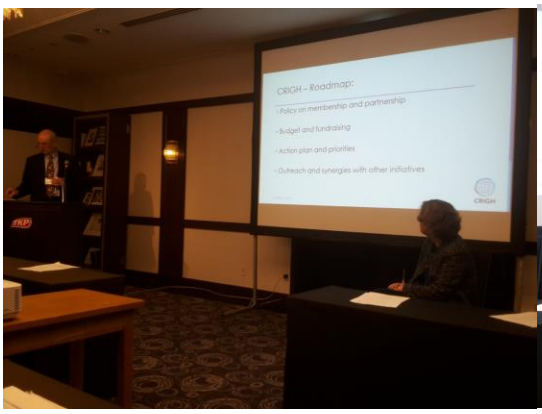
CRIGH General Assembly

March 7-8, 2017; Tokyo

The CRIGH initiative (www.crigh.org) aims to support international collaboration on clinical research by developing global standards and establishing a collaborative framework to address health issues worldwide.

The first CRIGH General Assembly (see agenda in Annex), organized back-to-back with the 3rd Global ARO meeting, was an opportunity to discuss the progress of the various activities, and establish a roadmap for the future actions. Some transversal and overarching aspects related to international clinical research were presented to feed the discussion, and breakout sessions were organized to discuss the topics covered by each of the CRIGH Projects.

- Jacques Demotes (ECRIN) introducing CRIGH and discussing the need for more international collaboration on clinical research in the public interest -



- Discussing the next steps for CRIGH (left to right: Ted Trimble, NCI; Christine Kubiak, ECRIN; Charles Wiysonge, SAMCR; Shimon Tashiro, NCCJ; Øyvind Melien, chair of CRIGH Management Board; Eva Denison, Norwegian Institute of Public Health) -

A. GENERAL CONCLUSIONS:

1. An amount of $12.000 is made available to each of the 5 active Projects to support their activities (workshops, other operation costs)
2. Optimizing the use and reuse of data appears as an emerging opportunity for international clinical research. We propose that clinical trial data issues should be addressed (either in P1, in P5, or in a new Project) to cover global implementation of existing initiatives (clinical trial data centre certification, access to national health databases), and to develop common policy recommendations and tools on other topics of common interest (data standardization, data sharing, reuse of health data and of registry data, etc)
3. A roadmap for CRIGH next activities in 2018 and 2019 will be prepared, with insights to developing the membership policy and expanding the partnership, how to increase the budget and fundraising, elaborating the action plan and establishing priorities, and general outreach. The Terms of Reference document should be updated accordingly with milestones and due dates for the deliverables
4. The members agreed on the importance of producing results that could inform a WHA resolution which would strengthen CRIGH's mandate
5. The OECD must evaluate the implementation of the OECD Council Recommendation on the Governance of Clinical Trials. This will require collection of metrics, in particular (but not only) with regards to the adoption of risk-based provisions at national, regional or global level (for instance the ICH-GCP has now adopted risk-based provisions). A discussion with OECD health division will help defining the relevant metrics; a survey will be prepared and conducted, in collaboration with CRIGH P1
6. The Project 6 on regulatory awareness did not start, due to the decision of EMA and FDA not to participate. However making regulatory and ethical information on the national / regional requirements for clinical trial authorization is essential for efficient international cooperation. Some initiatives exist (the ECRIN database, the NIAID ClinRegs). It should therefore be considered whether, based on these initiatives, the active Projects, in particular P1 and P3, could develop a shallow overview of regulatory and ethical requirements, to help investigators navigate.
7. An Executive Board teleconference will be organized during spring to address these issues. In parallel, letters of request for the 2018 contribution will be circulated to members.
8. It is proposed to have the next General Assembly meeting in Paris (2019), and to plan the next one (2020) in South Africa (Cape Town).

B. REPORT from the Breakout Sessions

- **P1 "Infrastructure and funding"** ***(presented by Christine Kubiak, ECRIN)***

Objective: To develop a global capacity to manage international trials (high quality and interoperable clinical trial centres supporting investigation and trial management, with national, regional and global networking), run pilot trials and promoting funding sources for independent, international trials.

Achievements and next steps: development of a questionnaire to map the infrastructures and the funding worldwide; first run a pilot within the group, then circulate the questionnaire among the CRIGH partners and external contacts. Consolidation and analysis of the results, with production of a report by January 2019. Feedback needed in particular from Project 2 and 3

- **P2 "Global Core Competencies"** ***(presented by Charles Wiysonge, SAMRC)***

Objective: To promote harmonized education, training and careers for investigators and clinical research professionals. Definition of Global Core Competencies; specifications for a common accreditation system; dissemination of guidelines.

Achievements and next steps: survey performed to identify key actors/organisations and relevant existing documents; draft Global Core Competencies based on the results. Possible approach: setup of a basic educational tool which could be adjusted according to regional and/or national specific requirements.

Explore the possibility to establish global standards, training harmonization (maybe a minimum set of standards?): for this a very large consultation among stakeholders would be necessary (needs, certification, etc.) as well as national regulation for education, diplomas, pharmaceutical institutions (often diploma are national and delivered by Universities).

As previously raised by the OECD, there is a need for education outside clinical trial staff – such as regulatory authorities. Discussion to establish early dialogues before entering huge clinical trial phases.

- **P3 "Research Ethics"** ***(presented by Shimon Tashiro, NCC Japan)***

Objective: Comparison and harmonization of research ethics system in non-commercial clinical trials

Achievements and next steps: survey conducted to collect data from 23 countries in Asia, Africa and Latin America. Consolidation of results and preparation of a manuscript by January 2019; possibly development of education resources and recommendations in collaboration with Project 3.

- **P4 "Patient involvement"** ***(presented by Ted Trimble, NCI)***

Objective: To foster patient involvement as trial participants, and also in trial design, in the definition of outcome measures, in Ethics Committees, and in establishing research priorities. Develop an inventory of training programs in place; develop recommendations for training courses.

Achievements and next steps: survey performed to identify available resources (materials and tools) online. Information will be summarized and recommendations made for consumer patient activities.

Building an umbrella organization that is disease agnostic for patient advocates/involvement; lack of system for patient advocates. Ex. EURORDIS organizes a 1-week training (go through the whole process of drug development, patient enrollment, etc.); HIV and breast cancer organization have excellent training models. Important to make sure that they are more widely available and translated in more languages.

Key issues: Using available technology (i.e. smartphones) for patient involvement; how to reach out to patients more often – patient report outcomes, patient experience. Looking at those models available in Australia (HIV) and Europe (EURORDIS). How to involve patients in the traditional research.

- **P5 "Comparative Effectiveness Research"** ***(presented by Eva Denison, NIPH)***

Objective: To promote methodologies for efficient comparison of treatment strategies, and to assess the medical, social and economic impact of these options.

Achievements and next steps: pilot study on assessment of comparative effectiveness trials completed; ongoing: mapping review of comparative effectiveness research methods as well as investigation of return on investment on comparative effectiveness trials.

Preliminary results show that matching research efforts in low income countries is very poor. Not done for topics that are important for them. Project 5 is focused in high-income countries, research has to be funded by public resources. Need to extend the concept to LMICs.

Additional activity: collection of information on data sharing (core outcome sets, data quality, ethics, regulatory) and pragmatic trials (how to improve methods).

ANNEX – CRIGH GENERAL ASSEMBLY AGENDA

Day 1: March 7th	
14:00	**Coffee & Welcome**
14:30	**General session I: Introduction** - Welcome words *(Masanori Fukushima)* - Introduction of CRIGH *(Øyvind Melien)* - Project status *(Jacques Demotes)*
15:00	**Set the scene I:** Harmonizing disease diagnosis in international clinical research *(Steven Silverberg)*
15:30	**Coffee break**
15:45	**Breakout sessions P1-2-3-4-5**
17:00	**Coffee break**
17:30	**Breakout sessions P1-2-3-4-5** (cont.)
18:40	**Set the scene II:** The importance of national policy to build capacity for clinical research in the public interest *(Kiyoshi Kurokawa)*
19:00	**End of day 1**

Day 2: March 8th	
8:30	**Feedback** from breakout sessions and **discussion on synergies between projects** *(project leaders and participants)*
10:00	**Coffee break**
10:30	**General session II/a: Support for collaboration on clinical trials** - "South Africa Medical Research Council initiatives" *(Jeffrey Mphahlele)* - "The Europe and Developing countries Clinical Trial Partnership – EDCTP" *(Magda Moutaftsi)* - "NIH/NCATS programme for international cooperation on rare diseases" *(Petra Kaufmann – video recorded)*

	- "Mission of AMED: Global Data Sharing" *(Takeya Adachi)*
11:50	**General session II/b: Challenges in conducting international trials** - "The WHO Research & Development BluePrint Plan" *(Pierre Gsell)* - "Data quality and reproducibility in clinical research" *(Malcolm McLeod – video)*
12:30 – 13:30	**Lunch** - "Challenges for investigator-initiated trials and international collaboration in Korea: KoNECT and KCSG" *(Seung Hwan Lee)* - "Lessons learned from global partnership in gynaecological cancer treatment trials" *(Keiichi Fujiwara)* - "Public-Private partnership in international clinical research" *(Yuji Sato)* - "Investigator-initiated clinical trials: return on investment" *(Frank Hulstaert – video)* - "Global ARO network" *(Masanori Fukushima)*
15:10	**Coffee break**
15:40	**General session III: the CRIGH roadmap** (round table) *Project leaders and Management Board chair - Moderator: Ted Trimble* - Policy on membership and partnership - Budget and fundraising - Action plan and priorities - Outreach and synergies with other initiatives
16:50	Wrap-up and next steps *(Jacques Demotes)*
17:00	**End of the meeting**