S1

Hello everyone - my name is Marina Mendonça. I am postdoc at the University of Warwick, and I have been working on the RECAP project since 2017.

One of RECAP's main goals has been to build up a pan-European and worldwide database of very preterm cohort studies, and I have been coordinating the data sharing process of cohort studies that have been following up individuals born VP from birth up to adulthood – these are called the adult cohort studies.

On this session I am going to tell you a bit my experience of bringing data from international studies together, and most importantly what I have learned throughout this process.

S2

So, in this session I am going to talk about the main challenges bringing data together from cohort studies world-wide; Then I am going to point out some important steps when creating a multi-study database; and finally, we are going to mention some skills I consider essential when managing a complex project, such as building up a multi-study database

S3

So, what makes building up multi-study database a complex project?

Well, first of all, it involves working with numerous research teams, partners and also other actors, such as IT services, and legal departments.

These people tend to play different, but interconnected roles within the project, which needs to be well coordinated, otherwise you will not be able to move forward.

As you can imagine, when you are trying to bring data together from multiple cohort studies that have been collecting data from birth up to adulthood, you will be dealing with many variables, as well as many details. This is another level of complexity that you need to consider.

Finally, another important aspect to keep in mind is that things do not always happen as initially planned. There might be external forces that are beyond your control and that can have a big impact in the initial plans and that you need to manage. In our case, those external forces were Brexit and now COVID-19.

S4

One of WP9's main research objectives has been to determine whether if there are universal adult outcomes of VP/VLBW across different areas of functioning. In order to address this, we needed to have access to data from different parts of the world. This then raised some important questions, such as:

- Which cohort studies have been collecting data on VP individuals from birth up to adulthood? Are these studies willing to collaborate with us?

- What kind of data has been collected?

- How can we have access to this data? How to do this?

These questions were the starting point of our process of building up multi-study database.

S5

You can see here in this map the VP adult cohort studies we were able to identify and contact. The ones in blue are part of RECAP's consortium, and the ones in yellow are not part and accepted to collaborate with RECAP. At the moment we have integrated 12 VP cohort studies in WP9 that are part of this multi-study database.

S6

Well, I have talked about complexity, and now I would like to focus on ways of tackling it.

One way of doing this, is by breaking complexity down into smaller and manageable steps and having a work plan.

In this slide, you can see the work plan we used in WP9 to build up this multi-study database.

I already talked about the 1st step, which was to identify the studies that would be part of our multi-study database. Then our next step was to check which data had been collected across the studies. We asked the different cohort studies to provide us information about their data over time. With this information were able to identify the variables that were relevant to address our research questions, and also common across the different studies and therefore comparable.

After identifying and selecting our variables, we then moved into step 3 where we performed our analyses plans. With the information we gathered, we were then able to decide which variables were going to be part of our analysis and how they were going to be analysed.

This information was very important for step 4 – data transfer agreements. At this stage we had to involve the legal departments of the different institutions sharing data. As part of the documentation of the contracts we had to add the lists of variables we were requesting from each study, and also the analysis plans explaining how those variables were going to be used. Step 4 was a long and complex process for us. Once we had these contracts signed across the different departments, we were than able to gather the data.

Out next step was to make the data comparable, as the data was not assessed in the exact same way across the different studies. One way of making data comparable is by performing data harmonisation, but Sylvia will talk more about this in the next presentation.

S7

Another important aspect in tackling complexity, is by managing time and meeting your milestones and deliverables. For the different steps I mentioned before, there should be a time frame for them to be completed which should also be aligned with the milestones and deliverables of the project. Another important aspect here is that this timeline should be clear and visible for all those who are involved in the process. It very important that everyone involved has this "road map" that they can follow and know what they need to do and by when should be done.

S8

Which skills are essential when creating a multi-study database?

The first one I would like to point out s flexibility. As I mentioned before things do not always go as planned and the ability to adjust and reframe your plans is very important. A good way of dealing with uncertainty is by planning in advance for all eventualities. Besides Plan A, it is always good to have some mitigation plans in place.

When dealing with a large and complex project involving numerous partners and collaborators, it essential to communicate in a clear and transparent way. For example, it's important that everyone has access to this road map I mentioned before. Clear is also essential in building up positive and collaborative relationships and having people on board with the project and willing to collaborate. The success of the project will depend mostly on teamwork.

Finally, when dealing with a complex project is essential to document, document, document – your memory will not be likely to keep up with the amount of information and decisions made.

S9

To sum up:

When creating a multi-study database it is important to breakdown the complexity of this task, by having a clear work plan and to manage time by working towards your milestones and deliverables. It is also very important to document every step of the way - not only in terms of the information you receive, but also why certain decisions where made.

Finally, a building up multi-study database is the product of teamwork, and this will largely depend on good communication with all partners and flexibility.

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Thank you all for your attention and if you have any question do not hesitate to contact me.