

Developing the roadmap for collaboration between patients and researchers about genome ELSI on clinical research and policy

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Objective

- Though the use of genomics, rare diseases (RDs) are an area of significant opportunity for improved diagnosis and treatment.
→ The way of recruiting patients and patient participation in genome research has slowly become more important and established at RD field in Japan.
- But RD patients don't have enough knowledge about genome research and ethical, legal, and social issues (ELSI) around genome research.
- Also genome researchers seldom have chances directly to meet RD patients and to understand their needs and issues about genome research.
- Our aim is to develop the long-term roadmap for collaboration between patients and researchers about genome ELSI on clinical research and policy.

Method

- Collecting data from eligible participants (see below) in the following 2 ways:
 - 1) Through semi-structured interviews
 - 2) Through our workshop series about patient participation in genome research
- Eligible participants:
 - Patient side : RD patients, their family members, and patient group/association leaders
 - Researcher side : Skilled genome research and development personnel, clinicians, medical and/or ELSI researchers, and executive officers
- Data analysis: Classified interview data and opinions from workshop series into related theme categories by content analysis method.
- Developing the roadmap for collaboration with patients about genome ELSI on clinical research and policy:
 - The authors discussed the long-term visions and action items of collaboration for genome research and its ELSI, and constructed a pilot version of roadmap.
 - Then we discussed this roadmap with both patient and researcher side and modified it referring to their opinions.
- Ethical consideration: We got an approval from ASrid IRB committee before starting to collect data.

Asked about knowledge and understanding about genome research and ELSI for participating in research, and the recognition of the other side.

Result

- Interview data from 23 people and opinions from 65 people participating workshop series were analyzed. (Table1)
- Researcher side includes genome analysts, R&D researchers, ELSI researchers, physicians, nurses, science communicators, and journalists.

Table 1. Background of research participant

	Interview	WS1	WS2	WS3	WS4	Total
Patient side, n	9	8	8	5	9	39
Researcher side, n	14	9	8	7	11	49

WS: Workshop

- As a result of content analysis, 6 categories and 33 subcategories about current recognition of collaboration for genome ELSI were identified. After repeated discussions by authors, we arranged these categories into 5 visions that should be accomplished in the next 10 years for the collaboration. (Figure 1)
- In the roadmap, the horizontal axis shows the targets in whom ELSI researchers and/or other entities intervene; Patient and Researcher side. The vertical axis indicates the time and it is divided into 4 phases, each of which has a small goal to achieve. (Figure 2)
- Phase 1:** ELSI researchers conduct surveys about the current situation and search previous literatures for the evidence of the following phases.
- Phase 2:** ELSI researchers develop training programs and guidelines.
- Phase 3:** ELSI researchers continuously execute training programs for both sides and issue a certificate for the completion of these training series to the person. Certificated people collaborate with each other as equal partners to promote.
- Phase 4:** Certificated people conduct cooperative and collaborative activities for clinical research.
- According to the goals at each phase, we identified concrete items showing who does what to whom.

Conclusion

- This is the first roadmap in Japan for collaboration between RD patients and researchers about genome ELSI on clinical research and policy.
- We show 5 specific visions and concrete action items to achieve these visions in 4 phases in the next 10 years.
- We hope this roadmap facilitates further discussion about patient participation and the collaboration with researchers in genome research and its ELSI.

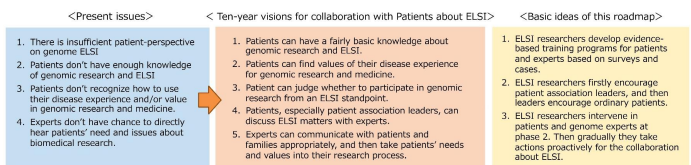


Figure1 : Present issues about collaboration for genome ELSI, 5 goals to resolve these issues, and basic ideas of the roadmap

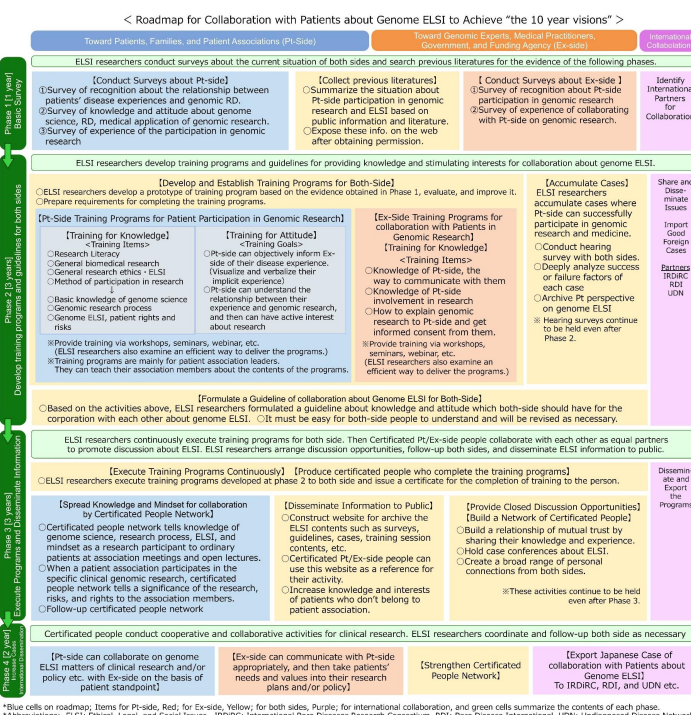


Figure2 : The roadmap for collaboration between patients and researchers about genome ELSI on clinical research and policy (for further discussion)