Executive summary

The PERMIT project is supported by two advisory boards, that provide insight and council for the good conduct of the project. The Scientific Advisory Board (SAB) and the Ethics Advisory Board (EAB) of the PERMIT project have been consolidated, with the collaboration and validation of the General Assembly. The SAB has held its first meeting and provided a number of recommendations on the overall approach of the literature review that is being carried out in WP2. The EAB was consolidated in early June 2020 and will meet for the first time at the end of June 2020 for a first introductory meeting. Both boards are now consolidated with members who have complementary expertise. The boards will be fully familiarized with the project within the first six months of the project. This will allow a smooth consultation of the boards during the next critical stages of the project.
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Document log

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<td>2020-07-17</td>
<td></td>
<td>Paula Garcia -ECRIN</td>
</tr>
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Background – Advisory Boards’ Mission

The PERMIT project is supported by two advisory boards, that provide insight and council for the good conduct of the project. The Scientific Advisory Board (SAB) provides strategic input for reaching the PERMIT objectives. Constituted of scientific experts, it assesses and advises the PERMIT consortium on the approach, the methodology and the scientific content of the project. The expertise of the SAB is especially pertinent on the execution of the mapping of current methodologies in PerMed research, and in the planning of the dedicated workshops. The Ethics Advisory Board (EAB) provides insight on all the ethical aspects related to PERMIT. This includes the ethical and personal data protection dimension of the recommendations produced by PERMIT regarding interventional trial design, and regarding the secondary use of data and samples during the stratification step. The recommendations from the EAB will be essential for the preparation of a report that will inventory these ethical and data protection challenges.

Approach – Defining the terms of reference and constituting the boards

In order to clearly outline the mission and scope of the boards, terms of reference (ToR) were established for each of the boards. A first draft of the ToR was produced by ECRIN, and circulated to all consortium participants for feedback and validation. The validated ToR (Annex I and II) would be shared with all identified experts that would be invited to serve on the board, in order to clearly outline the mission and the expectations.

During the PERMIT Kick-off-meeting in January 2020, the full consortium (including associated partners) was invited to brainstorm on experts that could potentially serve on the SAB or EAB. This was followed by a consultation via email, organized by ECRIN, where the full consortium was asked to provide the names and references of leading experts that could be invited to serve on the board. The list of nominated experts was consolidated by ECRIN. A shortlist of candidates was made for each board, with one expert covering each expertise area. Gender and geographical balance were also taken into consideration when consolidating the shortlists. The two shortlists were then circulated for validation by the General Assembly.

Following approval of the shortlists, each candidate was contacted individually, and received an invitation letter (Annex III) and the corresponding ToR of the board they were being invited to. All candidates who were initially invited to serve on the SAB accepted, and by April 2020 the board was consolidated. For the EAB, two of the initial candidates declined the invitation due to prior commitments. Two more candidates were identified through the consortium, validated by the General Assembly and invited to participate. Unfortunately, these second candidates also had to decline. Finally, at the end of May 2020 two new candidates were identified, validated by the General Assembly and invited to participate. These candidates accepted the invitation, and the EAB was consolidated on the first week of June 2020.

As soon as the SAB was consolidated, a first meeting was organized. Due to the ongoing COVID19 pandemic, the meeting was held online. It was attended by four of the five SAB members, as one
member had to cancel his participation last minute, and by the Steering Committee. The content and outcomes of the meeting are reported in the following section. Having consolidated the EAB only on the first week of June, the first EAB meeting will take place on June 25th.

Results – first board meetings

The Scientific Advisory Board

The five SAB members (detailed list in Annex IV) cover the following areas of expertise:

<table>
<thead>
<tr>
<th>Field of expertise</th>
<th>SAB Member</th>
<th>Institution, Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stratification and validation cohorts and data quality</td>
<td>Dr. Bettina Ryll</td>
<td>Melanoma Patient Network Europe, Sweden</td>
</tr>
<tr>
<td>Machine learning for stratification</td>
<td>Prof Annalisa Barla</td>
<td>Università degli studi di Genova, Italy</td>
</tr>
<tr>
<td></td>
<td>Lars Hulstaert</td>
<td>Microsoft, Belgium</td>
</tr>
<tr>
<td>Translational strategies in the Industry for the preclinical development of patient-targeted therapies</td>
<td>Prof Harald Schmidt</td>
<td>Maastricht University, Netherlands</td>
</tr>
<tr>
<td>Translational research to assign the most appropriate treatment to patient clusters</td>
<td>Prof Martin Posch</td>
<td>Medical University of Vienna, Austria</td>
</tr>
<tr>
<td>Design of clinical trials in PerMed research</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The first SAB meeting took place on May 4th, 2020 (full meeting minutes in Annex VI). It was held via web, and attended by all SAB members except Prof Schmidt who had a last minute engagement, and by the Steering Committee members. The meeting first focused on presenting the project to the SAB, who had previously received summary documents of the project. The meeting then focused on the work performed within WP2 since the launch of the project.

The SAB members had previously received a copy of the protocol for the scoping review that is being conducted in WP2, that is publicly available¹. The SAB was asked to provide their insight and suggestions regarding:

- The overall clarity and coherence of the protocol and the approach
- The operational definition of the “personalised medicine” that was adopted for the PERMIT project
- The perimeter of the scoping review
- The research questions that were selected for each task

¹ [https://zenodo.org/record/3770937#.Xul5C0UzbiX](https://zenodo.org/record/3770937#.Xul5C0UzbiX)
The SAB was also asked to share information on other ongoing personalised medicine initiatives that they were aware of, and that could be relevant for PERMIT, and to suggest names of field experts that could be invited to participate in PERMIT workshops. The first workshop will focus on a general gap analysis for recommendations. The subsequent workshops will then will focus on the recommendations for the specific stages of the personalised medicine research pipeline; stratification and validation cohorts, machine learning and artificial intelligence, translational and preclinical stages for discovery and validation, and design of clinical trials.

The SAB put forth the following recommendations:

- No overarching remarks or comments were made on the general approach of the scoping review, or the clarity of the protocol.
- Regarding the scope of personalised medicine: it was suggested that the aspect of patient preference also be taken into consideration. An example where patient preference was assessed for the treatment of pelvic sarcoma (radiation vs. surgery) was shared. Other examples may exist and could be explored in the stratification stage.
- The importance of keeping in mind, at every stage, what the initial objective for stratification was (taxonomy, response to treatment, etc.) was highlighted, as this will determine the subsequent methodologies to be applied.
- Acceptability criteria might differ for different stakeholders such as journals and funding bodies vs. regulatory bodies. As recommendations are drafted there might be a need to accommodate different expectations and acceptability criteria.
- The importance of the cycle that exists between pre-clinical exploration, clinical trials and the identification of sub-groups post-clinical trials (represented in Figure 1 of the scoping protocol) was highlighted. Assessing the methodologies to validate these subgroups will be important.
- In terms of the initial stages of patient stratification, the importance of assessing the type and quality of data that is used was stressed, as this will impact the quality of every stage of the research.
- Regarding the methods for stratification: it was confirmed by the Steering Committee that methods beyond machine learning will be assessed. The WP could be renamed to “Statistical learning” to portray that other statistical methods for stratification are also assessed.
- Regarding the disease areas that were selected: other suggestions on areas that could be explored were made, such as vaccines and pharmacogenomics, and immune-oncology and pharmacogenomics.

The SAB suggested the following regarding external expertise:

- Invite representatives from several HTAs with diverse expertise to the table, in order to have a full picture of HTAs’ expectations.
- If possible have HTAs share concrete examples and experience of technologies that are in the market and requirements that had to be met for this.
- Invite representatives from the right departments, with sufficient technical expertise but also with a sufficient level of decision making power.
- The same advice would apply to regulatory bodies, such as the EMA and HMAs, in order to have representatives who have hands-on expertise with personalised medicine research.
- Stephen Senn, an independent consultant, and published author on the personalised medicine research methodological challenges, was suggested as an expert with extensive research on personalised medicine research.

The Ethics Advisory Board
Although a first shortlist of experts was invited to join the EAB in early April 2020, it was not possible to consolidate the EAB until early June 2020 due to the unavailability of initially selected members and need to reiterate the identification/validation process two times. The COVID19 pandemic influenced the time lag of responses both from the consortium and the experts. The EAB now being consolidated, the first meeting will be held on June 25, 2020. This meeting will only be introductory and will focus on presenting the project to the EAB so they can be fully familiar with it. At this stage of the project, the ethical questions have not yet been identified, as the scoping review is only now entering its extraction phase.

Discussion and Conclusions

Both the SAB and the EAB are now fully constituted. As the PERMIT project arrives to the end of WP2, important questions will arise that will be consulted and discussed with the boards. The scoping review will have identified the main methodologies that are applied through the personalised medicine research pipeline and the existing gaps for standards and recommendations. Through this analysis the main ethical, legal and social questions that arise from the application of these methodologies will also be identified. The following board meetings will be able to provide strategic insight from an external viewpoint on how these questions should be addressed in the PERMIT recommendations, and in the dedicated report on ethical, legal and social challenges of personalised medicine research methodologies.

Next Steps

The next boards meetings will be scheduled for December 2020 or January/February 2021. The exact dates will depend on the evolution of the COVID19 epidemic, and the possibility of international travel and face-to-face gatherings. The boards will most likely meet after the dedicated workshop in WP2 that will gather experts within and beyond the consortium to discuss the gap analysis, stemming from the mapping performed through the scoping review. In this sense, the boards will be able to provide their appreciation of the gap analysis and will contribute to resolving remaining questions.

If the General Assembly or Steering Committee consider that one or both boards must gather sooner, an extraordinary meeting will be organized. Were any major events to occur within the project before the next board meeting, the Steering Committee will diligently inform them.
Appendix I - Terms of Reference Scientific Advisory Board
PERMIT SCIENTIFIC ADVISORY BOARD

TERMS OF REFERENCE

Background

The PERMIT project, funded by H2020 (Grant Agreement n° 874825) for two years, aims to develop recommendations for robust and reproducible personalised medicine (PerMed) research. PERMIT will perform a detailed mapping of current methodologies applied at every stage of the PerMed research pipeline and identify gaps and key areas for the definition of standards. It will then gather all key stakeholders in PerMed research (funding bodies, HTAs, HMA, scientific journals, research institutions, EU research infrastructures, and more) who are part of the PERMIT consortium, and leading field experts in a series of workshops to discuss and build consensus on standards for PerMed research, that will respond to regulatory expectations and will produce high quality, reproducible and reliable results.

Mission of the Scientific Advisory Board

The Scientific Advisory Board (SAB) will provide strategic input and insight for reaching the PERMIT objectives, especially in the execution of the mapping of current methodologies in PerMed research and in the planning of the dedicated workshops. The SAB will help to identify key field experts for each of the workshops, that will focus on:

1- Stratification and validation cohorts and data quality
2- Machine learning for stratification
3- Translational strategies in the Industry for the preclinical development of patient-targeted therapies
4- Translational research to assign the most appropriate treatment to patient clusters
5- Design of clinical trials in PerMed research

Meetings

The SAB will meet once a year, face-to-face, in Paris (or via web-conferencing). Additional meetings can be organized if this is deemed necessary by the PERMIT Steering Committee or by 1/3 of the Members of the General Assembly.

All travel costs of the SAB members for participating in the meetings will be covered by the PERMIT project, but SAB members will not be remunerated.

Composition

The SAB will be composed of 5 external experts, nominated and selected by the PERMIT consortium for the duration of the project, with complementary expertise in the following fields:

1- Stratification and validation cohorts and data quality
2- Machine learning and AI
3- Translational research
4- Design of complex clinical trials
Appendix II - Terms of Reference Ethics Advisory Board
PERMIT ETHICS ADVISORY BOARD

TERMS OF REFERENCE

Background

The PERMIT project, funded by H2020 (Grant Agreement n°874825) for two years, aims to develop recommendations for robust and reproducible personalised medicine (PerMed) research. PERMIT will perform a detailed mapping of current methodologies applied at every stage of the PerMed research pipeline and identify gaps and key areas for the definition of standards. It will then gather all key stakeholders in PerMed research (funding bodies, HTAs, HMAS, scientific journals, research institutions, EU research infrastructures, and more) who are part of the PERMIT consortium, and leading field experts in a series of workshops to discuss and build consensus on standards for PerMed research, that will respond to regulatory expectations and will produce high quality, reproducible and reliable results.

Mission of the Ethics Advisory Board

The Ethics Advisory Board (EAB) will provide insight on all the ethical aspects related to PERMIT. This will include the ethical and personal data protection dimension of the recommendations produced by PERMIT regarding interventional trial design (in particular how to select active treatments and comparators in each patient cluster), and regarding the secondary use of data and samples during the stratification step. The recommendations from the EAB will be essential for the preparation of a report that will inventory these ethical and data protection challenges.

Meetings

The EAB will meet once a year, face-to-face, in Paris (or via web-conferencing). Additional meetings can be organized if this is deemed necessary by the PERMIT Steering Committee or by 1/3 of the Members of the General Assembly.

All travel costs of the EAB members for participating in the meetings will be covered by the PERMIT project, but EAB members will not be remunerated.

Composition

The EAB will be composed of 5 external experts, nominated and selected by the PERMIT consortium for the duration of the project, from the following fields:

1- representatives of national ethics committees
2- experts in digital ethics
3- experts in data protection
4- patient representatives
Appendix III - Model invitation letter
Dear XXXX,

RE: Invitation to the PERMIT XXXXX Advisory Board

The PERMIT (PErsonalised Medicine Trials) project (www.permit-eu.org), funded by Horizon 2020 (Grant number 874825) aims to establish recommendations on personalised medicine (PM) research methodologies for robust and reproducible PM research. The PERMIT consortium is composed of European Research Infrastructures, research institutions, HTAs, scientific journals, funding bodies and regulatory agencies covering the main stakeholders of PM research and regulation. The PERMIT project will map the methodologies that are currently applied in PM research and identify existing gaps and needs for standards that will meet the expectations of the regulatory bodies, ethics committees and scientific journals. Through a series of workshops, it will consult field experts and develop recommendations for each stage of PM research programs. These recommendations will be made publicly available, and the PERMIT project will actively support the training on these recommendations to facilitate implementation.

Two Advisory Boards will support the PERMIT Project. The Scientific Advisory Board will be composed of experts in the fields of clinical trial design, machine learning and artificial intelligence, translational development and patient advocacy. It will provide strategic input and insight for reaching the PERMIT objectives, especially in the execution of the mapping of current methodologies in PM research and in the planning of the dedicated workshops. The Ethics Advisory Board will be composed of patient experts, members of ethics committees and experts on clinical trial design. It will provide insight on all the ethical aspects related to PERMIT and to the recommendations that the project will produce. It will also contribute with insight for a specific report that will inventory ethical and data protection challenges in PM research.

We would like to cordially invite you to serve as an expert on the PERMIT XXXXX Advisory Board. You have been recommended as a person with respected knowledge and experience, and as one who will make a valuable contribution to this Board.

The Ethics Advisory Board will meet once a year to provide strategic input to the project. The first meeting will be scheduled in XXXXX 2020 via web-conferencing.

Yours sincerely,

Jacques DEMOTES-MAINARD
Appendix IV- Final list of SAB members
# Expert Shortlist

<table>
<thead>
<tr>
<th>N°</th>
<th>Name, Last Name</th>
<th>Institution</th>
<th>Country</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prof Annalisa Barla</td>
<td>Universita degli studi di Genova</td>
<td>Italy</td>
<td>Physics, PhD in Computer Sciences – undergraduate and PhD focused on Machine Learning; worked for Siemens; computational biology; interested in developing regularization methods <a href="https://person.dibris.unige.it/barla-annalisa/cv.html">https://person.dibris.unige.it/barla-annalisa/cv.html</a></td>
</tr>
<tr>
<td>2</td>
<td>Prof Martin Posch</td>
<td>Medical University of Vienna</td>
<td>Austria</td>
<td>Statistician - Research Interests: Group sequential trials, adaptive designs and multiple testing, focusing on applications in clinical trials and Bioinformatics, former EMA statistical expert <a href="https://cemsiis.meduniwien.ac.at/user/posch-martin/about-me/">https://cemsiis.meduniwien.ac.at/user/posch-martin/about-me/</a></td>
</tr>
<tr>
<td>2</td>
<td>Harald Schmidt</td>
<td>Maastricht University</td>
<td>Netherlands</td>
<td>Medicine + Pharmacy; drug discovery, big data for network medicine, biomarkers within the context of personalised and precision medicine; entrepreneur. <a href="https://www.maastrichtuniversity.nl/h.schmidt">https://www.maastrichtuniversity.nl/h.schmidt</a></td>
</tr>
<tr>
<td>4</td>
<td>Lars Hulstaert</td>
<td>Microsoft (since 2017)</td>
<td>Belgium</td>
<td>Undergrad and Master in Computer Sciences – machine learning, deep learning, data science <a href="https://www.linkedin.com/in/larshulstaert/?originalSubdomain=be">https://www.linkedin.com/in/larshulstaert/?originalSubdomain=be</a></td>
</tr>
<tr>
<td>5</td>
<td>Dr. Bettina Ryll</td>
<td>Melanoma Patient Network Europe</td>
<td>Sweden</td>
<td>MD, PhD in Biomedical Sciences – sustainable healthcare models, access to treatment, innovative trial design, MAPPS (medicines’ adaptive pathways to patients) – chair of ESMO Patient Advocates Working Group; part of the Cancer Mission board for Horizon Europe <a href="https://www.esmo.org/Profiles/Bettina-Ryll">https://www.esmo.org/Profiles/Bettina-Ryll</a></td>
</tr>
</tbody>
</table>
Appendix V - Final list of EAB members
<table>
<thead>
<tr>
<th>N°</th>
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<th>Institution</th>
<th>Country</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Hildrun Sundseth</td>
<td>European Institute of Women’s Health (EIWH)</td>
<td>Belgium</td>
<td>President of EIWH; Industry experience and Former Head of EU policy, European Cancer Patient Coalition; helped to develop EFPIA guidelines for patient involvement; advocacy help push EU parliament to create actions for cancer <a href="https://www.alpbach.org/en/person/hildrun-sundseth/">https://www.alpbach.org/en/person/hildrun-sundseth/</a></td>
</tr>
<tr>
<td>3</td>
<td>David Perol</td>
<td>Department of Clinical Research – Centre Léon Berard</td>
<td>France</td>
<td>MD, Statistics and Epidemiology and Biostatistics - head of the Clinical Research and Biostatistics Department at Centre Léon Bérard - He is the current chairman of an IRB <a href="https://www.centreleonberard.fr/en/directory/perol-david">https://www.centreleonberard.fr/en/directory/perol-david</a></td>
</tr>
<tr>
<td>4</td>
<td>Virginie PIRARD</td>
<td>Pasteur Institute</td>
<td>France</td>
<td>Degree in Law and in Philosophy. Ethics research. Head of Pasteur’s Ethics Unit. Member of the Belgium’s Advisory Committee on bioethics since 2009 <a href="https://research.pasteur.fr/fr/member/virginie-pirard/">https://research.pasteur.fr/fr/member/virginie-pirard/</a></td>
</tr>
<tr>
<td>5</td>
<td>Simone NICLOU</td>
<td>LIH – Institute on Neuro-Oncology</td>
<td>Luxembourg</td>
<td>PhD Neuroscience; Cell Biology. Ongoing research on personalised medicine. Head of Unit Neuro-Oncology She has strong expertise in patient derived animal models for gliomas.</td>
</tr>
<tr>
<td>N°</td>
<td>Name, Last Name</td>
<td>Institution</td>
<td>Country</td>
<td>CV</td>
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Appendix VI - Meeting minutes SAB Meeting n°1
PERMIT SCIENTIFIC ADVISORY BOARD MEETING MINUTE

4 May, 2020

GoToMeeting

Participants:
- Jacques DEMOTES (JD) – ECRIN
- Paula GARCIA (PG) – ECRIN
- Christine KUBIAK (CK) – ECRIN
- Annalisa BARLA (AB) – SAB member
- Lars HULSTAERT (LH) – SAB member
- Martin POSCH (MP) – SAB member
- Bettina Ryll (BR) – SAB member
- Rita BANZI (RB) – IRFMN
- Cecilia SUPERCHI (CS) – UPD
- Chiara GERARDI (CG) - IRFMN
- Florence BIETRIX (FB) – EATRIS
- Emanuela OLDONI (EO) – EATRIS
- Vibeke FOSSE (VF) – UiB/EATRIS
- Josep Maria HARO (JMH) – PSSJD
- Teresa TORRES (TT) – PSSJD
- Enrico GLAAB (EG) – Elixir-Lu

Apologies:
- Harald SCHMIDT – SAB member
- Raphaël PORCHER – UPD

Objectives of the meeting:
- Present the PERMIT project to the SAB
- Discuss the scoping review protocol and the ongoing work in WP2
- Identify potential experts for the future workshops

Summary of discussions

Presentations
- PERMIT is a policy supporting project and part of a cluster of Coordination Support Actions (CSAs) that help to reinforce the actions of the International Consortium of Personalised Medicine (ICPerMed).
- Its main objective is to develop recommendations on personalised medicine research methodology involving all relevant stakeholders, aiming to ensure the scientific excellence, validity, robustness, reproducibility, and acceptability of results.
- The PERMIT consortium is composed at its core from the participants (Grant Agreement beneficiaries), the associated partners, and field experts. Together, the entire consortium will contribute to drafting the recommendations. The Scientific Advisory Board and Ethics Advisory Board support the consortium in its defining its strategy.
- ECRIN is part of a research alliance with two other European Research Infrastructure Consortiums (ERICs), BBMRI and EATRIS, who are part of the PERMIT project. Personalised Medicine is one of the fields where this alliance has a key role to play.
- The project was launched on January 24, 2020 and since this date, WP2 – Literature review and gap analysis has been active. It has developed a protocol for the scoping review to identify relevant literature on research methodologies at every state of the PM research pipeline. The protocol has been published and the first searches for scientific publications have been performed.
The following table summarizes the progress of WP2 up to May 4, 2020:

<table>
<thead>
<tr>
<th>WP</th>
<th>Focus area</th>
<th>Output</th>
<th>Screening Status</th>
<th>Records selected</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>Oncology</td>
<td>1711</td>
<td>Screened by two reviewers – ongoing discussion of discordant records</td>
<td>More than potentially interesting – 184 focus on methods</td>
</tr>
<tr>
<td></td>
<td>Alzheimer’s</td>
<td>PENDING</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
<td>PENDING</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Machine learning for stratification</td>
<td>1199</td>
<td>Screened by two reviewers</td>
<td>Aprox 500 articles – expect to reduce to 200-300</td>
</tr>
<tr>
<td>5</td>
<td>Mental disorders</td>
<td>1516</td>
<td>Screened by first reviewer</td>
<td>360 – expects to reduce to 150</td>
</tr>
<tr>
<td></td>
<td>Oncology</td>
<td>1292</td>
<td>Screened by first reviewer</td>
<td>272 – expects to reduce to 150</td>
</tr>
<tr>
<td>6</td>
<td>Clinical trials</td>
<td>2992</td>
<td>Ongoing</td>
<td></td>
</tr>
</tbody>
</table>

**Discussion**

- No overarching remarks or comments were made on the general approach of the scoping review, or the clarity of the protocol.
- Regarding the scope of personalised medicine, BR suggested that the aspect of patient preference also be taken into consideration. She shared an example where patient preference was assessed for the treatment of pelvic sarcoma (radiation vs. surgery). Other examples may exist and could be explored in the stratification stage.
- MP highlighted the importance of keeping in mind, at every stage, what the initial objective for stratification was (taxonomy, response to treatment, etc.) as this will determine the subsequent methodologies to be applied.
- MP also pointed out that acceptability criteria might differ for different stakeholders such as journals and funding bodies vs. regulatory bodies. As recommendations are drafted there might be a need to accommodate different expectations and acceptability criteria.
- BR highlighted the importance of the cycle that exists between pre-clinical exploration, clinical trials and the identification of sub-groups post-clinical trials (represented in Figure 1 of the scoping protocol). Assessing the methodologies to validate these subgroups will be important.
- In terms of the initial stages of patient stratification, MP stressed the importance of assessing the type and quality of data that is used, as this will impact the quality of every stage of the research.
- Regarding the methods for stratification, EG confirmed that methods beyond machine learning will be assessed. The WP could be renamed to “Statistical learning” to portray that other statistical methods for stratification are also assessed.
- Following LHs questioning of the cut-off for the selection of methods, EG clarified that the main focus will be multivariate, multi-marker analysis.
- Regarding the disease areas that were selected other suggestions on areas that could be explored were made by the SAB such as vaccines and pharmacogenomics, and immuno-oncology and pharmacogenomics.
- The SAB suggested the following regarding external expertise:
  - Invite representatives from several HTAs with diverse expertise to the table, in order to have a full picture of HTAs’ expectations.
  - If possible have HTAs share concrete examples and experience of technologies that are in the market and requirements that had to be met for this.
  - Invite representatives from the right departments, with sufficient technical expertise but also with a sufficient level of decision making power.
  - The same advice would apply to regulatory bodies, such as the EMA and HMAs, in order to have representatives who have hands-on expertise with personalised medicine research.
  - Stephen Senn was suggested as an expert with extensive research on personalised medicine research.

**Conclusions**
- The SAB made constructive contributions to the scope of the project which will be discussed with the General Assembly.
- SAB should meet again in one year’s time; May 2021. But extraordinary meetings can be scheduled if the General Assembly or Steering Committee request this.