ADOPT BBMRI-ERIC
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DELIVERABLE REPORT

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OPERATIONAL PLATFORM FOR SHARING EXPERIENCE

Executive Summary

In order to establish, operate and maintain a **platform for experience sharing across countries regarding ELSI aspects encountered the workshop** *Towards Mutual RECognition?* (2016) concluded that BBMRI-ERIC would be accepted in providing such a platform. Most crucially, the role of ELSI Helpdesk Coordinator was established to ensure the coordination of such activities, most notably annual Ethics Cafés (external communication, dissemination and discussion of results & experiences) and file sharing. Ultimately, this has to be part of the BBMRI-ERIC ELSI Heldpesk and Knowledge Base.

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1. Background

This deliverable is related to **Task 4.4: setting up a fully operational platform for experience sharing across Countries regarding ELSI aspects encountered.** This deliverable is informed by previous achievements of D5.2 Annual Workshops and meetings, in particular the Workshop *Towards Mutual RECognition?* (2016).

The Workshop was held ahead of time and concluded that BBMRI-ERIC would be accepted as a platform for experience sharing and could guarantee sustainability, but that it would be a long road to achieve harmonisation when it comes to national and local ethics committees. Nonetheless, issues and concerns for transnational transfer of data and samples and the ethical reviews shall be discussed in various formats.

2. Approaches (Methods)

In order to share experiences to a wider and trans-disciplinary audience (members of ethics committees, researchers, ELSI experts, policy makers) in an appropriate manner the following strategies were taken:

- Organising regular (annual) Ethics Cafés (dissemination of results via e-newsflash, new media)
- Establish the role of the ELSI Helpdesk Coordinator
- Host experience sharing platforms (external and internal)

The format of an Ethics Café provides an opportunity to share views on specific topics in an informal setting. A debate is kick-started by a provocative opening statement or an engaging talk. The audience is invited to participate, ask questions and provide new insights for an ultimately thought-provoking dialogue.

The establishment of the role of ELSI Helpdesk coordinator ensures appropriate coordination and implementations of the findings as well as to maintain the platform for sharing experiences operational.

The platform for sharing experience is envisioned as integral part of the ELSI Helpdesk and Knowledge Base (esp. hosting webinars & ethics cafés).

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3. Results

3.1 Ethics Café on exploring existing and novel models for use of research data, Vienna 2016 09 14

(in collaboration with ADOPT BBMRI-ERIC, ESBB, BBMRI-ERIC and GCOF in the context of the European Biobank Week)

The ethics café was co-organised by GCOF WP4 on exploring existing and novel models for use of research data, especially focusing on biobanks on 14th of September 2016 in joint collaboration with BBMRI-ERIC (Common Service ELSI) and ESBB. The main questions were: What are possible *benefits to participants* and communities in *research?* Is the information about the current health status enough to qualify as a benefit? Can we work towards shared European rules on what results should/have to be shared to whom and how? Should the researchers inform donors about the latest results actively? Or, should the donors seek the results from the researchers? In any case, what is the right format not to create an overload of information? What could be the role of the genetics clinics in helping people to understand the meaning(s) of the results? In contrast, what is/could be/should be the role of private companies or science communication agencies? Moderation by Michaela Mayrhofer, provoking statements by Jasper Bovenberg, Helena Kariainen and Mats Hansson.

- **Audience: approx. 100 people**
- **Internal report, see Appendix II**

3.2 Ethics Café: Are Donor Rights Valuable?, Stockholm 2017 09 15

(report supported by ADOPT BBMRI-ERIC in the context of the Global Biobank Week)

it was kick-started by two provocative opening statement by Prof J.Kaye and E.B van Veen, moderated by Dr. M. Mayrhofer. The audience was invited to participate, ask questions, provide new insights for an ultimately thought-provoking dialogue. The discussion was stimulated by the following remarks: Careful protection of personal information is a key concern in our society. In biomedical research and the biobank context, which rights do donors/research participants have? How varied are these rights across countries and what is presumed to be a right? Should donors have the right to decide for each research endeavor if they (dis)agree with the usage of their samples/data? What intermediate level of control does exist between "agreement for each use" and "unspecified broad agreement"? Should they be enabled to access and administer their own data? What would be the consequences? Is it empowerment for citizens or an overload of the technological society? Are rights the priority or is it the capability of the system to adapt to different levels of engagement, willingness, wishes of the participants? Do the institutions welcome the initiatives, ideas, implications of participants or do they paternalistically administrate their "rights"? Is there a hierarchy in rights and who is deciding on it? Ultimately, what is a right worth if it cannot be protected? In conclusion, the ethics café can be summarised that an open dialogue between actors (researchers, patients, RECs, etc.) is needed.

- **Audience: approx. 200 people**
- **A report is forthcoming Q1 2018.**

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The deliverable is on time. The deliverable report was slightly delayed due to a sick leave of the WP lead.

4. Discussion and Conclusions

Two ethics cafés have taken place in September 2016 and 2017 respectively. The doubling the number of attendees from one year to the next to 200 participants shows the great success of the format. It allows to disseminate results to a wider audience and immediate feedback in a transdisciplinary setting. At the same time, it has become apparent that virtual platforms for experience sharing have to become an integral part of such a platform. BBMRI-ERIC hosts such a platform and makes it integral part of its ELSI Helpdesk and Knowledge Base and links to its Stakeholder Forum. The platform has 2 levels:

1. Internal BBMRI-ERIC: via sharepoint (example, see Appendix)
2. External: via webinars

5. Next Steps

- Organise Ethics Café 2018, Antwerp
- Enlarge on sharing experiences via virtual platforms (esp. discussion forums, example see Annex I)

6. References

Workshop Report, Towards Mutual RECognition (2016), http://www.bbmri-eric.eu/wp-content/uploads/2016/07/BBMRI_LPC_B3Africa_RECMeetingVienna2016report.pdf

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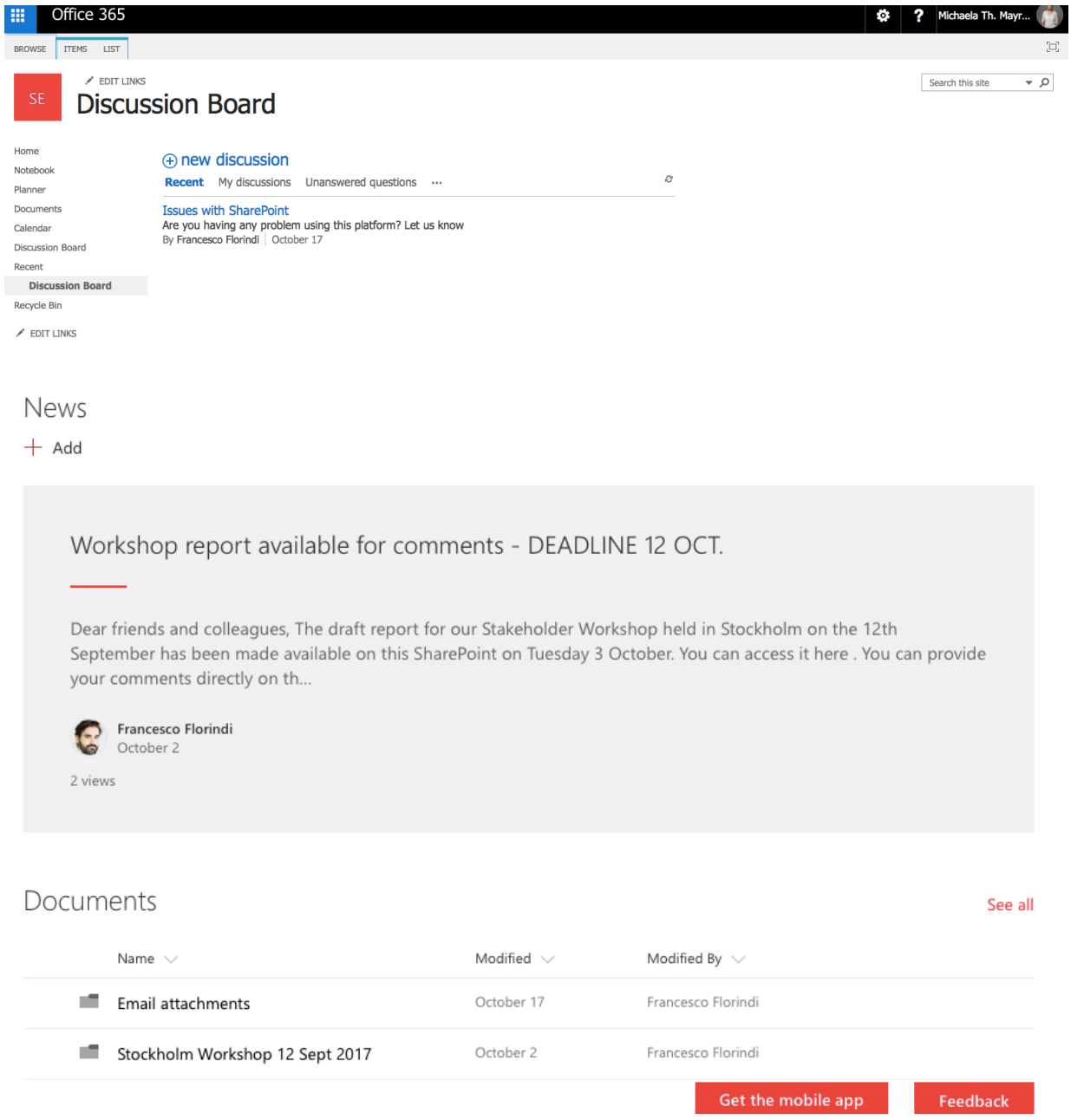
Appendix I - Stakeholder Forum Discussion Board

Figure 1 : Screenshots of Sharepoint from the Stakeholder Forum (set up October 2017)



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Appendix II – Summary of Expert Workshop

Summary of Expert Workshop:

Ethics Café on exploring existing and novel models for use of research data, especially focusing on biobanks on 14th of September 2016

GCOF WP4 organized an expert workshop in the format of an 'Ethics Café' on exploring existing and novel models for use of research data, especially focusing on biobanks on 14th of September 2016 in joint collaboration with BBMRI-ERIC (Common Service ELSI) and ESBB. The format of an Ethics Café provides an opportunity to share views on specific topics in an informal setting. A debate is kick-started by a provocative opening statement or an engaging talk. The audience is invited to participate, ask questions and provide new insights for an ultimately thought-provoking dialogue.

The main questions were:

What are possible *benefits to participants* and communities in *research?* Is the information about the current health status enough to qualify as a benefit? Can we work towards shared European rules on what results should/have to be shared to whom and how? Should the researchers inform donors about the latest results actively? Or, should the donors seek the results from the researchers? In any case, what is the right format not to create an overload of information? What could be the role of the genetics clinics in helping people to understand the meaning(s) of the results? In contrast, what is/could be/should be the role of private companies or science communication agencies?

This Ethics Café took place during Europe Biobank Week: Biobanking for Health Innovation, Vienna 12-16 September 2016. The 'Ethics Café: Sharing results with donors' was attended by more than 100 participants (exact number not known as people were moving between parallel programs).

Summary:

The Ethics Café managed to gather a wide range of various stakeholders to discuss strategies for returning (or not returning) results to the donors. Stakeholders are defined as individuals and/or organisations that can be affected or affect a certain domain. There were at least representatives of biobank personnel, biobank and other researchers, ethicists, lawyers, social scientists, policy makers and clinicians. One aim was to discuss how the issue of returning results should be approached at the consent process and whether a uniform consent (in this respect) could be attained among European biobanks or even worldwide.

The 'Ethics Café' was opened with three presentations to set the scene. Helena Kääriäinen presented a short summary of the results of the Survey performed by GCOF WP4, Jasper Bovenberg reflected on ethical and legal issues relating to medical research in general and finally Matts Hansson, as agreed before, presented arguments especially against sharing results with the donors. After the presentations, the audience participated in the form of very lively discussion. Notes were taken during the discussion. Michaela Mayrhofer moderated the event.

For the specific question whether to return results or not, the audience presented opposing opinions which were partly related to the differences in national legislation and practices. For the same reasons, the audience had strong doubts about reaching a uniform consent process relating to receiving personal results from biobank research. In addition, the audience stated that biobanks are so different from each other

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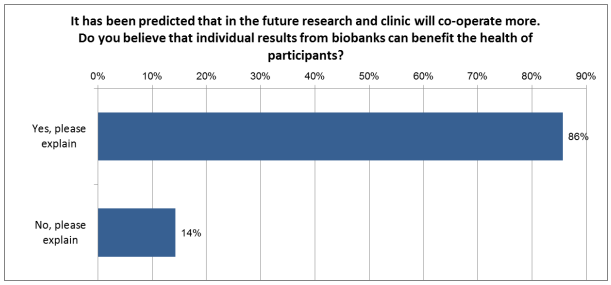
reaching from rather small and clinically uniform diagnostic collections all the way to huge population based biobanks, that the same type of consent process may not be feasible. Clinical cohorts might benefit from a dynamic consent process which might be in practice not suitable for large population based collections.

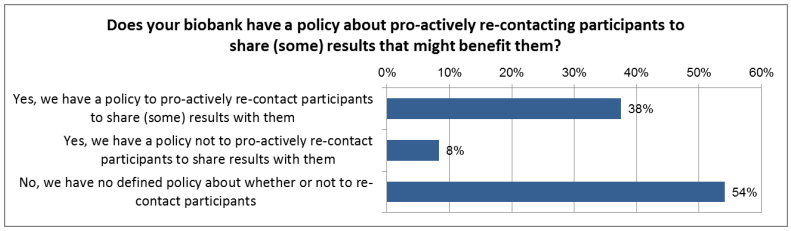
The conclusion was that the principles on returning individual results, at least in the near future, cannot be uniform in different countries and different types of biobanks. Returning research results in a more general level was seen more straightforward and important as this is a way to add transparency on the activities of the biobanks as such (e.g. Is research done with the majority of samples/data collected? What kind of research has been done? Which results have been achieved, if any?). It was also concluded that working towards a shared consent process in BBMRI-ERIC or for European biobanks more generally is at present not realistic. Returning results also requires resources and clinical experience which the biobanks do not necessarily have. However, the discussion towards developing some shared elements to the consent process has to continue.

Extracts from the presentations:

Helena Kääriäinen: BBMRI/GCOF Survey on Returning Results to Donors.

This Webropol Survey was performed autumn 2015 among all BBMRI Biobanks; responses were received from 72 biobanks representing all the BBMRI-ERIC countries (at that time). Some results of the Survey were presented as an introduction to the Ethics Café, the slides are shown below. They clearly show the very different practices of the biobanks.





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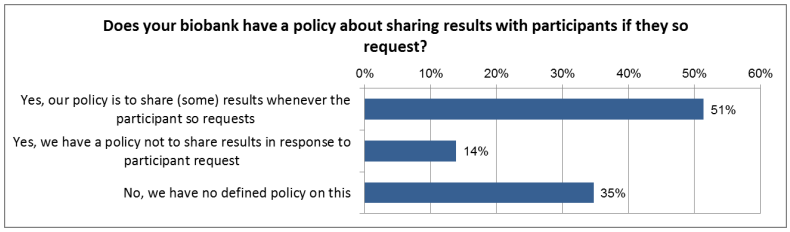

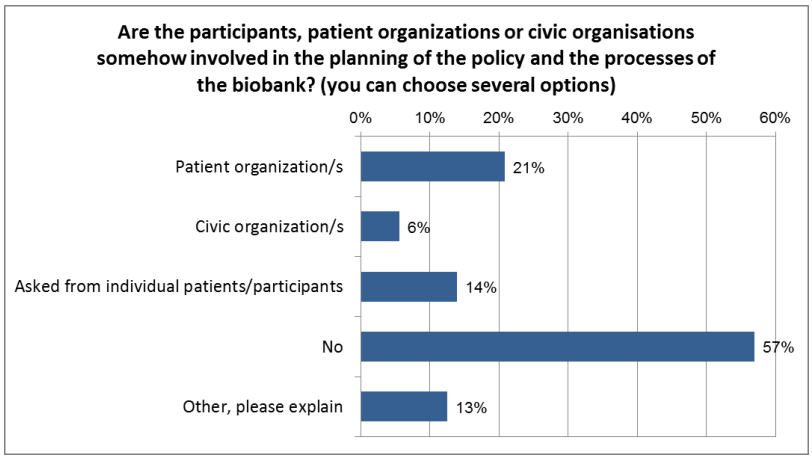

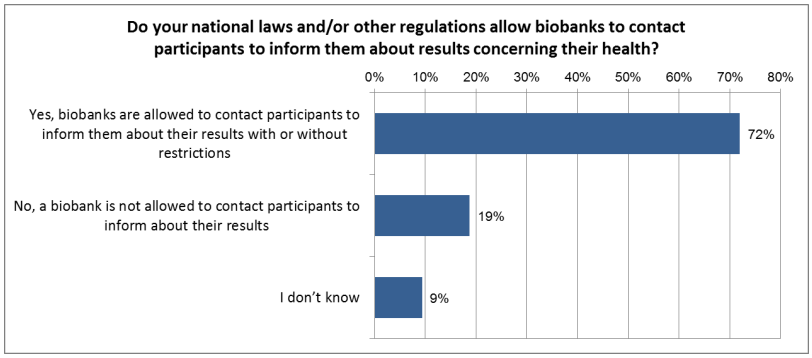

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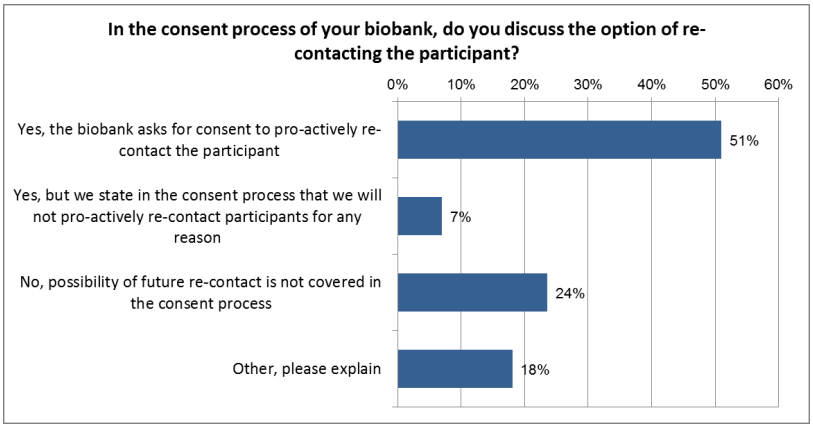

Matts Hansson: Arguments for and against returning results

- May be beneficent for individual donors
  - if the information has analytic validity, clinical validity and clinical utility
- Promotes autonomy if information relevant to their health is disclosed
  - if they are well-informed about this
- Getting something back – a sign of respect and may help recruiting
  - reciprocity yes, but only if the information is of value to them
- Some individuals want to know
  - but do they want to know if they are informed about the limitations of the information?
- Potential health consequences that could result from false positive or false negative assessments for high-risk indications
- A great variability of biobanks, samples are sent around and used in different projects over a long period of time
- Setting up assessment committees in biobank structures costly and complex
- Conclusion by Matts Hansson: Let results of research be disseminated to individuals through the ordinary channels: e.g. Through translation of published research into clinical practice

Jasper Bovenberg presented general arguments relating to research ethics misuse of the trust of the study subjects, based on examples (Tuskegee Experiment 1932-1972; Framingham Heart Study 1948). Tuskegee Experiment (1932-1972) was a long term observational study performed US Public Health Service to observe the natural progression of syphilis, if left untreated. The research participants were not informed of their diagnosis, never treated for syphilis nor informed of the results of the Study. The study had to be terminated after exposure. Framingham Heart Study (1948) had as its aim to identify the root cause of heart disease by following a large cohort of participants. The study linked obesity and smoking to heart disease, but the study participants were not informed or guided relating to these risks. These examples

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were used to better understand why today legal instruments as well as oversight by ethical committees are seen as an important part of research.

Discussion:

Among others, the following arguments for and against returning results were presented:

The way how to present the results has to be investigated.

We have no duty to prevent participants from taking the risk to get results.

Most of the participants (in Finland) when asked want to get their results (more than 90%).

The possible results (especially genetic results) cannot be considered “final” as knowledge is still growing.

Do the participants understand the results correctly? This has to be investigated.

The distinction between research and clinic is not as clear as before.

There should be tools to give the results that would allow new interpretations, continuous contact with the participant via the tool.

There has been discussion on “actionable gene results (ACMG)” but this has meant medically actionable, what about personally actionable (like life planning).

To validate the research results needs a lot of resources.

The result may have another meaning when also family history is taken into account.

Why in other type of studies (clinical studies to develop medicines) results are regularly returned to patients, why not in biobank research.

The good examples of dynamic consent in some cohorts are not feasible in huge population biobanks: the participants are not active enough to change their consents (many do not even remember that they once participated).

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