report.

Table 7: KPIs to monitor engagement rates and reach for task 5.3 communications campaigns.

Activity	Tool	Responsible
Website traffic PV system landing page on ConcePTION website	Google analytics	WP8
Twitter metrics (engagement rates, retweets, likes, etc, and	Twitter analytics	WP8
audience growth)	tools	
Open rates and link clicks in newsletters	Mailchimp	WP8
Direct impact measurements (e.g. poll among donors to see if	Poll data from	WP4
women have seen promotional materials from ConcePTION)	collection sites	
Sign-ups to contact forms/newsletters	Audience growth,	WP8
	responses	

11 Targeted pilot campaign 1: Promotion of PV reporting via UKTIS BUMPS

11.1 Introduction to UKTIS and BUMPS

The UK Teratology Information Service (UKTIS) is commissioned by Public Health England (PHE) to provide expert clinical teratology advice to National Health Service (NHS) healthcare professionals and their patients. This teratology information advice is now primarily provided to service users through online patient information leaflets which are based upon systematic evidence reviews written for healthcare professionals. In addition to this written guidance, the service also operates a telephone advice system through which health professionals can contact experts trained in teratology information counselling for more specific advice.

Healthcare professionals who contact TISs may do so for a variety of reasons. These most typically involve discussions of the possible fetal effects of planned or ongoing gestational exposures, usually involving prescription medication use, radiological diagnostic tests or occupational chemicals. Less frequently, healthcare professionals may also contact the TIS to discuss cases where fetuses, neonates or infants are either displaying or have had symptoms consistent with congenital illnesses, attempting to identify or refute casual associations with confirmed gestational exposures. UKTIS also collects data directly from pregnant women via a



patient portal that allows women to create a pregnancy record (*BUMPS* record). The UKTIS teratogen surveillance system therefore consists of three datasets, the first assumes the primary contact scenarios of planned or ongoing gestational exposures and allows for the prospective longitudinal follow-up of pregnancy exposures and outcomes. The second dataset assumes the alternative contact scenario and retrospectively records adverse pregnancy outcomes following documented gestational exposure events. The third is a patient-reported dataset which may contain prospective or retrospective data. For the purpose of this pilot campaign we will focus on increasing utilisation of the latter, the *BUMPS* record, as this is a relatively new feature and has had limited promotion thus far.

UKTIS has several existing channels that can be utilised in this pilot campaign. UKTIS has an organisational healthcare professional facing website <u>http://www.uktis.org/</u>. UKTIS *BUMPS* also has its own website <u>https://www.medicinesinpregnancy.org/</u> that had over one million hits in the last financial year. UKTIS *BUMPS* is also on Twitter (@medsinpregnancy) with a following of approximately 1,500 people/organisations, many of whom are pharmacists and on Facebook (currently 428 followers). A new Instagram account has been launched for UKTIS.

11.2 Tailored tools, tactics and messaging for stimulating PV reporting through BUMPS

Based on the key messages presented in section 7.2.4 we have developed specific messaging to elicit reporting to UKTIS *BUMPS*. Messaging will be available predominantly in English but where feasible we will aim to increase inclusivity by exploring the possibility of translating messaging into Welsh, Polish and Punjabi.

Objectives for external communications (ECO)	Specific messages for external communications (ECM)	Tailored tools and tactics
ECO3 Raise awareness of UKTIS and BUMPS	ECM6 Know that a woman can create a <i>BUMPS</i> record and that	PV Infographic (ConcePTION branded)
among HCPs	HCPs can report to UKTIS	Question-Answer video on UKTIS and PV with UKTIS head of service (UKTIS
ECO4 Increase patient reporting of exposures to	ECM5 Be aware of pharmacovigilance, what it is and	and ConcePTION branded)
UKTIS through a <i>BUMPS</i> record and HCP reporting	why it is important	Tweet with call to action to create a BUMPS record, accompanied by
via enquiry line	ECM7 Knowledge on safety of medicines during pregnancy is	retweet of general PV ConcePTION tweet (shared to Facebook, Instagram
ECO5 Increase use of	lacking/In order to know more	and Linked in)



LIKTIS and PLIMPS	about the safety of medicines in	1
UKTIS and BUMPS medicines in pregnancy resources	about the safety of medicines in pregnancy, we need your help. If you are pregnant, tell us (UKTIS) about the medicines you use. If you don't use any medicines, this gives us useful information too ECM8 Know that UKTIS has resources to help women make informed choices about medicine use in pregnancy	Tweet with call to action to explore resources on UKTIS <i>BUMPS</i> (shared to Facebook, Instagram and Linked in) Story for Emma's diary (booklet given to pregnant women in the UK) in collaboration with RCOG. (share e-print to social media channels)* Story on medicine use in pregnancy for pregnancy magazine (to coincide with an awareness week) * Tweet on medicines in pregnancy and call to action to read <i>BUMPS</i> resources (to coincide with awareness weeks/months and shared to Facebook, Instagram, and LinkedIn) Tweet about MS and medicines in pregnancy with call to action to visit <i>BUMPs</i> resources (to coincide with MS education month in March and shared to Facebook, Instagram and LinkedIn Manuscript on importance of PV, highlighting <i>BUMPS</i> Blog on UKTIS <i>BUMPS</i> (shared on all UKTIS social media channels). Blog posts to include a call to action to create a <i>BUMPS</i> record. UKTIS is involved in external research- what we are doing in IMI ConcePTION. Link to IMI ConcePTION branded infographic) A day in the life of a Medical Information Scientist/Obstetrician Taking part in research- sharing your data safely piece Allergies Multiple Sclerosis blog (March) Maigraine (June 21st) Pain (to coincide with pain month September).



Ad hoc tweets with specific messaging
to correspond with social media
calendar (Annex.). May be used in
conjunction with other tools already
described.
*channels still to be approached to
check feasibility

12 Targeted pilot campaign 2: Promotion of PV reporting through pREGnant

12.1 Introduction to pREGnant

The Pregnancy Drug Registry (a system for proactive monitoring of medication use during pregnancy and breastfeeding), is an initiative of the Teratology Information Service of the Netherlands Pharmacovigilance Centre, Lareb.

The Dutch Pregnancy Drug Register pREGnant was set up to obtain insight into medication use among pregnant and breastfeeding women and potential effects on maternal and fetal/infant health. This systematically documented data on medication use during pregnancy and lactation in pREGnant will contribute to future knowledge on medicines safety. The registry has a prospective cohort design and the population is derived from pregnant women throughout the Netherlands. Data collection started in April 2014 and enrolment of women is continuous. Data on current pregnancy, obstetric history, maternal lifestyle, health and medication use, delivery, and infant health are collected through web-based questionnaires completed by the participating women (three times during pregnancy and three times during the infant's first year of life).

The women are recruited in several ways, including through a digital invitation sent by their HCP around the first prenatal care visit and through information leaflets or promotion on relevant websites. In total, 5101 women participate(d) in pREGnant (reference date 01-07-2020). In the first six months of 2020 the number of new participants was 481. Steps are currently being taken to increase the familiarity with pREGnant among HCPs and (pregnant) women and to enlarge the number of participants in pREGnant in the Netherlands. However, there is significant opportunity to increase the awareness of this resource.



On the website of Lareb PV centre there is the Dutch digital Knowledge Bank for up to date information on drug use (including over the counter medicines) before and during pregnancy and breastfeeding. In 2019, visitors of the Lareb website opened 720,687 unique page views of TIS information. In the first six months of 2020 this was 546,763. Lareb also has a social media presence on Twitter (92 followers), LinkedIn (3302 followers) and Facebook (983 followers). There is however opportunity to enhance the social media presence of Lareb, particularly on Twitter.

12.2 Tailored objectives, messages and tools and tactics for stimulating participation in pREGNANT

Table 9: Objectives, key messages and tools for targeted pilot campaign 2

Objectives for external communications (ECO)	Specific messages for external communications (ECM)	Tailored tools and tactics
ECO1 Increase awareness of the issue ECO3 Raise awareness of pREGnant among HCPs ECO4 Increase participation in pREGnant ECO5 Increase use of TIS Knowledge Bank	ECM5 Be aware of pharmacovigilance, what it is and why it is important ECM6 Know that a woman can report her pregnancy exposure to pREGnant ECM7 Knowledge on safety of medicines during pregnancy is lacking. In order to know more about the safety of medicines in pregnancy, we need your help. If you are pregnant, tell us (pREGnant) about the medicines you use. If you don't use any medicines, this gives us useful information too ECM8 Know that Lareb TIS has resources to help women make informed choices about medicine use in pregnancy	Appealing basic materials and campaign plan will be developed by an experienced external publicity agency. The messages will be tailor made for the local situation. Materials to be developed will be: - Videos and short articles of pregnant women to emphasize the importance / urge (story telling; relating to others in the 'community'; experiences of peers)- Social media messages - Leaflets This material will be used in a continuous campaign using different channels sequentially. Approach public/pregnant women - Social media: Twitter, LinkedIn,



Facebook
- Website for pregnant women
- Patient organisations
- Influencers
- Magazines for pregnant women
Approach for HCP: mainly by existing channels of professional organisations. Focus will be the combination of usable information on practical situations with importance of gathering more data based on practice experience
- Magazine/ journals for HCP
- Newsletters for HCP
- Social media: LinkedIn

Action Plan

A detailed plan for task 5.3 communications until Summer 2022 is presented below.

Timing	Comms intent	Comms tool	Comms channel	Multipliers	Objective	Key message	Responsibl e
All audien	ces						
October 2020	Providing resources	List of PV systems where women and HCP's can report exposure	Website	Social media	Encourage PV reporting	This is how you do it.	Sally Stephens (TIS) & Annlouise Assaf (Industry systems)
Novembe r 2020	#MedSafetyWee k	Campaign, driving traffic to campaign landing page (PV system list)	Twitter & editorial text	Partner's social media	Branding Awareness Encourage PV reporting	Please report exposure, this is where you do it	Josepine Fernow
3 March 2021	National Birth Defects Prevention Month	Campaign, driving traffic to campaign landing page (PV system list)	Twitter & editorial text	Partner's social media	Branding Awareness Encourage PV reporting	Please report exposure, this is where you do it	Josepine Fernow



HCPs							
Q2/Q3 2021	Promotion of biobank	Campaign	Twitter & editorial text (reuse blog post by Jennifer Drevin for Baking Babies)	Professional organisation s & hospitals	Branding Awareness Encourage PV reporting Promote biobank	We are building a unique resource. We need your help to generate knowledge	Josepine Fernow from 5.3 supporting Jennifer Drevin (WP4)
11-17 Novembe r 2020	World Antibiotic Awareness week	Campaign targeting GP's	Twitter & editorial text	Partner's social media, professional organisation s	Branding Awareness Encourage PV reporting ink to ConcePTIO N resource	These are the existing resources, and this is how you report exposure	Josepine Fernow
5 May 2021	International Day of the Midwife	Social media & web news item targeting midwives	Twitter & editorial text	Partner's social media, professional organisation s	Branding Awareness Encourage PV reporting ink to ConcePTIO N resource	These are the existing resources, and this is how you report exposure	Josepine Fernow
10 October 2021	World Mental Health Day	Social media & web news item targeting psychiatrists/psychiatri c nurses	Twitter & editorial text	Professional organisation s	Branding Awareness Encourage PV reporting ink to ConcePTIO N resource	These are the existing resources, and this is how you report exposure	Josepine Fernow
12 October 2021	World Arthritis Day	Social media & web news item targeting rheumatologists	Twitter & editorial text	Professional organisation s	Branding Awareness Encourage PV reporting ink to ConcePTIO N resource	These are the existing resources, and this is how you report exposure	Josepine Fernow
14 Novembe r 2021	World Diabetes Day	Social media & web news item targeting GP's and endocrinologists	Twitter & editorial text	Professional organisation s	Branding Awareness Encourage PV reporting link to ConcePTIO N resource	These are the existing resources, and this is how you report exposure	Josepine Fernow
Women	Dramatics of	Compoint	T	Defined	Deserved	14/2 275	
Q3 2021	Promotion of biobank (priming women to donate) in Sweden	Campaign	Twitter & editorial text (reuse blog post by Jennifer Drevin for Baking Babies)	Patient organisation s	Branding Awareness Encourage PV reporting Promote biobank	We are building a unique resource. We need your help to generate knowledge	Josepine Fernow from 5.3 supporting Jennifer Drevin (WP4)
Q2 2022	Promotion of biobank (priming	Campaign	Twitter & editorial	Patient organisation	Branding Awareness	We are building a	Josepine Fernow from



	women to donate) in Norway		text	S	Encourage PV reporting Promote biobank	unique resource. We need your help to generate knowledge	5.3 supporting Hedvig Egeland Nordeng (WP4)
Q2 2022	Promotion of biobank (priming women to donate) in France	Campaign	Twitter & editorial text	Patient organisation s	Branding Awareness Encourage PV reporting Promote biobank	We are building a unique resource. We need your help to generate knowledge !	Josepine Fernow from 5.3 supporting Peggy Gandia (WP4)
Q2 2022	Promotion of biobank (priming women to donate) in Switzerland	Campaign	Twitter & editorial text	Patient organisation s	Branding Awareness Encourage PV reporting Promote biobank	We are building a unique resource. We need your help to generate knowledge	Josepine Fernow from 5.3 supporting Alice Panchaud (WP4)
October 2020	Safe Motherhood week	Campaign driving traffic to campaign landing page (PV system list)	Twitter & editorial text	Partner's social media	Branding Awareness Encourage PV reporting	Please report exposure, this is where you do it	Roxana Radu
May 2021	Maternal Mental Health Awareness Week	Campaign driving traffic to campaign landing page (PV system list)	Twitter & editorial text reusing editorial by Sally Stephens from this campaig n May 2020	Partner's social media	Branding Awareness Encourage PV reporting	Please report exposure, this is where you do it	Josepine Fernow
August 2021	World Breastfeeding Week	Campaign, driving traffic to campaign landing page (PV system list)	Twitter & editorial text	Partner's social media	Branding Awareness Encourage PV reporting	Please report exposure, this is where you do it	Josepine Fernow
January 2021- June 2022	Promotion of UKTIS BUMPs	Pilot campaign, driving traffic to BUMPS signup page	Twitter & editorial text	Twitter followers, Partner social media and ConcePTIO N channels	Encourage PV reporting and use of TIS resources.	Please report exposure, this is where you do it	Sally Stephens and Alison Oliver
January 2021- June 2022	Promotion of pREGnant	Pilot campaign, driving traffic to pREGnant signup page	Twitter & editorial text	Twitter followers, Partner social media and ConcePTIO N channels	Encourage PV reporting and use of TIS resources	Please report exposure, this is where you do it	Agnes Kant
Biobanking	& biomolecular rese	arch community					
August	World	Social media and	Twitter &	BBMRI-	Branding,	We are	Josepine



2021 Pharma in	Breastfeeding Week dustry	newsletter	editorial text	ERIC newsflash	awareness Encourage PV reporting Promote results & ecosystem	building a unique biobank & knowledge on how to build safety evidence	Fernow from 5.3 supporting Jennifer Drevin (WP4)
August 2021	World Breastfeeding Week	Social media & editorial text	Twitter & editorial text	ConcePTIO N partner's channels	Branding, awareness Promote results & ecosystem	We are building a unique biobank & knowledge on how to build safety evidence	Annlouise Assaf

14 Summary

This communication plan has outlined a strategy and plan to build awareness and promote PV reporting and engage women and HCPs so that they can play an active role in research in the context of ConcePTION. This document will be updated and modified as communication needs evolve and change throughout the project.

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16 Annexes

Annex 1- SWOT analysis

Annex 2- Social media and events calendar

Annex 3- Inventory of social media and communication channels

Annex 1. ConcePTION WP5.3 communications SWOT analysis SWOT analysis to inform communications plan for 5.3 (PV reporting and participation in research, in the context of the ConcePTION project).

Strengths

List of strengths internal to the ConcePTION consortium that can support external communications about PV and research (e.g. milk biobank), associated benefits, and exploitation strategies.

Benefit (category)	Strengths	Exploitation strategy
Consortium		
Partners and people	EFPIA representation	Create inventory and make use of
	ENTIS representation	channels and networks provided
	Representation from academia	by people in the consortium.
	Experienced scientific	
	researchers	Encourage partners to translate
	Josepine- comms strategist	official content, develop and



	The Synergist Experienced pharmacists BBMRI-ERIC	propose content for ConcePTION and their own channels. Ensure that engaged researchers in the project become visible to external audiences and that they are thanked for their contributions (by-lines, photos, credit).
International	Collaboration all around the world Linked 3 rd parties outside EU (OTIS) Different EU countries present in the team Non-EU countries present in the team (Israel, South Africa, UK) International dimension Perspective of international partners	Use multi-lingual consortium to translate content. This will be helpful for implementing partners in communicating inside their organisations and to national policy makers, but also show other audiences that we are an international consortium.
Diverse	Diversity of expertise (involved people with many different specialities) Diversity of institutions and organisations Many partners Both men and women involved	Map out expertise so that it can be used and exploited.
Experience/knowledge sharing	Sharing experience in the maternal medicines in pregnancy and breastfeeding field Sharing good practice Comparing different experiences Spreading the experience to other institutions	Use editorial text (e.g. blog, or opinion editorials in journals) to describe the <i>how</i> and <i>why</i> of PV reporting in the context of ConcePTION Invite external audiences (HCPs) to webinars
Project model	Guiding principles for comms already created in WP6 Unique- first of its kind Different experiences (partners) common aim (improve PV reporting and research in the field of medicines in pregnancy and breastfeeding)	Use guiding principles to inform comms strategy
Торіс	Medicines in pregnancy and breastfeeding Pharmacovigilance	Important topic for society



	Signal detection	
Cradibility/truat		
Credibility/trust Partners	Universities and organisations associated with local health services and public health bodies (for example UKTIS- a PHE commissioned service, hosted by the NHS). EFPIA partners responsible for post authorisation PV	Use partner institutions' names and logos (credibility).
People	Involvement of "important people" (high positions) Highly experienced partners in their fields	Use individual researchers' names and photos (for credibility, expertise and experience)- ask members to sign consent for photo use. Create question-answer videos (with subtitles) which capture attention and explain concepts (such as PV).
Relevance	Societal relevance Importance to women's health and bodily autonomy. Importance to child health and development. Importance to women with chronic conditions who need to take medicines when pregnant.	 Frame messages in terms of societal relevance. Use women and child health organisations to cascade messages. Create diary of #days that are associated with maternal health so that social media messages can use these taglines. Create messaging which women with chronic conditions can identify with (focus group input needed) and can be cascaded by patient organisations (MS society for example).
Established infrastructure and resources	Existing PV databases ENTIS website ConcePTION website	Take advantage of experience and resources already established by ConcePTION partners.



websites of individual TISs

Weaknesses

List of weaknesses internal to the ConcePTION consortium that could impede external communications about PV and research, risk posed, and ways to mitigate them.

Category	Type of weakness	Mitigation strategy	
Cultural and language			
	Multinational consortium	Careful thought to wording and translation	
	Cultural aspects of communicating about	of messages.	
	medicines in pregnancy	Inclusive graphics to represent women of	
	Not every country has a TIS	diverse backgrounds.	
Timeline	Different communication needs throughout the project	Communication plan to have flexibility to respond with ad hoc communications when required. Designate contact person for these requests and make sure other WPs know who that person is.	
Multi-stakeholder challenges	Poor common language between general public, scientists, industry and HCPs	Think about communications about PV as twofold: 1) for HCP and 2) for "lay" audiences (e.g. pregnant and breastfeeding women). Both require translation from in-science language to plain language to be understood.	



	Different places where data is held	Call to actions must direct HCPs and women to the correct place to report their exposures.
	Industry cannot communicate directly with HCPs and public/women.	Use general messaging from ConcePTION to stimulate reporting to industry.
Consortium interaction		
Resources	Difficult to match objectives and resources	Make use of resources developed already for ConcePTION as well as free to use resources and low-cost methods of producing materials.
Communication & interaction	Communications responsibilities are fragmented	Use communications task force to help bridge gaps.
	Confusion surrounding the scope of 5.3	Make use of communication tools and tactics already
	Many partners to coordinate	developed. Identify members of the
	Too little communication between work packages	team with links to WP4 and WP2 so that we can time communications to align with need.
Competence missing	Midwife representative General public (woman) representative	Approach patient organisations to ask if they have any patient advocates who would be willing to help with



Lack of representation from women with a chronic	review.
condition.	Take advantage of patient focus groups
	and surveys to test promotional materials.

Opportunities

Opportunities external to the ConcePTION consortium that can help communications about PV and research from the project, associated benefits, and exploitation strategies.

Benefit (category)	Opportunities	Exploitation strategy
Events	International events	Propose public
	(organised by us and others)	engagement
		opportunities
	Participation in conferences	Create a visually engaging poster on PV (based on infographics used for the social media campaign) and encourage partners to take to conferences/patient engagement events.
		Support ConcePTION partners with communication materials (flyers, video, PPT) when participating in events.
Network	Greater collaboration between industry, academia and teratology services	Inventory existing networks and identifying gatekeepers (someone who can support or hinder buy-in and/or uptake of the output).
		Coordinators and Steering Committee to review and decide



Partners/local	Press releases by partners	Liaise with partner organisations' PR departments for press releases and access to channels.
Publication	Publication Lessons learnt, knowledge	Explore possibilities for special issues on pregnancy PV in healthcare/medical journals.
Audience	Promoting the project among different stakeholders	Use newsletters, social media and other channels to reach all audiences. Engage with patient associations to drive uptake.
Framing to build interest	Connect messages to Europe 2020 strategy Connect messages to CV-19 30 th anniversary of ENTIS	Encourage connection to current debates (national and/or international).
Being useful	Providing resources	Developing web resource listing where women can report exposure
Channels	Cooperation with media Press releases in local languages Interaction with partners Contacts with media Other IMI project channels (Share4Rare, PREFER) Social media channels: blogs, podcasts, Facebook, twitter, Instagram New communication skills	Liaise with partner PR offices to give publicity to implementing partner's result publications. Connect with other IMI projects who may have engaged people with potential medicine users already (people



	Opportunities to communicate New communication skills	with chronic conditions) to cascade messages through their channels).
		Use the already developed communication toolboxes.
Timing	Covid-19 Opportunity to support PV reporting associated with medicines used in Cv-19 (or potentially PV reporting associated with vaccine use)	Messaging using CV- 19 to create interest and give context. Support PV reporting associated with medicines used in Cv- 19 (or potentially a vaccine

Threats

List of threats to ConcePTION communication (external to the consortium), risk posed, and suggested mitigations.

Risk (category)	Threats Mitigation strategy	
COVID-19	Delays with knock-on effects	
Lack of 'buy-in' from key stakeholders	HCPs already overstretched	Make it easy for HCPs to report and emphasise societal importance.
		Emphasise societal importance Consider using opinion editorials in national media to raise interest and awareness.
	No direct and immediate benefit for women of participating	Emphasise societal importance Consider using opinion
	Lack of interest and awareness from general public	editorials in national media to raise interest and awareness.
	Public perception of pharma	Communications to be



		transparent about industry involvement (signpost to ConcePTION website). Consider using/creating resources that explain public-private partnership.
	Concerns surrounding data security	Consider an editorial on data use in PV and research. Also signpost to appropriate ConcePTION webpage.
	Perception of pregnant women as a vulnerable group to be protected from research.	Use guiding principles and empowering language to encourage participation. Emphasise that research has ethical approval.
Awareness and understanding of teratology	The definition of the word 'teratology' is not widely known or used The word 'teratology' has negative connotations.	Use general messaging for women toolkit to help engage audience before explaining more specific concepts (similar messaging toolkit needs to be developed for HCPs)
		Wording of messages should avoid causing distress or guilt (consider ethical review)
Awareness and understanding of pharmacovigilance	Lack of awareness and understanding of PV and its importance	Use general messaging for women toolkit to help engage audience before explaining more specific concepts (similar messaging toolkit needs to be developed for HCPs)
		Use infographics to explain pregnancy PV- use along with social media messaging and video mentioned earlier. Explore if there are resources we can use available already or make at low cost in PPT.



Annex 2. Social media and events calendar

Date	Event
Feb 7-14	Congenital Heart Defect Awareness Week
Feb 28	Rare Disease Day
March	Multiple Sclerosis Education and Awareness Month
March 13	World Sleep Day
March 15-21	National Poison Prevention Week
March	National Bed Month (UK)
	The Sleep Council
March 8	International Women's Day
March 8	World Kidney Day
April 7	World Health Day
May 3	World Asthma Day
Мау	Mental Health Awareness Month
	Mental Health America (MHA)
May 12	ME/CFS and Fibromyalgia International
	Awareness Day
May 13-19	National Alcohol- and Other Drug-Related Birth
	Defects Awareness Week
7-15 June	British Heart Week
12-18 June June 13	Diabetes week Family health and fitness day
June 21	Shades for Migraine: Global Migraine Awarenes
June 21	Day
July	National Cleft and Craniofacial Awareness and
	Prevention Month (US)
August	National Breastfeeding Awareness Month (US)
August 1 Z	United States Breastfeeding Committee
August 1-7 Aug 25th-31st	World Breastfeeding Week Black Breastfeeding Week
31st July 1st and 2nd August 2020	the BIG Virtual Latch On
	https://biglatchon.org/
September	Pain Awareness Month
	American Chronic Pain Association, US Pain Foundation
September 17	Foundation
	WHO: World Patient Safety Day
September 29	World Heart Day
Sept 30	National Women's Health and Fitness day (US)
July	Newborn Screening Awareness month
Oct 4-10	Mental Illness Awareness week
Oct 8	National Depression Screening Day (US)
Oct 10	World Mental Health Day



Oct 20-24 Oct 21-24

Nov 11-17

Nov 14

Nov 17

World Arthritis Day National Health Education Week (US) ABM Annual Meeting

World Antibiotic Awareness week World Diabetes Day World Prematurity Day



Annex 3. Inventory of third-party social media and communication channels for

Organisation	Language	Country	Audience	Description
Mumsnet	English	UK	women/parents	www.mumsnet.com website for parents, forum, twitter @MumsnetTowers
Made For Mums	English	worldwide	women/parents	www.madeformums.com @MadeForMums
Netmums	English	UK	women/parents	@netmums
Britmums	English	UK	women/parents	@BritMums
Loved by Parents	English	UK	women/parents	www.lovedbyparents.com @lovedbyparents website, podcast, twitter, Instagram
Babycentre	English	UK	women/parents	www.babycentre.co.uk @babycenter
NHSH Breastfeeding	English	UK, Scotland	women	@NHSH_Breastfeed
Breastfeeding news Better Breastfeeding	English	worldwide	women	@dailyBFnews weekly newspaper Campaign <u>www.betterbreastfeeding.uk</u> @BetterBfing
The Unmumsy Mum	English	UK	parents	@ TheUnmumsyMum
Doula UK	English	UK	parents	Professional organisation https://doula.org.uk/ Doula magazine (2 editions per year) @doulaUK
European Doula Network				
WRISK all4maternity		worldwide	HCPs	@WRISK_projectOnline platform for midwivesand all maternity workers.@all4maternity
Maternity and Midwifery forum				News, video and insights for midwives. Host of free to attend maternity and midwifery festivals around the UK and @ watchMATFLIX founders @ MidwiferyFOrum
Hearts Milk Bank Infant Feeding		UK		@heartsmilkbank The All Party Parliamentary Group on infant feeding

amplification of messages



APPG inequalities @APPGIFI Maternal English UK A coalition of over 90 UK Mental Health organisations working together Alliance with clinicians to make perinatal mental health a priority. @MMHAlliance Prof Amy Influencer. Breastfeeding English Brown advocate @Prof_AmyBrown Influencer: Breastfeeding bf and English supporter and pharmacist. medication @BfWendy MBE www.breastfeeding-and medication.co.uk Human Milk Charity-breastfeeding support, supply (supports Foundation @heartsmilkbank) and research. www.humanmilkfoundation.or g @milk_foundation @WeMidwives We Midwives