

IMI2 821520 - ConcePTION

ConcePTION

WP8 – Scientific coordination, project management & sustainability

D8.14 Minutes of annual general assembly meetings 1

Lead contributor	1 – UMCU (UNIVERSITAIR MEDISCH CENTRUM UTRECHT) 38 – NVS (NOVARTIS PHARMA AG)
Other contributors	WP Leads 2 – ULST (UNIVERSITY OF ULSTER) 3 – UU (UPPSALA UNIVERSITET) 6 – i-HD (THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA) 7 – KUL (KATHOLIEKE UNIVERSITEIT LEUVEN) 9 – LAREB (STITCHING LAREB) 13 – UKZN (UNIVERSITY OF KWAZULU-NATAL) 37 – JANSSEN (JANSSEN PHARMACEUTICA NV) 39 – SANOFI (SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT) 41 – GSK (GLAXOSMITHKLINE RESEARCH AND DEVELOPMENT LTD.) 47 – UCB (UCB BIOPHARMA SRL) 53 – Takeda AG (TAKEDA PHARMACEUTICALS INTERNATIONAL AG)

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Summary

The virtual General Assembly meeting was held on October 21 and 22, 2020 and provided the work packages with the ability to share a flash forward of year two of the project and ConcePTION's high-level Communication and Sustainability plans were also presented.

It was a great opportunity for all the members to catch up with the work other WPs are undertaking to address our overarching vision *'to radically and rapidly reduce uncertainty about the effects of medication used during pregnancy and breastfeeding'*.

Due to the COVID-19 pandemic, and the uncertainties about progression in the upcoming period and the travel restrictions in a large number of companies, the Management Team decided in March to cancel the General Assembly meeting scheduled for May in Milan and postpone it to October 2020. To create a point of contact for the whole consortium before the end of 2020, the PMO organized two 2-hour meetings to provide everyone with a flash forward of year 2 of the ConcePTION project.

Planning and Outcome

The PMO was involved in the coordination and organisation of the virtual General Assembly meeting (GAM) which was held on a popular video web-conferencing and webinar platform (Zoom). The various agendas for the virtual GAM were laid-out and circulated in advance. All the partners, stakeholders and colleagues actively involved in ConcePTION were invited to this virtual General Assembly.

Over 140 consortium members joined the virtual GAM and on both the days, the Project Coordinator and the Project Lead welcomed all the participants and laid out the structure for the meeting. The following agendas and topics were presented and discussed:

Day 1

Work Package 1 – *Moving beyond pregnancy registries to enhance our understanding of disease-related pregnancy outcomes, medication use and safety of use during pregnancy*

This presentation covered WP1's efforts in incorporating advice from external advisors and laying out the foundations of the *"Core Evidence Elements"* that should be used for conducting pharmacoepidemiological population-based studies among pregnant women. Next, the importance of these *"Core Evidence Elements"* were emphasized along with more information on the timeline and the steps leading to the final version. Finally, an explanation on how *"Core Evidence Elements"* would be extracted from the information provided by the DAPs (data access providers) of ConcePTION was elucidated.

Work Package 2 – *Enhance safety data collection in pregnancy and the analysis of case reports*

WP2 aims to bring pregnancy safety data from "chaos to order". They presented their plan and strategy to a) develop and test standardized & optimized methodologies (by using Multiple Sclerosis as a model for demonstration projects) to analyze prospectively collated pregnancy pharmacovigilance data from various sources, b) to achieve coordinated analysis of existing data by analyzing the data on a centralized platform (LifeTIME) and c) address the gaps in the current system by creating a dedicated ConcePTION app for prospective pregnancy and breastfeeding data collection.

Work Package 3 – *Determine drug transfer and infant drug exposure during lactation: generation of quantitative and translatable data*

WP3's flash forward of year 2 provided a general overview and strategy of the tasks they will perform including task 3.2 (improve in vitro models to identify parameters determining the rate and extent of blood-milk excretion), task 3.3 (perform in vitro experiments in lactating non-clinical species) and task 3.4 (Enhancing PBPK modelling efforts). The impact of the work is to be able to provide reliable predictions of medicines transfer into breast milk based on the animal data for the initial label

Work Package 4 – *Establishment of a non-commercial, Europe-wide breast milk biobank and analytical centre*

The WP4 leads provided an overlook including the strategies and challenges of their tasks for year 2 and the near future. Those are setting up protocols & study documents and seeking approval for studies involving Infliximab and Metformin in collaboration with various hospitals, plasma breast milk sample collection and analytics, and the development of a bioanalytical center (with the various analytics and parameters to be still decided). WP4's vision is to have a sustainable breast milk samples from treated women deposited in the first pan-European biobanking and analytical capacity where academic partners and industry partners can access established methods and practices and conduct human breast milk studies.

Work Package 5 – *Dissemination and education for HCPs, pregnant and breastfeeding women and general public*

WP5 presented some of the activities that they plan to undertake and complete in the second year, namely, publish data gained from landscape analysis in year 1, plan awareness campaigns for reporting and participating in research, define learning plans for HCP continuous professional education. The work on the knowledge bank will be involve the development of the SOPs for content pages development as well as the web design. Finally, the audience was called on to vote for the name of the knowledge bank.

Work Package 6 – *Cross-stakeholder engagement, endorsement and adoption*

WP6 provided an outlook and potential impact of their work along with brief snapshot of some of the project deliverables of WP6 that can be expected in year 2 – a glossary of terms (both in electronic & paper versions) for consortium use and their INTERACT toolbox for engagement that could be utilised by all WPs. Moreover, WP6 provided a timeline and steps involved for teams seeking an Innovation Taskforce / Qualification Advice.

Work Package 7 – *Information and data governance, ethics, technology and data catalogue and quality support*

This talk started with WP7's work from year 1, particularly, the various steps and processes involved in building an architecture (particularly technical infrastructure via development of a suite of tools) for distributed analysis that aims to generate high-quality real-world evidence on the effects of medication during pregnancy and lactation. This was followed by a flash forward of year 2 where WP7 will focus on testing the pipeline of tools developed through data characterisation of 20 population-based healthcare & surveillance DAPs (data access providers) that are partners or third parties. Finally, following the final deployment of the data transformation pipeline, WP7 hopes to submit it to the EMA for scientific qualification advice.

Work Package 8 – Scientific coordination, project management & sustainability

WP8 presented the various tasks and priorities for year 2 – increase project visibility in a streamlined manner with input from all participants with the help of the recently established communications team in Uppsala University. Further tasks will involve development of multiple guidelines, processes and reference documents to ensure best alignment across WPs. WP8 is currently working on the documentation of all changes that have occurred in year 1 as part of an amendment to the Grant Agreement. Finally, the sustainability team will focus on developing the sustainability plan for the future R&D ecosystem in close collaboration with WP leads.

Each of the above presentations was followed by a short but interactive and engaging Q&A session.

Day 2

The external contribution of ConcePTION

This talk was given by the perspective from EMA about ConcePTION's role in informing medicine use in pregnancy & breastfeeding. The talk started with an overall look into the of medicine use in pregnancy, followed by the role of regulators like EMA and an extensive look into where they acquire their information about medicine safety in pregnancy & breastfeeding. The second half of the presentation was “*A note on signal generation*”, an outlook into previously conducted work by EMA that could potentially help enrich the output of ConcePTION.

The presentation concluded with a brief look into how ConcePTION can help EMA to make a plea to the world for using better testing methods and help bridge the gap in practises related to the inefficiency of single drug pregnancy registries, as only a fraction of them manage to recruit the required number of patients to draw conclusions. Overall, the talk presented the presenters view on how the regulators could use the methods and systems developed by the ConcePTION project.

Sustainability of ConcePTION

This talk was on the sustainability of the project results, i.e., what needs to be sustainable after the completion of the project. The aspiration is to achieve a paradigm shift in the way we generate and disseminate evidence on the effects of medicines in pregnancy and breastfeeding and integrate newly collected health data and create a trusted ecosystem.

There are different levels of success and the ideal or ultimate situation that ConcePTION should aim to achieve would be transformational output with long-term financial commitment of the ecosystem for decades to come. Examples of long-term financial commitment can be in the form of i) continuous contributions from health ministries or government funding bodies, ii) a clear roadmap of pharmacovigilance project-based funding, and/or iii) create a stable stream of assignments from funding bodies, regulators or companies.

This was followed by a summary of some of the priorities of the Sustainability tasks such as testing different funding models in real-life scenarios, develop the tools that will maintain and deliver, services and studies (sustainable assets & processes) and create a broader awareness of the needs we are addressing (political & awareness campaigns).

Covid-19 infection and medicines in pregnancy

This was a short sub-talk on CONSIGN – a project funded by the EMA from July 2020 to July 2021 to guide evidence-based decision-making for regulators about COVID-19 vaccine indications, vaccination policies and treatment options for pregnant women. CONSIGN works with strong networks in the pregnancy field such as INOSS, COVI-PREG and ConcePTION.

This talk, which was presented as a part of the sustainability talk, also showcased first-hand how the principles, expertise, and tools of ConcePTION can provide solutions to pressing questions that can arise in the public health domain.

The communication plans of ConcePTION

A member of the communications team provided a concise look into the different contents the project needs to communicate on such as the branding of the project, the importance of pharmacovigilance reporting, and the results arising from the project, followed by a brief introduction of the newly appointed Communications Managers and its various roles and functions.

The talk concluded with a flash forward to year 2 that would involve tasks such as setting up structures to WP communication needs, updating the project handbook and developing a high-level communications and strategy plan for the project.

The IMI Project Officer of ConcePTION was then invited to provide her opinion and IMI's views on the project:

The Project Officer emphasized the importance of the ConcePTION project for IMI, highlighting its one-of-a-kind nature and ambitious goals. She then praised the consortium for turning in great work over the last year and wished everyone luck for the challenges that lay ahead.

Conclusion

In conclusion, the virtual GAM was an efficient and effective activity for sharing & learning and provided a 'touch base' moment for all the consortium members in the situation caused by the Covid-19 pandemic.

Engagement and awareness via social media

In order to engage participation and increase awareness about ConcePTION's goals, impact & results as well as pregnancy safety data in general, the meeting also introduced a hashtag for the attendees to use on social media: **#ConcePTIONvirtual2020**. The Twitter account of ConcePTION shared multiple posts related to the GAM and the project in general and these received several responses that praised the goals and ambitions of the project.

A small collection of these responses (posts and retweets from Twitter) can be found in *Annex 1*.

Repository for primary data¹

The presentation slides and the recording of the webinar can be downloaded from ConcePTION's internal project web space.

Annex 1

Some posts from Twitter showcasing interaction and feedback to ConcePTION's various goals and potential impact:





More posts by the ConcePTION Twitter account about the virtual GAM and engagement of public to create awareness about the goals and impact of the project can be accessed here:

1. <https://twitter.com/IMIConcePTION/status/1319277038969106433>
2. <https://twitter.com/IMIConcePTION/status/1319274160816754689>