Minutes of the 8th Consortium Assembly Meeting

March 30, 2018
EXECUTIVE SUMMARY

The Consortium Assembly (CA) of the International Rare Diseases Research Consortium (IRDiRC) met on March 30, 2018, via web/teleconference. It was attended by 29 participants representing 21 member organizations, the Scientific Committees (SC) and the Scientific Secretariat (Sci Sec).

1. Updates from the CA Chair
   ▶ OC updates
     ○ The Roadmap 2018 was prepared and subsequently presented to and approved by the CA
     ○ Leadership of the Patient Engagement Task Force (TF) was taken over by the Patient Advocates Constituent Committee (PACC) and activity ceased due to other activities in the Roadmap 2018
     ○ Funding member data collection was discussed; the FCC is working on specific elements, prior to the request being launched to all funding members
     ○ New PACC membership criteria were drafted and prepared for discussion by the CA
   ▶ Membership updates
     ○ Ultragenyx, a company based in Basel, is a new IRDiRC member
     ○ Dominique Dunon-Bluteau replaces Catherine Dargemont, representing ANR
     ○ Manuel Posada replaces Pedro Cortegoso, representing ISCIII
   ▶ The IRDiRC CA/SC face-to-face meetings are taking place on May 14-16, 2018 in Vienna, Austria
     ○ May 14: Parallel SC meetings, joint SC meeting, and informal dinner SC/CA
     ○ May 15: Joint CA-SC meeting and opening CA meeting
     ○ May 16: Parallel Constituent Committee (CC) meetings and wrap-up CA meeting
   ▶ The IRDiRC Sci Sec has soft-launched the new IRDiRC website, and welcomes all members to comment. A specific request will be sent shortly.

2. Governance update
   ▶ Due to the influx of patient advocacy organization interested in becoming an IRDiRC member, decided to revisit patient advocacy membership criteria.
     ○ Specific points of discussion
     ○ Points will be redefined with CA discussion points, prior to representation and vote
   ▶ Several organisations have expressed an interest in IRDiRC that do not fully align to the IRDiRC membership criteria
     ○ Idea to set up a “Friends-of-IRDiRC” group was discussed, but ultimately rejected due to the limited benefit

3. IRDiRC Committees
   ▶ Companies Constituent Committee (CCC) is currently electing a Chair and Vice Chair and started discussion on Activity D
Funders Constituent Committee (FCC) is working on Activity A, drafting a questionnaire regarding funding coordination.

PACC has elected Yukiko Nishimura as Vice Chair, and started discussion on Activity B.

Interdisciplinary Scientific Committee (ISC) has several mandates ending, and asks all CA members to vote for new members.
1. Update from the CA Chair

1.1 Operating Committee (OC) activities and progress and December 2017 – March 2018

- **Roadmap for 2018**
  - Potential actions from Committee submissions in Japan CA meeting compiled, prioritized and analyzed
  - Shortlist of highest priorities discussed along with capacity and scope of the Sci Sec
  - Presented at dedicated January CA TC and voted on/approved by CA
  - Comments and updates to verbiage suggested by CA were provided for the Chairs to take into consideration when moving forward with actions and drafting proposals
  - Chairs presented updates on status of their respective activities later in the meeting
    - Committees started work on proposals and actions

- **Patient Engagement TF**
  - Leadership of the TF was taken over by the PACC (from the Therapies Scientific Committee (TSC)) and activity ceased due to newly developed activities within the Roadmap for 2018
  - Thank you letters sent to all members

- **Joint CA/SC Q1-2 2018 face-to-face meeting**
  - Organized alongside ECRD in May in Vienna
  - CA Chair presented details regarding the face-to-face meeting later in the meeting

- **Funding member data collection**
  - Potential data fields discussed
  - The Working Group for the implementation of Action A is tackling this issue; additional details presented later in the meeting

- **PACC membership criteria**
  - Given the evolution of IRDiRC with regards to its membership, scope, goals, and activities and an influx of applications, revisited the PACC membership criteria
  - Discussed and fine-tuned; additional discussion included later in the meeting

1.2 IRDiRC membership changes

- **New member:**
  - Ultragenyx
    - Tom Pulles, Head of Medical Affairs & Patient Advocacy

- **Two changes in representation within the FCC:**
  - Agence Nationale pour la Recherche (ANR)
    - Dominique Dunon-Bluteau replaces Catherine Dargemont
1.3 Vienna face-to-face meetings

- Vienna joint CA/SC meeting will be taking place in conjunction with ECRD 2018 (May 11-12)
  - Sci Sec sent detailed logistics information in Jan and Feb
  - CA members are responsible for booking their own accommodations
    - Recommend CA members arrive by Monday, May 14 evening (by 5 PM for joint dinner at 7 PM) and stay until Wednesday, May 16 evening (recommend flights after 8 PM).

- Vienna joint CA/SC meeting format
  - Monday, May 14
    - Morning: Parallel SC meetings
    - Afternoon: Joint SC meeting
    - Evening: Joint informal CA/SC dinner (7 PM)
  - Tuesday, May 15
    - Morning: Joint SC and CA meeting
    - Afternoon: Roundtable / Opening CA meeting
  - Wednesday, May 16
    - Morning: Parallel Constituent Committees (CC) meeting
    - Afternoon: Wrap-up CA meeting

- CA members are asked to send their key actions/events for the roundtable, using the roundtable template
  - Traditionally round table is one of the most informative parts of the CA meetings
  - CA members to report key actions/events within their organization, indicating to which of the IRDiRC Goals 2017-2027 it is related
  - Same roundtable format as successfully used in Tokyo meeting
  - Members are asked to submit template by April 30, 2018

➔ CA members should book accommodation for the CA meeting in Vienna
➔ CA members are asked to submit completed roundtable template by April 30, 2018

1.4 Communication update

- The Sci Sec has soft-launched a new IRDiRC website
- Re-organization of already existing content
  - Updated ages dedicated to members and activities
- Creation of new content
  - Pages dedicated to each Committee
  - New FAQ page
  - Updated methods for getting involved in IRDiRC
- Interest Scientific Contribution page
  - For the collection of research experts interested in taking part in IRDiRC activities (e.g., SCs, TFs, review of documents/reports)
- Become a Funding Member section
  - Not clear if you are a member of IRDiRC or if you are funding IRDiRC and appears to exclude companies
  - Suggested change: Learn more about becoming a member
- Contact Us page
  - Includes updated form with related categorization drop down to enable easier triage of requests.

[Post-meeting note: the implemented change is still a bit confusing and infers that umbrella patient groups are a different type of member. Suggested change: create a single “Become a Member” page with button links to “Become a Funders Member (including Companies)” and “Become an Umbrella Patient Group Member” (like the CC main page with buttons for each of the individual CCs).]

- **New features**
  - Search box
  - Possibility to connect to Twitter
  - Possibility to subscribe to newsletter
  - Vision on all pages
  - Disclaimer
    - Membership is not endorsement of all IRDiRC activities
    - Not consistent with Letter of Intent that members sign upon becoming IRDiRC member
- **Sci Sec** hopes that all members can “own” the content of the website, therefore all members are encouraged to provide comments and suggestions
  - Specific email request for CA comments will be sent shortly
  - Consultation period for CA members in mid-April
  - Feedback can be sent:
    - Via the Contact Us form
    - By email directly to IRDiRC’s Communication Manager
- Website will be officially launched after CA consultation period, but members are always welcome to send comments and suggestions

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2. Governance update

2.1 Potential update PACC Criteria

- IRDiRC has continuously evolved with regards to its membership, scope, goals, and activities
  - Given that and influx of applications, decided to revisit PACC membership criteria
  - Draft presented to OC in early March, refined with comments from OC and PACC
- Current actual verbiage re Patient Advocacy Group membership in IRDiRC Governance:
  - “To be considered as an IRDiRC Patient Advocacy Group member, the umbrella organization must be a patient organization representing broad patients’ interests for all rare diseases in at least one country or larger area. In general, IRDiRC expects patient groups that are members of an umbrella organization already a member of IRDiRC to be represented appropriately by that organization within IRDiRC. Once approved, each umbrella organization can nominate one representative to the Consortium Assembly, who will also serve on the Patient Advocates Constituent Committee.”
- This includes:
  - Umbrella or pan-rare disease focus (i.e., not single disease or organ specific)
  - Country or greater representation
  - Groups that are members of an umbrella organization already a member of IRDiRC are expected to be appropriately represented by that organization within IRDiRC
- Suggested additions to Governance verbiage have been presented to the CA for comments

Discuss criteria patient organizations further in the PACC and update with suggestions from CA members, prior to further OC and CA review, followed by a CA vote

2.2 Potential update “Friends-of-IRDiRC”

- IRDiRC has continuously evolved with regards to its membership, scope, goals, and activities
- Several organisations have expressed an interest in IRDiRC that do not fully align to the IRDiRC membership criteria
- “Friends-of-IRDiRC” would be targeting:
  - High-level rare disease coordination groups
  - Organizations representing a country or region that have primarily a rare disease policy, advocacy, and/or support mission
- Main purpose:
  - To provide a forum to share ideas and lessons learned
  - Receive feedback on and coordinate activities, when appropriate
- Discussion
  - Will take significant energy, without resulting in much action
  - Idea has been proposed previously, but not pursued as well
3. IRDiRC Committees

3.1 Update by CCC

- CCC is currently electing a Chair and Vice Chair
- CCC has started the discussion regarding Activity D
  - Currently setting up a call with Chairs FCC and TSC for further planning

3.2 Update by FCC

- The application for European Joint Programme (EJP) Co-Fund for Rare Diseases will be submitted on April 18
- Re Working Group (WG) for Activity A
  - Discussion regarding actual data collection:
    - Adding new categories of type of project
    - Adding field to determine what type of costs are being reported
  - Will solicit input from FCC WG on open call for tenders for Activity A (once submitted grant amendment is officially approved)
  - FCC WG preparing questionnaire for FCC on collaboration possibilities for future calls. Questions to be included:
    - What is the financial planning of research funders for the next 5 to 10 years - what is their funding agenda and funding strategy, and is it possible to connect and collaborate on these funding strategies (e.g., pro-active approach)?
    - What are potential steps for setting up a funding collaboration, such as in E-Rare?
    - Where can we find possibilities for joint funding calls?
- FCC did a survey on ELSI grants and research. This is summarized, but discussion is needed on next steps. Future activity will be assumed by individual members interested in this topic.

3.3 Update by PACC

- Yukiko Nishimura elected as Vice Chair of PACC
- PACC worked on patient advocacy organizations membership criteria, and will continue to do so
- PACC started work on Activity B
- Next call is set up in early May

Discuss criteria patient organizations further and update with suggestions from CA members, prior to further OC and CA review, followed by a CA vote

3.4 Update by ISC

- Ended mandates:
  - Bartha Knoppers
New nominations submitted to the CA vote:
- Dixie Baker
- Melissa Haendel
- Elizabeth McNeil
- Matthew Might
- David van Enckevort

ISC will have a call late-April to welcome all members and prepare for the Vienna SC meeting

ISC has started the IRDiRC-GA4GH MCC Task Force (TF)
- Members have been invited
- Workshop dates have been selected
- TF will have its first call early April
- Sci Sec is currently collecting and summarizing consent clauses used across the world

TF proposal on CRN RD needs to be re-drafted w/ FCC; subsequent discussion by OC and approval by CA (ISC to take the lead)

**Actions and deliverables**

- Book accommodation for the CA meeting in Vienna.
  - If members have not already made their travel arrangements, please try to arrive by Monday, May 14 evening (by 5 PM for joint dinner at 7 PM) and stay until Wednesday, May 16 evening (recommend flights after 8 PM).
- Submit completed roundtable template **by April 30, 2018**
- Comment on the new IRDiRC website (specific request for CA consultation period to be sent in mid-April)
- Discuss criteria patient organizations further and update with suggestions from CA members, prior to further OC and CA review, followed by a CA vote
- Update website with CA members suggestions
Annex - List of participants

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<tr>
<th>Members</th>
<th>Representative</th>
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<tbody>
<tr>
<td>National Center for Advancing Translational Sciences (NCATS), USA</td>
<td>Christopher Austin (Chair)</td>
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<tr>
<td>European Organisation for Treatment &amp; Research on Cancer, Belgium</td>
<td>Denis Lacombe</td>
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<tr>
<td>Canadian Organization for Rare Disorders (CORD), Canada</td>
<td>Durhane Wong-Rieger</td>
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<td>E-Rare Consortium, Europe</td>
<td>Daria Julkowska</td>
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<td>Rare Diseases Europe-EURORDIS, Europe</td>
<td>Virginie Bros-Facer</td>
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<td>French Muscular Dystrophy Association, AFM-Téléthon, France</td>
<td>Alexandre Mejat</td>
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<td>Children’s New Hospitals Management Group, Georgia</td>
<td>Oleg Kvlividize</td>
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<td>Shire Pharmaceuticals, Ireland</td>
<td>Madhu Natarajan</td>
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<td>Istituto Superiore de Sanita, Italy</td>
<td>Domenica Taruscio</td>
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<td>Telethon Foundation, Italy</td>
<td>Lucia Monaco</td>
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<tr>
<td>Japan Agency for Medical Research and Development (AMED), Japan</td>
<td>Makoto Suematsu, Nariaki Imanishi</td>
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<td>The Netherlands Organisation for Health Research and Development, the Netherlands</td>
<td>Sonja van Weely</td>
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<td>National Institute of Health Carlos III, Spain</td>
<td>Manual Posada</td>
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<td>Cydan II, USA</td>
<td>James McArthur</td>
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<td>Food and Drug Administration (FDA), USA</td>
<td>Katherine Needleman</td>
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<td>Genetic Alliance, USA</td>
<td>Sharon Terry, Katherine Lambertson</td>
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<tr>
<td>National Institute of Child Health and Human Development (NICHD), USA</td>
<td>Melissa Parisi</td>
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<td>Pfizer, USA</td>
<td>Katherine Beaverson</td>
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<td>Recursion Pharmaceuticals Inc, USA</td>
<td>Tim Considine</td>
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<td>Sanford Research, USA</td>
<td>Sarah Hague</td>
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<th>Scientific Committees</th>
<th>Petra Kaufmann</th>
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<tr>
<td>SUPPORT-IRDIRC Project</td>
<td>Marlene Jagut, Anneliene Jonker, Ana Rath</td>
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<td>NIH/NCATS</td>
<td>Christine Cutillo, Lilian Lau</td>
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### Apologies

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<td>Western Australian Department of Health, Australia</td>
<td>Hugh Dawkins</td>
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<td>Rare Voices Australia, Australia</td>
<td>Nicole Millis</td>
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<td>Canadian Institutes of Health Research (CIHR), Canada</td>
<td>Paul Lasko</td>
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<td>Genome Canada, Canada</td>
<td>Cindy Bell</td>
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<td>Chinese Rare Diseases Research Consortium, China</td>
<td>Qing Kenneth Wang</td>
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<td>Ning Li</td>
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<td>WuXi AppTec Co. Ltd., China</td>
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<td>Chinese Organization for Rare Disorders, China</td>
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<td>European Commission, DG Research and Innovation, EU</td>
<td>Iiro Eerola, Irene Norstedt</td>
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<td>Academy of Finland, Finland</td>
<td>Heikki Vilen</td>
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<td>French Foundation for Rare Diseases, France</td>
<td>Roseline Favresse</td>
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<td>Lysogene, France</td>
<td>Karen Aiach</td>
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<td>Federal Ministry of Education and Research, Germany</td>
<td>Ralph Schuster</td>
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<td>Indian Organization for Rare Diseases, India/USA</td>
<td>Ramaiah Muthyala</td>
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<td>Chiesi Farmaceutici S.p.A, Italy</td>
<td>Andrea Chiesi</td>
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<td>Advocacy Service for Rare and Intractable Diseases’ multi-stakeholders in Japan (ASrid), Japan</td>
<td>Yukiko Nishimura</td>
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<td>National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN), Japan</td>
<td>Yoshihiro Yoneda</td>
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<td>Saudi Human Genome Project, Kingdom of Saudi Arabia</td>
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<td>Korea National Institute of Health, South Korea</td>
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<td>Roche, Switzerland</td>
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<td>National Human Genome Research Institute (NHGRI), USA</td>
<td>Teri Manolio</td>
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<td>National Institute of Arthritis and Musculoskeletal and Skin Diseases, (NIAMS), USA</td>
<td>Stephen Katz</td>
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<td>Peter Saltonstall</td>
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