

## IMI2 821520 - ConcePTION

### ConcePTION

#### WP8 – Scientific coordination, project management & sustainability

# D8.15 Minutes of annual general assembly meetings 2

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### Document History

Version	Date	Description
V0.1	15 04 2021	First Draft
V0.2	20 05 2021	MT Review
V1.0	27 05 2021	Final Version

## Abstract

The 2<sup>nd</sup> virtual General Assembly meeting was held on April 13 and 14, 2021 and provided the work packages with the ability to share a flash forward of year of the project, highlighting the key achievements of the project. During the GAM ConcePTION's high-level Communication and Sustainability activities and plans were also presented.

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

Despite the limitations due to the COVID-19 pandemic, leaders of work packages and members of ConcePTION attended the meeting and participated during the presentations. The members of the Advisory Board of ConcePTION also attended the GAM meeting and provided their feedback. The feedback provided by the members of the Advisory Board will be used for the deliverable D8.8 - Report from Advisory Board and Ethic report. The IMI Project Officer of ConcePTION was also present during the meeting and gave a presentation to the consortium regarding the importance of ConcePTION for IMI and provided a general feedback.

## 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 130 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 agenda and topics were presented and discussed during the first day of the GAM:



**Agenda - ConcePTION GAM (April 13 and 14, 15:00-17:00 CET)**

**Figure 1:**

Agenda Tuesday, April 13	Speakers	Time (CET)
Public private partnership video	Josepine Fernow (Uppsala University)	15:00 – 15:05 (5 min)
Welcome and introduction	Miriam Sturkenboom; Ida Niklson	15:05 – 15:10 (5 min)
Structure of the meeting		
The importance of ConcePTION for IMI, and general feedback	Nathalie Seigneuret, Project Officer, IMI	15:10 – 15:25 (15 min)
Achievements in ConcePTION on year 2, and goals for year 3	Marie Teil	15:25 – 15:40 (15 min)
Presentations on key topics:		
<ul style="list-style-type: none"> <li>• Demonstration studies: WP1, WP2, WP3 and WP4</li> <li>• WP5 - Update knowledge bank</li> <li>• WP6 - Tools and resources available for the consortium, including online glossary</li> <li>• WP7 - Ethics study outcome</li> </ul>	WP leaders	15:40 – 16:45 (65 min)
Q&A		16:45 – 16:55 (10 min)
Closing	Miriam Sturkenboom; Ida Niklson	16:55 – 17:00 (5 min)

### Agenda for day 1 of the GAM

## GAM - Day 1

### **Communications Team - *Public private and partnership video***

The meeting started by sharing the ***Public private and partnership video of ConcePTION***. Women who are pregnant and the babies they breastfeed, deserve to know if a medicine is safe. The ConcePTION project has a huge and difficult task ahead: Building a system for drug safety in pregnancy and breastfeeding. Universities, the pharmaceutical companies that develop medicines, the authorities that approve medicines and monitor safety, women and their doctors need to work together to solve a complicated puzzle: Turning data into evidence!.

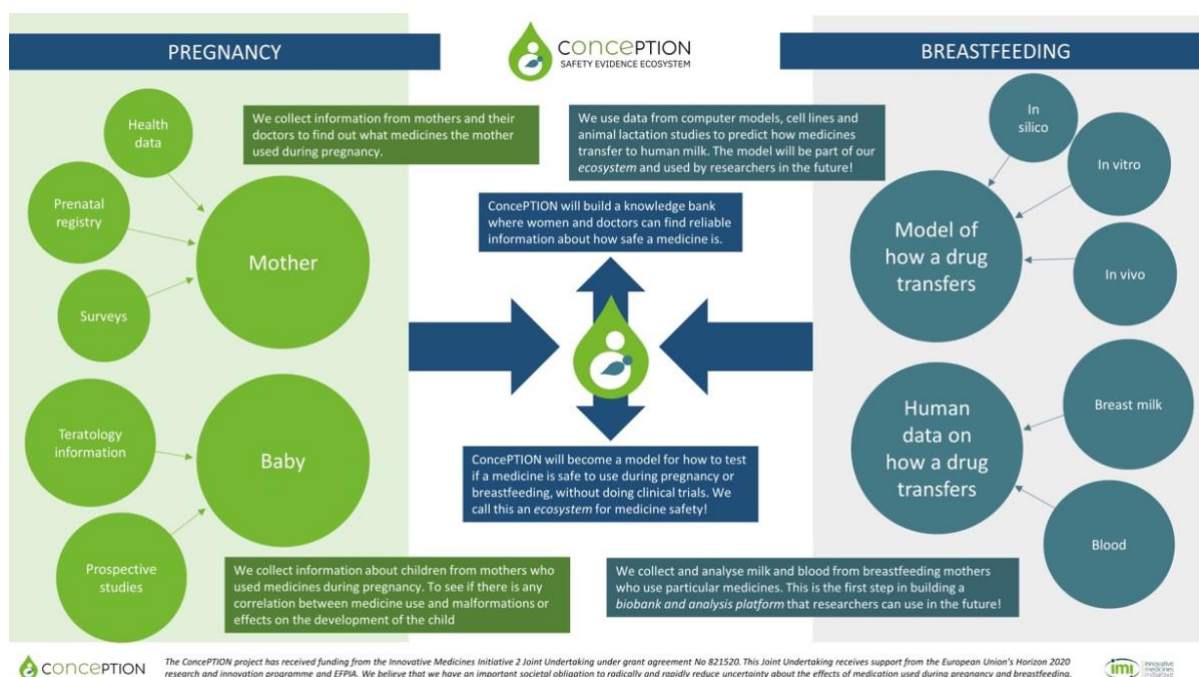
More information with the video can be found at [imi-conception.eu](http://imi-conception.eu) or on [https://www.youtube.com/watch?v=dREHHwxRn\\_s&t=116s](https://www.youtube.com/watch?v=dREHHwxRn_s&t=116s)

### **The importance of ConcePTION for IMI and provided a general feedback - *by Nathalie Seigneuret, IMI Project Officer of ConcePTION***

This presentation covered what is expected from IMI projects including ConcePTION, such as: deliver tangible results to contribute to IMI2 objectives and ensure maximum impact for patient's benefits. ConcePTION is important for IMI because it tackles a big societal challenge, address industrial challenges as well as public health needs, brings together actors from public and private sectors not used to work together, no other projects on this scale in the world. The presentation also included recommendation for sustainability plans, and examples of other IMI projects.

### **ConcePTION Achievements of year 2 –*by Marie Teil on behalf of ConcePTION***

The aim of this presentation was to show the most important achievements of ConcePTION in year 2. For this, every work package leader sent major achievements from their respective work package. The PMO in collaboration of Marie Teil compiled it as a single presentation which provided the consortium with the big picture and overview of the progress of the project. The presentation included the mission of ConcePTION, the ecosystem and structure of the consortium, and an infographic of the project (*Figure 2*).



**Figure 2. ConcePTION infographic**

### Presentation on key topics:

The leaders from every work package had the opportunity to present the most relevant topic or study from year 2. The following topics from every work package were presented:

- Work Package 1 – Conducting studies on available population – based health data.**

WP1 provided an overview on demonstration study - To demonstrate how secondary data sources across Europe can be used to study safety of medication use in pregnancy by conducting five methodologically diverse projects. The presentation included on how the study will be conducted and how the study will contribute to ConcePTION ecosystem. This is : the 5 DPs will demonstrate how the ConcePTION platform could facilitate future studies of medication use and safety based on data from health registries and linked databases in Europe in a distributed, timely, and scientifically sound way.
- Work package 2 – Conducting studies on reported pregnancy cases**

WP2 provided an overview on demonstration study on analysis of pregnancy PV data from Individual Case Safety Reports (ICSRs) and literature (Study 1). This demonstration study contains 5 sub studies which were also briefly discussed. The presentation included the methodology and overview of the sub study 2 (as example).
- Work Package 3 – Developing animal lactation models**

The aim of the demonstration studies conducted in WP3 is to obtain quantitative data on the transfer of medicine to breast milk using the Göttingen minipig as novel *in vivo* lactation model. They provided explanation on how the study will be conducted at UNIBO. This study will contribute to ConcePTION ecosystem by making **risk evaluation** feasible and thus, provide a basis to **advise women** who would like to breastfeed.
- Work Package 4 – Human lactation studies**

The aim of the demonstration studies conducted in WP4 is to determine the drug and metabolite concentration-time profiles in breast milk (Venlafaxine, Levocetirizine), as well as

in maternal plasma (Amoxicillin) and infant plasma/serum (Metformin, Infliximab). This study will contribute to the ConcePTION ecosystem with a proof of concept for collection, shipment, storage and pharmacokinetic analyses of breast milk and blood.

- **Work Package 5 – Knowledge dissemination**

The presentation of WP5 included information such as: Understanding user needs – landscape analysis; Development, testing, and branding of the Knowledge Bank; and Information pages: process of writing and format of content

- **Work Package 6 – Stakeholder engagement**

The goal of WP6 is to work in an open and inclusive way, with the spirit of mutual respect and trust (Figure 3). They also explained the guiding principles and INTERACT guides for ConcePTION. In addition, they provided more information regarding the ConcePTION glossary. The glossary is designed and maintained by The European Institute for Innovation Through Health Data and RAMIT (More information at: [glossary on the RAMIT website](#))



**Figure 3. Stakeholder engagement – goal of WP6**

- **Work Package 7 – Information on Ethics, data governance, and data science**

The presentation from WP7 included the Ethics study outcome from qualitative interviews. The aim of this is to explore the views of women (preconception, pregnant and nursing) on a Learning Healthcare System (LHS). The methods used and results were explained. The presentation also included potential lessons from ConcePTION such as: Rethink the role of pregnant and breastfeeding women in the ConcePTION ecosystem (explain that the lack of knowledge is a shared problem, clarify how women can contribute to the ConcePTION ecosystem, and explain how women will benefit from the ConcePTION ecosystem); rethink the role of HCPs in the ConcePTION ecosystem; and consider engagement as a tool to increase the level of trust.

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

**Q&A – feedback during GAM DAY 1**

- Nathalie Seigneuret, IMI Project Office shared positive feedback regarding video – private/public collaboration, and progress and achievements of the project.
- The slides of the presentation are available in the member area of the ConcePTION website.
- The final version of the infographic is also available in the ConcePTION website.

- Robert Califf from Advisory Board asked whether there are plans for prospective studies. This would try to be included later, at the moment studies are being focused in the preclinical part – construction of Biobank. Some members were interested of Robert could share protocols or relevant questions to consider in prospective studies.
- Christina Chambers from Advisory Board suggested it is important to also think about the type of exposures before considering the start of a clinical trial. She will be interested to participate by providing advice and suggestions.

## GAM – Day 2

The following agenda and topics were presented and discussed during the second day of the GAM:



### Agenda - ConcePTION GAM (April 13 and 14, 15:00-17:00 CET)

Agenda Wednesday, April 14	Speakers	Time (CET)
Welcome and introduction	Miriam Sturkenboom; Ida Niklson	15:00 – 15:05 (5 min)
Structure of the meeting		
WP8 - Communication achievements and activities of ConcePTION	Josepine Fernow (Uppsala University)	15:05 – 15:15 (10 min)
Sustainability next steps of ConcePTION - current thinking • Study process	Jasper Levink (ttopstart) Siddhanth Kedhagae (PMO)	15:15 – 15:35 (20 min)
Breakout sessions (4 groups) Topics to be discussed: sustainability and communication	Communications team and PMO	15:35 – 16:00 (25 min)
Presentations after breakout session	Leader from each group	Presentations: 16:00 – 16:45 10 minutes each (approx. 45 min)
Q&A and closing	Miriam Sturkenboom; Ida Niklson	Q&A: 16:45 – 16:55 Closing: 16:55-17:00



The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking  
ConcePTION grant n° 821520



Figure 4. Agenda for day 2 of the GAM

### Work Package 8 – *Communication achievements and activities of ConcePTION by Josepine Fernow, Uppsala University*

The presentation from WP8 included information relevant for the branding and explanation of the ecosystem. They also presented the infographic for ConcePTION (Figure 2). They have performed a test for reaching audience.

The aim of the ethics study outcome from qualitative interviews is to explore the views of women (preconception, pregnant and nursing) on a Learning Healthcare System (LHS). The methods used and results were explained. The results of the campaign performance on March 8 on International Women's Day showed:

1186 native views in our tweet  
 169 on YouTube  
 104 views in IMI native tweet  
 44 Uppsala University native tweet  
 683 Sandra Lopez-Leon

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 = 2186 video views

Comms team have been working on mitigation strategy for animal data (WP3 webinar for consortium, plan on how to handle negative publicity); they will be focusing on how to report exposure during pregnancy; and developing centralized communications strategy.

They also reminded they consortium to circulate the manuscript with all partners 30 days before submitting, include acknowledgement and disclaimer, keep the PMO and communications team in the loop, and have a look at the publication policy in the member area.

*“Remember to keep us in the loop! For more information or activities regarding communications you can send an e-mail to [josepine.fernnow@crb.uu.se](mailto:josepine.fernnow@crb.uu.se)”*

### **Sustainability next steps of ConcePTION – current thinking and study processes** by Jasper Levink (*ttopstart*) and Siddhanth Kedhagae (*PMO ConcePTION*)

Jasper Levink on behalf of the Sustainability Task Force provided a high-level overview of all the planned sustainable activities of ConcePTION, a) Landscape analysis to identify market potential of a spin-off of ConcePTION, b) Feasibility assessments planned to be conducted within the ConcePTION ecosystem and how the learnings would be compiled into a report, c) Invitation to WPs to engage on discussions about sustaining the key outcomes of the project.

Siddhanth Kedhagae then provided an overview of the various proof-of-concept feasibility assessments being conducted within the ConcePTION ecosystem. There are 2 ongoing – the MS study from Sanofi and the Sickle Cell Disease from Novartis. The consortium also received three more requests recently, two from GSK and one request from UCB. These requests are being refined and a form for “expression of interest” has been sent to all the public partners of the consortium.

### **Breakout sessions (Communication & Sustainability)**

Four breakout sessions, each with 30-35 attendees, were set-up to discuss about the communication & sustainability of the project. While the communication-themed sessions were chaired by Anna Holm & Josepine Fernow from Uppsala University (Communications Task Force), the sustainability-themed sessions were chaired by Jasper Levink and Michael Steel respectively.

The communication break sessions consisted of two interactive sessions where the participants provided feedback on the various “Opportunities” and “Threats” respectively from a communications point-of-view. On the other hand, the two sustainability breakout sessions focussed on the Knowledge Bank, and particularly around brainstorming for key elements to consider for sustainability planning of knowledge bank. The moderators from each of these sessions later presented the discussions.

### **Q&A – feedback during GAM DAY 2**

- Information on how to report exposure in pregnancy, including video can be found in: [https://www.imi-conception.eu/news-details/?news\\_id=712](https://www.imi-conception.eu/news-details/?news_id=712)

- Videos can be found on the YouTube channel <https://www.youtube.com/channel/UC-K76tkUSDoFMqaU-LhgZAq>
- Newsfeed with editorial content about publications and other activities (please share in your channels if relevant, and know that you are welcome to contribute content) <https://www.imi-conception.eu/news/>
- These are the published papers <https://www.imi-conception.eu/papers/> (the rules for IP review and acknowledgements are in the member area)
- Laura Yates - why are the studies focused only on secondary use of existing data. It would be important to also include primary data collection
- Carl - any activity needs to be described in the DoA. Full feasibility studies are yet not part of the ConcePTION DoA, only the feasibility assessments/pilots.
- Nathalie Seigneuret, IMI Project Office, was grateful to see the progress and congratulated to the whole consortium for the great work performed.

## 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. The participants were actively involved during the presentations and during the breakout sessions. The presentation of the achievements of the project, provided a clear overview of the progress of the project. The presentations given by the WP leaders provided more specific information/overview regarding the activities carried out by every work package.

In addition, the members of the Advisory Board attended the 1<sup>st</sup> and the 2<sup>nd</sup> day. They provided a positive feedback and suggestions on how to move forward. The feedback provided by the members will be used as part of deliverable *D8.8 Report from Advisory Board and Ethic report*, which will be submitted to IMI at the end of May 2021.

## Repository for primary data

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