

## IMI2 821520 - ConcePTION

### ConcePTION

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

# D8.17 Minutes of annual general assembly meeting 4

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### Document History

| Version | Date       | Description   |
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| V0.1    | 27 03 2023 | First Draft   |
| V0.2    | 03 04 2023 | MT Review     |
| V1.0    | 06 04 2023 | Final Version |

## Summary

The 4th face-to-face General Assembly meeting was held on March 27 and 28, 2023 and provided the work packages with the ability to share their key achievements during the project and work on a roadmap on how to finish the work before the end of the project. During the GAM ConcePTION's sustainability activities and plans were also presented and integrated into the roadmap.

It was a great opportunity for all the members to celebrate and share key achievements and to reconnect on a personal level, as the COVID-19 pandemic prohibited meeting face-to-face during the last General Assemblies; and to discuss the sustainability of the ecosystem, so that follow-up steps can be taken.

Almost a hundred members of the ConcePTION consortium attended the meeting and participated in the plenary sessions as well as the break-out sessions. Some of the members of the Advisory Board of ConcePTION also attended the GAM meeting and provided their feedback during the meeting as well as in written form. The feedback provided by the members of the Advisory Board will be used for the deliverable D8.11 - Report from Advisory Board and Ethic report year 4. 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 General Assembly meeting (GAM) which was kindly hosted at De Bazel, Amsterdam. The various agendas for the GAM were laid-out and circulated in advance. All the partners, stakeholders and colleagues actively involved in ConcePTION were invited to this General Assembly.

On both the days, the Project Coordinator and the Project Lead welcomed all the participants and laid out the structure for the meeting. The program of the GAM can be found below.

## Program GAM

### Monday 27-03

Possibility of reserving a space for earlier sessions if wanted

- |               |   |
|---------------|---|
| 12:00 – 13:00 | Welcome and lunch   |
| 13:00 – 13:15 | Plenary session – <b>Opening</b><br>The design of the ConcePTION ecosystem and where we are (Miriam Sturkenboom)  |
| 13:15 – 15:00 | Key achievements building the <b>ConcePTION ecosystem (each 8' + questions)</b> <ul style="list-style-type: none"> <li>• EHR data Algorithms for identifying conditions (WP1 AnnaBelle Beau, Marie Beslay)</li> <li>• How to collect new data on exposed pregnancies: the APP (WP2 Amalia Alexe)</li> <li>• Latest results from the LifeTiME system pilot (WP2 Rebecca Bromley)</li> <li>• Lactation studies: the minipig model to predict transfer of medicines to milk (WP3 Domenico Ventrella)</li> <li>• Lactation studies: the first human ConcePTION lactation studies (WP4 Erik Melander)</li> <li>• Teratology e-learning program &amp; Knowledgebank update (WP5 Hesther Van Gulick)</li> <li>• How to engage women report drug exposure (WP5 Marjolein Willemen)</li> </ul> |

- EHR data The RWD quality check pipeline (WP7 Vjola Hoxhaj)
- How to find available data on pregnancies? ConcePTION Catalogue (WP7 Morris Swertz / Rosa Gini)

15:00 – 15:30 Coffee break  
 15:30 – 17:00 Break-out session 1 - **Get the work finished and project extension**  
 Planning for the end of the project and create a 1<sup>st</sup> version of a roadmap  
 17:00 – 17:20 **Plenary Session – IHI**  
 The importance of ConcePTION for IHI (Nathalie Seigneuret)  
 17:20 – 17:30 Wrap up of day 1 (Miriam **Sturkenboom**)  
 19:00 – 21:00 Consortium Working Dinner in Amsterdam

### Tuesday 28-03

09:00 Walk-in with coffee  
 09.15 - 09.30 Plenary session – Welcome  
 Opening and expectations of day 2 (Michael Steel)  
 09:30 – 10:10 Plenary session - **Sustainability (Arno Schoevaars and Nicholas Brooke)**  
 10:10 – 12:15 Break out session **2 – Continuation of roadmap and sustainability**  
 Feedback of the sustainability session into roadmap  
 12:15 – 13:15 Lunch  
 13:15 – 14:30 Plenary session – **Roadmap discussions (each WP 8')**  
 Feedback from each WP about their roadmap  
 14:30 – 15:15 Plenary session - **Closing**

- Observations/advise advisory board (SAB) 20'
- Final Q&A (All) 15'
- Closing (Marie Teil) 10'

 15:15 – 16:00 MB meeting – **Reflections on the GAM**

## **GAM - Day 1**

The presentation slides can be downloaded from ConcePTION's internal project web space. In this section you can find a short summary of each of the topics were presented and discussed during the GAM Day 1. Each of the plenary presentations was followed by a short but interactive and engaging Q&A session. If there were any questions or comments, these are in the included.

### **Opening – plenary presentation**

The meeting started with the opening presentation by Miriam Sturkenboom. During this presentation she reflected on the work so far in ConcePTION, how the pandemic impacted both pregnant women and the ConcePTION project on many levels, and how the ConcePTION ecosystem parts could support COVID-19 response to monitor medicines safely. In addition, information of the potential reallocation of budget was discussed and the main aims of the GAM were highlighted.

### **Key achievements building the ConcePTION ecosystem – plenary presentations**

The aim of these presentations was to show some of the most important achievements of ConcePTION. For this, every work package had the opportunity to present major achievements from their work package. The following topics from every work package were presented:

#### **1. Work Package 1 – EHR data Algorithms for identifying conditions during pregnancy**

In this presentation, it was presented how WP1 in collaboration with WP7 and the DAPs has designed algorithms to identify conditions during pregnancy, with the main aim to disentangle the adverse effects of the disease and medication.

#### Questions and feedback:

- No questions

### 2. Work package 2 – *How to collect new data on exposed pregnancies: the APP*

In this presentation the Meds4Mums2B App was presented. The launch of this app is planned for Q1 2023 in the UK. The goal of the app is to establish a sustainable system for pregnancy information. The communication plan for the app launch was presented as well.

#### Questions and feedback:

- Mats: Sweden interested to participate. Find a more simple name for app.
- Question on how to involve longer-term follow-up – there is the possibility to add more questions and questionnaires. Also, moms in current programs could continue using the app. Or other programs could be started up.
- Primary data collection via EHR could potentially be combined with the app - Possible to have one app only for ConcePTION; one app to be used for all
- Michael: slide 55, how does the app link to ConcePTION? There is a privacy link present and we could further discuss with a privacy expert.

### 3. Work package 2 – *Latest results from the LifeTiME system pilot*

In this presentation the LIFETIME framework and the status of the first pilot were presented, as well as the follow-up plans. This LIFETIME framework is designed to get a better insight into neurodevelopmental outcomes following medication use in pregnancy.

#### Questions and feedback:

- Including demonstration project 3. How will be this linked to app-WP2. Meds for mothers. This will be looked into.
- Mats: Export criteria in app to collect also those data. Questionnaires can also be online this planned to be combined with app.

### 4. Work Package 3 – *Lactation studies: the minipig model to predict transfer of medicines to milk*

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 is being conducted at UNIBO. This study contributes to the ConcePTION ecosystem by making **risk evaluation** feasible and thus, provide a basis to **advise women** who would like to breastfeed.

#### Questions and feedback:

- Successful ITF meeting – see slide
- How are drugs selected? - ask WP4 so data will be comparable. Physical-chemical characteristics – to check behaviour with different molecules. The drugs were selected at the start of the experiments.

### 5. Work Package 4 – *Lactation studies: the first human ConcePTION 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). In the presentation, the

development of the Population PK model for Cetirizine in breast milk was presented; the structural model, the parameter estimates, and the data used for model building was described.

**Questions and feedback:**

- Question: were there any reports from mothers? - Mothers could report by themselves. No discomfort reported during study.

**6. Work Package 5 – Teratology e-learning program & Knowledgebank update**

During this presentation a live demonstration of the e-learning platform was presented.

**Questions and feedback:**

- E-learning program was presented. Question on whether it will be available in other languages or only English?
- Publicly available later, first on the Elevate Health Platform – planned to launch it at ENTIS meeting soon.
- Question whether it is available on mobile phone - Interesting to make an available version together with the app.
- Only for health care professionals? Yes, so not for patients.
- Does it give links to further resources, yes content for other sources, reading materials. Potential to add new contacts like ENTIS contacts

**7. Work Package 5 – How to engage women report drug exposure**

During this presentation, the ConcePTION toolkit for campaigns to increase reporting of medicines in pregnancy and breastfeeding was presented. This Toolkit incorporates the learnings from two pilot campaigns: A campaign in the Netherlands by TIS-Centre Lareb and a campaign in the UK by the UK Teratology Information Services (UKTIS)

**Questions and feedback:**

- If you share slides-tool would be possible to measure the uptake of this? Yes – they are uploaded on Zenodo and you can track the amount of downloads. Possibility to also add this to the website.
- How did you choose the key messages – There are no pre-set key messages, this depends on the criteria you set as a user, but there are examples and tips and tricks. It provides you with the thinking process behind it.

**8. Work Package 7 – EHR data The RWD quality check pipeline**

During this presentation, the design of the Real World Data Quality Pipeline was presented: what is the process and who is involved? In addition, it was discussed how the ConcePTION RWD quality check relate to the EMA Data Quality Framework and how it is used in other networks outside of ConcePTION.

**Questions and feedback:**

- Are there post-authorisation data studies (ways of trying to feedback from studies to pipeline). Currently not doing this – the unprocessed data is checked and whether it qualifies for the study. The quality check data pipeline stands on its own and can be used in other projects. ConcePTION not doing validation studies.

**9. Work Package 7 – How to find available data on pregnancies? ConcePTION Catalogue**

During this presentation, the ConcePTION catalogue was presented. Both the conceptual framework, what it looks like, and the development strategy were highlighted. A proposal for the sustainability strategy was addressed: to join the open access catalogue community online

**Questions and feedback:**

- Members should have access to catalogue. How you can access the catalogue will be disseminated.

### **Get the work finished and project extension – Break-out session 1**

The goal of the break-out sessions was to create a roadmap for the remaining part of the ConcePTION project. Work Package leaders were free to discuss this according to their own preferences. However, the PMO did create some questions that needed to be addressed during the break-out sessions. These questions were amongst other on new descriptions and due dates for deliverables in case the extension would be granted, interdependencies with other Work Packages and potential hurdles for getting the work finished.

### **The importance of ConcePTION for IMI – Plenary presentation**

This presentation covered the transition of IMI to IHI, what the IHI program entails: What budget is available and its general objectives. It was stressed that new ideas for potential topics from stakeholders are very welcome. Following, the ConcePTION project and the expected impact of its outcomes were discussed. According to Nathalie “The journey is not yet over...but so far a perfect example showing the power of PPP in bringing all stakeholders around the table to address a clear challenge, balancing public health needs and commercial interests and to deliver outstanding results.

### **Wrap up of day 1 – Plenary presentation**

During this short wrap-up, the project coordinator discussed the main topics of the day and expressed their gratefulness for all the provided input and participation.

## **GAM – Day 2**

The main focus of the second day of the GAM were the consortium sustainability activities. Apart from presenting the plans, there was also an active session for the Work Packages to work on implementing the sustainability activities into their roadmap. The presentation slides can be downloaded from ConcePTION’s internal project web space. In this section you can find a short summary of each of the topics were presented and discussed during the GAM Day 2. Each of the plenary presentations was followed by a short but interactive and engaging Q&A session. If there were any questions or comments, these are in the included.

### **Opening of day 2 – Plenary presentation**

During the opening presentation, Michael Steel gave a short recap of day one and provided the consortium with the expectations of day two, stressing the importance of the sustainability activities of ConcePTION.

### **Sustainability – Plenary presentation**

Nicholas Brooke and Arno Schoevaars presented the sustainability session. They first discussed what sustainability entails and how it is present in other IMI projects. Then they presented which potential items for sustainability have been identified within the Work Packages and how these can be grouped into 1) sustainability & engagement, 2) knowledge generation, and 3) knowledge dissemination. For these three clusters, different sustainability activities will be developed (see slides). In addition, a canvas was created based on input from the WPs (see slides).

### **Questions and feedback:**



- Amanda: People generating data need to be fully involved. It needs to be our concern that they are considered because they are providing data – we need to think about how we involve our customers. How do we involve the parties that provide the data. DAPs only provide access to the data but not the data itself. Before knowledge generation data is needed.
- Marieke performed interviews and she created an overview of the DAPs involvement. Business model is to have a plan for sustainability, and this does not mean making profit. It is important to make this clear.
- Should be clear that industry is involved in this project. Industry is focussed on making things safer and better with whatever model that will come out of the ConcePTION project.
- R&D - new open activities upcoming to engage ConcePTION (USA meetings)
- Important to think about where funding is coming from for each cluster. This should be added to the model that shows the different clusters.
- Comment from IHI: EHDEN IMI project use of RWD – studies done during COVID, to keep in mind – for DAP involvement. Similar structure to ConcePTION. In the design of the Common Data Model similar clinical tables – similar to that project. In conception we ask DAPs to provide data 2 steps syntactic and semantic harmonization. If we want to connect to EHDEN would be possible opportunity to join. Built on top of their experience. Nathalie - important for the value proposition discussion. Try to see whether and how to collaborate with them instead of competing.

### **Continuation of roadmap and sustainability – Break-out session**

In the break-out session, the WPs continued their work from day 1. In addition, they thought about the following questions to put in their roadmap:

- How will you address and incorporate the next steps in sustainability for your cluster area within your roadmap?
- What needs or sustainability challenges could be clarified through stakeholder engagement?
- What are some remaining open questions you might have before signing the letter of intent?
- What specific expertise or support do you need to be able to move forward?

Also, during this session WP4 had a meeting with Christina Chambers of the scientific advisory board. And the scientific advisory board had a reflection session together.

### **Roadmap discussions – plenary session**

During this session, the WPs (except from WP8) presented what they had worked on during the two days. This input will be also sent to PMO in written form and used for the upcoming periodic report and amendment. The presentations from the WPs can be found in the slides, when they were provided. Otherwise a short summary can be found below. Some questions that were asked to the WPs can be found below.

#### **Questions and feedback for WP1**

- What are the options for development/training of the team? VAC4EU was discussed as option as collaboration; human resources are a big challenge; we need to create opportunity both as training/education as a professional career.

#### **Questions and feedback for WP2**

- Are the 9 months for the extension definitively decided on? If not, WP2 requests for 12 months to be able to finalize studies and to apply qualification advice. Consideration for extension is budget issue. PMO also needs to be maintained and may not be feasible. Qualification advice might take longer than even a study extension of 12 months.
- Nathalie (IMI): possible to directly go only to qualification advice and not through ITF. Maybe cutting this may save time/effort. Subsequently Christine Allen confirmed ITF first is definitely preferable – otherwise much time could be lost on a QA submission that may never succeed

### Presentation WP3

There is clear link between WP3 and WP4 in the work performed. There was a good discussion for deliverables deadline between these 2 work packages (roadmap). WP3 -roadmap: assumed with extension of 9 month for now: Most deliverables on track – some 6 months deliverable delay. They started already the procedure for Qualification advise; they had a first meeting last year for this. Regarding sustainability, they have started to upload in silico models in GitHub. They have done also in silico work and in vitro studies. Maybe metabolomics studies could be performed for milk samples for medicines and chemicals. In terms of dissemination, they have delivered different webinars – upcoming to share process for qualification advise procedure/social media coverage also performed.

### No questions and feedback for WP3

### Presentation WP4

Possibilities for items that can be sustained for the future: standardized procedures in accordance with regulatory requirements, such as the processes for the assessments of each drug in milk and plasma. These are based on stability assessments.

Successful examples

- Milk only – cetirizine
- Milk and woman plasma – amoxicillin
- Milk women plasma and infant plasma – 2 studies: merformin and prednisolone done in Sweden.
- Plasma requires clinical networks – maybe different for different drugs and according to national guidelines.

Current plan is for BBMRI-ERIC directory of quality assured breast milk banks/studies aligned with the San Diego Biobank US-network for breast milk studies.

### Questions and feedback for WP4

- Potential collaborations to be explored i.e mother to baby breastmilk research biobank.

### Questions and feedback for WP5

Laura Yates: The database could be used by someone living in UK, but clicking on information that was created and based on regulations in another country – will this be standardized per country according to country regulations? Harmonizing will occur maybe naturally it is only a guideline, and it may be modified to certain country requirements.

### Presentation WP6

D6.5 engagement. They have D6.5 engagement on hold. Their role is to look at external stakeholders that can engage with sustainability activities. Picking the right moment to reach out is critical. They feel like they do yet have a convincing case. The feeling of WP6 is that the process has been too slow. Sustainability plans are yet too conversational and there no concrete work on this. Feeling of WP6 is that they must still postpone work. They have engaged a few stakeholders to help out, but it is most important that WPs change their view on sustainability and realize the amount of work needed.

### Questions and feedback for WP6

- WP4 to further discuss with Dipak to try to understand about WP6 tasks and possible collaboration.
- WP2 to reach out Dipak to discuss potential individual products.

### Presentation WP7

- For them governance is more important than business model
- Try to organize event for the secondary use of data
- Issues with offering a secure/permanent contract – issue to secure PhD – issue to provide sustainability to keep working people/resources
- Offer fellowship within ConcePTION



- Maintain young investigators – goal
- Organize an event to invite health providers to explain activities/starting EU level/invite national people and follow up and authorities

### **No questions and feedback for WP7**

### **Closing – plenary session**

During the closing session, first the scientific advisory board provided their thoughts and input based on what they had seen during the GAM. This feedback will be presented to IMI as a separate deliverable report, but below, some points that were raised can be found.

- The most important question is: How to keep this going? Direction where project is going is right, but how to sustain these activities is the next big chapter.
- Many people still don't know what ConcePTION is, more visibility needed. Building a reputation is very important.
- Data collection – app. Two efforts to build this in the USA have already failed. They should make this possible in ConcePTION.
- Transition to sustainability: look at the core elements in conception and choose some and go/succeed in those. Find possible sources of funding.
- Engage on a global scale.
- Neurodevelopment following medication use during pregnancy (WP2) – this work is very valuable and make impact because it has not been done.
- ConcePTION could consider signal detection as another objective
- Impressed with working on available sources.
- Jan regarding education – tools that can help to medical decision making/educational tools would be impactful.
- It is very important to bring new people dedicated to and experienced in this field, so if the project can provide training and learning this will be of high impact
- Positive feedback – great job done.

After this feedback Marie Teil closed the meeting and thanked everybody for their attendance.