Plan Overview

A Data Management Plan created using DMPonline

Title: The perspective of Academia and Small & Medium-sized enterprises on the Scientific Advice by the Medicines Evaluation Board

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Project abstract:

Background: The MEB is providing a reduced fee tailor-made scientific advice to SMEs and academia since 2015 on request during drug development. Research has shown that academia has not enough regulatory knowledge, and there is a lack of mutual understanding between academic drug developers and regulators. The usability of the MEBs' scientific advice is still unknown and not evaluated before. The MEB would like to know the perspective of SMEs and academia on the received scientific advice and the status of the drug product at the moment.

Aim: This research aims to find out what the experiences of the academia and SMEs are and what points of improvement can be made for other scientific advices in the future.

Method: All tailor-made scientific advice of the MEB between 2015 and 26th of May 2023 were collected. A random selection of 22 applicants were invited for semi-structured interviews: 11 SMEs and 11 academia. The goal was to reach between 10 and 15 interviews to get data saturation. An interview guide was used based on the theoretical model of Guntzviller *et al.* Interviews were transcribed and coded.

Results: In total 57 scientific advice applications were received by the MEB of which more than half were by SMEs and about a quarter were by academia. Eventually, 13 interviews were performed with 6 SMEs and 7 academia. Four of the SMEs from the performed interviews made progress since the received advice and only two of the academia moved forward. For 5 out of 7 interviewees from academia, it was not feasible to follow the advice, e.g. due to lack of funding. A clear difference was observed between academia and SMEs where SMEs had much more knowledge about the regulatory aspects compared to academia. About half of the interviewed SMEs had made use of a consultant, whereas no consultants were used by the interviewed academia. SMEs and academia were in general satisfied with the expertise and knowledge of the MEB and found the advice carefully considered and helpful.

Conclusion: Overall, the quality of the MEBs' tailor-made scientific advice was high according to both the SMEs and academia. All the SMEs were able to adapt their protocol based on the received advice and to move forward, however the scientific advice is not always practically feasible for the academia and they are in need of more support to reduce the gap between academia and regulators.

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Copyright information:

The perspective of Academia and Small & Medium-sized enterprises on the Scientific Advice by the Medicines Evaluation Board

0. General information

0.1 Document version & date

Version 1.0
Date: 01/02/2024

0.2 Project title

The perspective of Academia and Small & Medium-sized enterprises on the Scientific Advice by the Medicines Evaluation Board

0.3 Project summary

Background
The Medicines Evaluation Board (MEB or Dutch: College ter Beoordeling Geneesmiddelen CBG) is the Dutch regulatory agency. The MEB has four main tasks to contribute to the welfare of everyone who uses drugs. The MEB is responsible for the authorization of drugs in the Netherlands, assess and monitors the drug for quality, efficacy and safety and promote proper use of the drugs. In addition,
the MEB also provides scientific advice on request to companies of research groups during the development of drugs. Since 2015, the MEB also provides reduced fee tailor-made scientific advice to academia and small & medium-sized enterprises (SMEs).

Research has shown that there is a lack of mutual understanding between academic drug developers and regulators. Besides, the academia has not enough regulatory knowledge and there is a communication gap between academia and regulators. In this project, the focus will be on the tailor-made scientific advice of the MEB to academia and SMEs. The usability of the MEB's scientific advice is still unknown and not evaluated before. The MEB would like to know the experience and opinion of SMEs and academia on the received tailor-made scientific advice and the status of the drug product now.

Aim
This research aims to find out what the experiences of the academia and SMEs are and what points of improvement can be made for other scientific advice in the future. The research objective is to contribute to the effective communication of the MEB to academia and SMEs, by analyzing their opinion about the received scientific advice. So, the main research question is: 'What is the perspective of academia and small and medium-sized enterprises about the tailor-made scientific advice of the MEB?'

Method
All tailor-made scientific advice of the MEB between 2015 and 26th of May 2023 were collected. A random selection of 22 applicants were invited for semi-structured interviews: 11 SMEs and 11 academia. The goal was to reach between 10 and 15 interviews to get data saturation. An interview guide was used based on the theoretical model of Guntzviller *et al.* Interviews were transcribed and coded until no new codes were founded anymore. To answer the main research question, four sub-questions were made based on the concepts of the theoretical model of Guntzviller *et al.* and the different codes were used to divide the collected data over the sub-questions.

Results
A total 57 of scientific advice applications were received by the MEB of which more than the half were by SMEs and about a quarter were by academia. Eventually, 13 interviews were performed with 6 SMEs and 7 academia. One of them was a combination advice with the Central Committee for Research involving Human Subjects (CCMO) and two were with the National Health Care Institute (ZiN). About half of the interviewed SMEs had made use of a consultant, whereas no consultants were used by the interviewed academia.

Four SMEs from the performed interviews made progress since the received advice and only two of the academia moved forward. Four applications of the SMEs and five of the academia were about drug rediscovery active substances. In addition, three SMEs and four academia are not planning to register the drug product by themselves but through another partner. The SMEs think that they are too small for this and that registering a product has too much responsibility, and the academia do not have the capacity.

All SMEs and 5 out of 7 academia were satisfied with the high quality of the scientific advice, the MEB's expertise, the advice

content, the advice politeness, and the relation with the MEB. The SMEs liked the structure and clarity, and five academia were satisfied with how the MEB handled with their inexperience and both found the advice carefully considered and helpful. They were able to adapt their study design based on the advice. Two academia mentioned that they are not familiar with the legislations and laws and found the legislations part of a large bureaucratic whole.

The SMEs and academia faced different limitations by the studies which were not all related to the scientific advice. They all experienced difficulties with the expensiveness of the studies and lack of fundings. A clear difference was observed between SMEs and academia where SMEs had much more knowledge about the regulatory aspects compared to academia. In addition, all SMEs will recommend the MEB's scientific advice to others and two SMEs appointed the MEB as top agency, and only four academia will recommend it. The other three do not know the value yet.

Conclusion
Overall, the quality of the MEB's tailor-made scientific advice was high according to both the SMEs and academia. All the SMEs were able to adapt their protocol based on the received advice and to move forward, however the scientific advice is not always practically feasible for the academia, and they need more support to reduce the gap between academia and regulators.

0.4 At which VU Faculty is this project situated?

- Faculty of Science (BETA)

0.5 Your contact details

Shaimaa Nasr
06-81134302
Vrije Universiteit van Amsterdam
Medicines Evaluation Board
Science departement

0.6 List other people involved, including those at partner organisations in the project (if applicable)

Medicines Evaluation Board
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Faculty of Science

0.7 Funding organisation & grant number (if applicable)

0.8 Project code (if applicable)

0.9 Consulted data management expert(s)

1. Data description

1.1 Will you collect and/or process personal data in this project?

- Yes

1.2 Will you use existing data? If yes, what is their source?

The extensive system of the Medicines Evaluation Board (ICI)

1.3 Will you collect or produce new data? If yes, please describe how.

All the scientific advices from 2015 to the 26th of May 2023 will be collected.

1.4 Describe the population/participants/subjects that will be studied

Academia and small & medium-sized enterprises (SMEs) who received tailor-made scientific advice in the past.

1.5 Do you process any of the following (personal) data?

- Digital information (e.g. IP addresses, user names, and such)
- Contact details
- Name

1.6 Do you process the personal data based on informed consent?

- Yes, using digital consent

1.7 On what legal ground will the data processing take place if it is not based on informed consent?

- Not applicable, I use informed consent

1.8 Does the data collection include any of the following types of personal data?

1.9 If your research involves special categories of personal data (previous question) and you will not use explicit informed consent, what is the legal ground for the exemption?

Question not answered.

1.10 What kinds of outputs will you produce in this project? Please describe these data assets.

Raw data:
Data asset: Audio files
Description: Interviews
Format: MP3

Processed data:
Data asset: Word files
Description: Trancription of interviews
Format: Docx

Processed data:
Data asset: Codebook
Description: Codes of transcripts
Format: Docx
Analyzed data:
Data asset: Excel sheets
Description: Data spreadsheet
Format: xlsx

Other:
Research documentation: Word file
Presentation: Powerpoint
Analysis software: Atlas.ti

1.11 How much digital data storage will your project require?

- 0 - 50 GB

1.12 Will you collect physical data? If yes, please describe these.

Informed consent forms

1.13 Will you take measures to ensure data quality? Please describe these, if applicable.

Quality assurance - the interview guide will be checked by the supervisors and two members of the Medicines Evaluation Board
Quality control - a pilot interview will be performed to test the interview guide

2. Legal and ethical requirements, codes of conduct

2.1 What legislation applies to your research project? Please tick the relevant boxes for your project.

- General Data Protection Regulation (GDPR)/ Algemene Verordening Gegevensbescherming (AVG)

2.3 Do you require approval of an ethical committee for this project? If yes, please indicate which ethical committee and whether you have obtained approval for this project.

- No

2.4 Will you work with data for which intellectual property and/ or confidentiality are an issue? If yes, please describe.

- Yes

All information shared during the interview will be kept confidential, will be anonymized to protect your privacy, and will be solely used for research purposes. Results will not be directly shared with the assessors, who were involved in your advice, but only as a summary. In addition, data and any quotes cannot be traced back to you personally or your drug development program.

2.5 Do you plan on generating a marketable product from your research project? if yes, please describe

- No

3. Storage and back-up during the research process

3.1 What measures will you take to secure and protect data during the research process? Please describe, for each separate data asset you described for question 1.10, how you will ensure data security, where the data assets are stored & backed up, and who has authorization to access the asset.

All the data will be stored and protected in the working environment of the Medicines Evaluation Board. The confidential information will be only accessible for myself and the supervisor of the Medicines Evaluation Board.
After the internship the data will be stored in a hidden enviroment only accessible for my the head of the departement.
Backup files will be made by saving the documents multiple times in different files and sending the files to myself by e-mail.

3.3 Which tools are used in the collection, processing or storage of data during research?

- OneDrive
- Zoom
- Atlas.Ti *

3.4 What other tools or software do you intend to use during your research?

Question not answered.

3.5 Is it necessary to transfer the (physical or digital) data assets to other locations or research partners? If yes, please describe how you secure the file transfer.

- No

3.7 Do you transfer personal data outside of the European Economic Area (EEA)? If Yes, please provide additional information

- No

4. Data archiving and publishing

4.1 Which data assets will be archived and which will be published?

All the transcripts and Excell sheets will be stored in the secure work enviroment of the Medicines Evaluation Board where only the head has access.
The audio files will be deleted.

4.2 Where will you archive your data assets?

- Other, see next question

4.3 What other archive(s) do you intend to use to archive data assets?

Name: Medicines Evaluation Board secure enviroment
Role: General Data Protection Regulation (GDPR)
Country: The Netherlands

4.4 For how long will the data be available in the archive?

For many years, undetermined.

4.6 Where will you publish your data assets?

4.8 How will you ensure your data assets get a persistent identifier (e.g. a DOI-code)?

Question not answered.

4.9 Will you register your datasets in an online registry other than PURE? If yes, where?

4.10 Are there restrictions to data publishing? If yes, please specify the reasons and list the data assets you do not wish to share publicly.

It must be in agreement with the Medicines Evaluation Board.

4.12 When will you share the data? If not immediately after completion of the project, please specify the reasons.

The data will not be shared with any others than the Medicines Evaluation Board. Only the report can be shared.

4.13 Please indicate the license and/ or terms of use under which you share your data.

Question not answered.

5. Documentation

5.1 What documentation and metadata will accompany the project?

The information that other researchers can use in the future will be collected in Excell sheets and word files and will be stored in the protected enviroment of the Medicines Evaluation Board.

5.2 What metadata and documentation will accompany the data assets?

The names and background of the participants will be removed and labels will be assigned to every transcript.

5.3 What methods, software or hardware are needed to access and use your data?

Excel, powerpoint and word.

6. Data management responsibilities and resources

6.1 Who will be responsible for management of the data assets during the project? Please specify their name, position, role in the project, and faculty/ institution/ group.

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Medicines Evaluation Board
Science departement

6.2 Who will be responsible for management of the data assets after completion of the project (e.g. the project lead/ dedicated data manager/ department head)? Please specify their name, position, role in the project, and faculty/ institution/ group.

Medicines Evaluation Board
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Medicines Evaluation Board
Science departement

6.3 For data that are only available upon request, what methods will be used to handle requests for access and how will data be made available to those requesting access?

The data is only accessible via Marjon Pasmooij and only anonymized data can be seen.

6.4 What resources (for example financial and time) will be dedicated to research data management? Please estimate their cost.

All the possible costs are funded by the Medicines Evaluation Board.