

EAIN 2419-Roadmap

Date (08/1/2016)

Abbreviations:

- **CAB:** Community Advisory Board
- **CER:** Comparative Effectiveness Research
- **PCOR:** Patient-Centered Outcomes Research
- **PCORI:** Patient-Centered Outcomes Research Institute
- **PL:** Project Lead

OBJECTIVE

The objective of this Engagement Award (EAIN-2419) was to develop a partnership with a wide range of stakeholders (researchers, patients/family members and physicians/healthcare providers) to build a Roadmap (instructions) to engage them in research, dissemination, and evaluation of the concept of using genetic information in PCOR and CER.

Project Duration: Start: 10/1/2015, End: 9/30/2016

SUMMARY of FINDINGS

We formed a Community Advisory Board, consisting of 33 members:

- 11 Patients/Parents [33.3%],
- 9 Physicians [27.3%],
- 4 Caregivers [12.1%],
- 15 Scientists [45.5%], and
- 7 Others [21.20%]

to discuss the topic of If/How genetic information may be used in PCOR studies. Wide range of interests of our stakeholders was shown by different disease groups they represented:

- Autism: 13 [39.4%],
- Cancer: 9 [27.3%],
- Cardiovascular disease: 9 [27.3%],
- Others: 9 [27.3%] (sleep disorders, metabolic disease, genetics, rehabilitation medicine, research informatics, nephrology, bipolar disorder, ADHD, allergies, asthma, Turner syndrome, and infectious diseases).

We structured our meetings as a combination of PowerPoint presentations, surveys, and in-person group discussions to share educational materials with our CAB members, listen and learn from their experiences, preferences, and needs in this context. This structure for meetings was suggested by our CAB members and found to be effective and convenient for successful review of the provided materials (when surveyed, 100% of our participants approved the suggested structure for the meetings). We collected and assessed the CAB's opinions, suggestions and input about how genetic information may be used to improve PCOR studies.

Overall, feedback from our participants indicated their high level of interest on the topics covered, willingness to share personal experiences and to learn other stakeholders' perspective. They highly valued the educational aspect of our project and noted the need to further expand such activities, particularly to raise awareness among the research community about finding ways to incorporate genetic information in patient-centered studies. Topics to be covered during the course of the project were carefully selected to be able to give the most meaningful overview, considering time

limitations. Successful implementation of this aspect was monitored via surveys, as exemplified in the below table.

Participants' Personal Perspectives	
Topic:	Average Rating
Familiarity with PCOR and CER	7.5/10
Importance of incorporating genetic information into CER	8.3/10
Interest level in using genetic information in CER studies	8.3/10
Participants' Assessment of Educational Aspect of the Project	
Approval of the topics covered	100%
Overall clarity of presentations	8.9/10
Topics with the highest rating	
Patient personal stories	9.4/10
Precision Medicine Initiative	9.2/10
Genetic research done by our CAB members-Examples	9.0/10
Electronic Medical Record systems-Examples	9.2/10

After getting our CAB members' feedback and incorporating their suggestions, the present Roadmap was drafted, and will be assessed and finalized by our CAB members.

DETAILS

We reviewed feedback/comments received from our CAB members throughout the study. The general themes identified by our CAB members, reflecting barriers, facilitators, and needs, are summarized here:

Barriers:

1. Obtaining Meaningful Input from Every Participant
2. Including Genetic Information in Clinical Practice (*insurance coverage and genetic counseling access*)
3. Insufficient Physicians' Training about Genetic Testing
4. Insufficient Technical Knowledge Level of non-Scientific Study Participants
5. Technical Challenges (*varied platforms defies data integration and sharing*)

Facilitators:

1. Meaningful Role for Every Participant (*collaborative nature of the project, sharing personal experiences, and hearing both technical and non-technical perspectives*)
2. Educational Aspects for Participants (*learning about new resources and concepts*)
3. Stimulating Thoughts for Participants (*identifying research gaps and potential collaboration avenues*)

We assessed and processed the identified barriers and facilitators and developed a list of elements that need to be addressed to enhance study participants' contribution and overall implementation of the results generated from such engagement projects in the research community.

Needs:

Elements Facilitating Study Participants' Contribution

1. Explaining research data in a non-technical language
2. Designing studies by taking into consideration participants' time-constraints
3. Providing a glossary of terminologies related to the project
4. Providing a lay abstract for technical topics
5. Providing educational materials about the disease condition and genetic risk factors

Lessons Learned (Future Directions/Recommendations)

1. Many useful resources containing genetic/clinical data have already been developed, but study participants, including scientific/clinical members, may not be aware of them.
2. Providing a framework for how to access existing genetic data would facilitate incorporating it in health outcomes research.
3. Setting reasonable expectations for study participants is needed to maintain each member's meaningful contribution without slowing down the overall research process.
4. Study participants' motivation and time devotion are essential in reviewing the provided educational materials.
5. Reviewing actual research examples would facilitate better understanding of the topic, particularly, for non-technical study participants.
6. Visual aids (e.g., videos, webinars, and illustrations) are great educational tools and help with explaining complex contexts.
7. Focusing on one disease would be helpful for:
 - developing practical example(s) for incorporating genetic data,
 - identifying more specific barriers and needs, as well as
 - implementing results among the research community

SUGGESTED INSTRUCTIONS

The following tasks will facilitate implementation of findings from the EAIN-2419 Engagement project and reaching the ultimate goal (i.e., promoting incorporation of genetic information in patient-centered studies):

1. Raising Awareness in Research Community

Despite a growing interest among different groups of stakeholders, it appears that research community is not fully aware of the need to promote incorporation of genetic information in PCOR studies. To stimulate interest towards developing patient-centered genetic research projects, genetic research community needs to be aware of PCOR initiatives, such as this Engagement project.

2. Developing Effective Educational Models

Online educational courses and workshops could serve as an effective and least time-consuming learning method for participants, particularly considering their busy schedules. A combination of online courses, website postings, and in-person meetings/workshops can be used to design an educational model aiming to motivate the research community to consider using genetic information in PCOR projects. Educational materials can be archived in an online source (e.g., project website) to allow convenient access and review for study participants.

3. Developing Disease-Specific Examples

The current Engagement project identified several key issues on the general topic of incorporating genetic information in PCOR studies. To develop a more detailed engagement and implementation plan, disease-specific projects need to be developed. Focusing on a given disease will enable implementing the lessons learned from such engagement activities to establish research partnerships with the relevant stakeholders. Step-by-step instructions for a practical workflow and potential gaps (i.e., patient/community engagement, hypothesis development, data retrieval from genetic/phenotypic databases, and statistical analysis) could be assessed by developing disease-specific research examples.

4. Developing Searchable Registries

There are several publicly available resources dedicated to collect/store both genetic and clinical information (also known as databases). Furthermore, data generated from PCORI funded projects could also be considered as another valuable resource. Despite the availability of such rich databases, genetic information has not been used in PCOR studies. Existing genetic/phenotypic databases provide a real opportunity to re-analyze already collected data and apply it to address clinically meaningful questions. A searchable registry summarizing data from existing databases is needed to facilitate re-analyzing existing genetic/phenotypic data in PCOR studies. This technical barrier needs to be overcome to facilitate more effective engagement and contribution of participants, especially non-technical members, in developing patient-centered genetic research projects.

5. Building Multi-Disciplinary Teams

Project team should consist of representatives from local communities and a wide range of stakeholders, including researchers and clinicians from academic medical centers; parent/patient representatives; research organizations and initiatives and other stakeholders including industry representatives. Due to the sensitivity of using genetic data for patient health, participants with diverse perspectives (involved in policy making, genetic data analysis, bioethics, and bioinformatics) should be also included in such multi-disciplinary teams.

Note: A detailed description of the EAIN-2419 project and findings (including topics covered in the meetings, questions included in the surveys, tasks, and final statistics), will be included in the final report to PCORI and submitted for publication in a position paper, at the end of the project.

Amendment: This Roadmap may be modified or amended by the Research Team and CAB members, if needed, during the course of the study.

Final version of the Roadmap will be submitted to PCORI, at the end of the project.