I-PWG F2F Meeting Summary

Monthly Meeting

Tuesday 14th February 2023

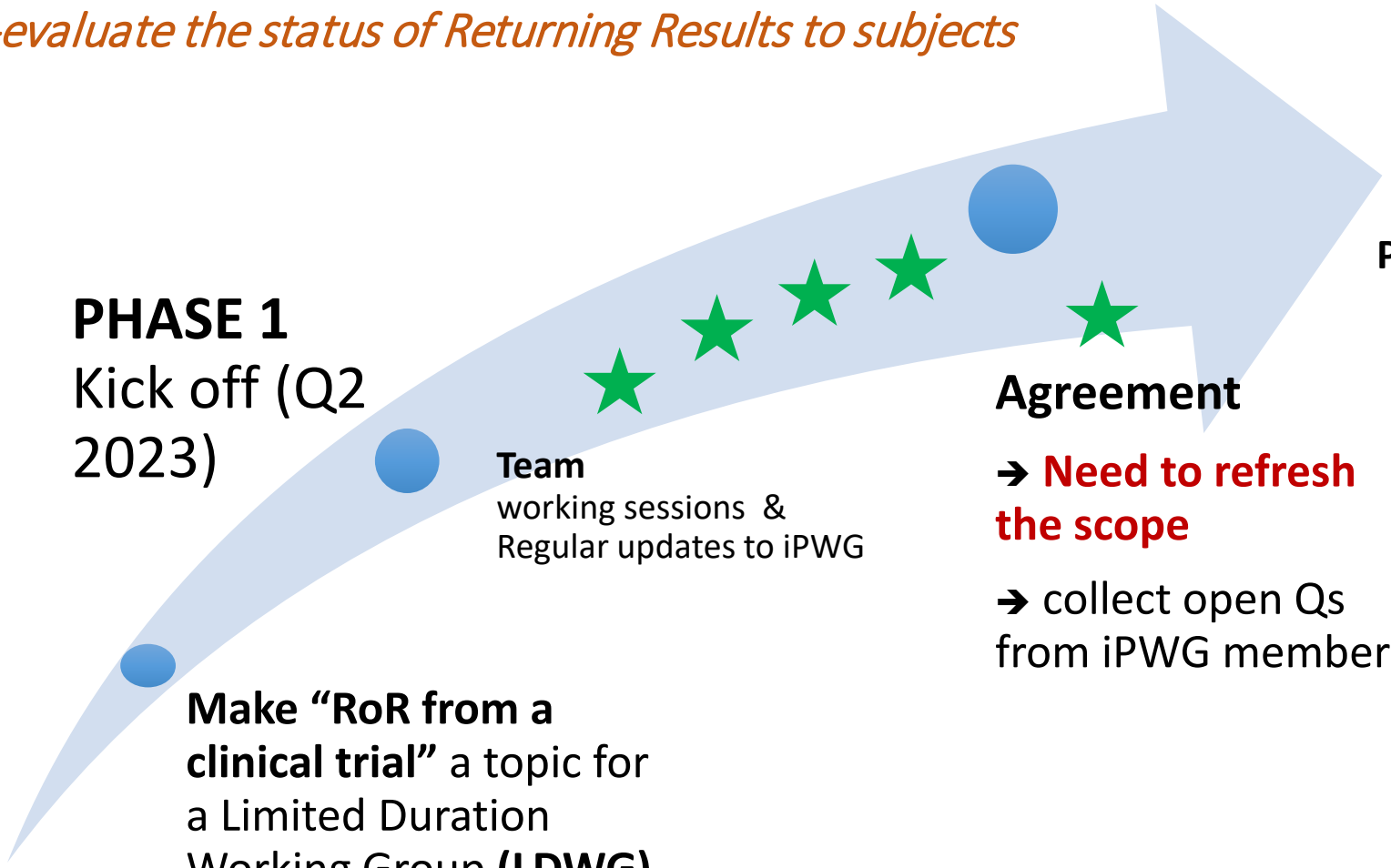
2023 Strategic Objectives

- Development of a ROR Position Paper
- Development of a Country Regulations Database
- Completion of the RTF China White Paper
- Completion of the ADME TF White paper
- Assess the need/Develop a HGRAC Engagement Plan

Session 1 - ROR Workshop

What Did We Do?

Re-evaluate the status of Returning Results to subjects



PHASE 1
Kick off (Q2 2023)

Make "RoR from a clinical trial" a topic for a Limited Duration Working Group **(LDWG) in 2023**

Team
working sessions &
Regular updates to iPWG

Agreement

➔ **Need to refresh the scope**

➔ collect open Qs from iPWG members

Phase 2

I - PWG

Workshop

Session 2: Brainstorm the questions collected from i-PWG members

Informed consent?
Genetic consultancy
Protocol
Physician recommendations

Immediately
At end of study
Retrospectively

It's my right
it saves my life
For my treatment
Ethical, responsible

All what was tested ?
Clinically actionable?
General health
Oncology
PGx
Raw / interpreted

Via PI & clinical site
Informatic pipeline
CLIA Lab

Scope
refresher

Why returning results ➔ what to return ➔ which related info ➔ how to return ➔ when to return

Phase 2 Workshop

The Sensitivity about the what to return, and the position the I-PWG is still a challenge: we decided to give a next round of thinking around the scope.

2) F2F Workshop: Work together, focusing on the reclarified scope

- The topic is of huge interest ! Very intensive brainstorming & lots of ideas came out

3) Next step:

- compile the results of the brainstorming
- Have a small group to develop the ideas
- Call for co-Lead - Since the optic might be enormous to articulate and develop
- Draft an i-PWG position paper
- Initiate/continue engagement with key stakeholders during the development of the I-PWG ROR position paper.

Country Regulations Database (CRD)

- Helen Stevens (AZ) and Gowri Murthy (Merck) have agreed to co-lead this activity
- Plan to initiate a Limited Duration Working Group (LDWG) to scope out and initiate activity before end of 1Q23
- Need membership volunteers (from relevant functional groups) to become active members of the LDWG
- LDWG will develop a CRD that will be “fit for purpose” for use across the membership

Session 2 – I-PWG Plans for 2023

Monthly Meetings feedback:

- Overall positive feedback from the group that the style of the meetings (and speakers) is excellent and suits the current needs of the membership

Monthly Meetings suggestions:

- Co-Chairs to request that each member company propose 2 speaker suggestions
- Request that all members attend the meeting with their cameras switched on
- Switch to MS Teams platform
- Request that member companies invite a broader mix of colleagues to the Monthly Meetings
- “Drop-in” topics to be suggested and followed-up for discussion within smaller member groups
- Monthly Meeting summaries need to be re-initiated and circulated to the membership

Session 2 – I-PWG Plans for 2023

I-PWG Surveys:

- Overall positive feedback that the style/format of the surveys is good and that this is an extremely useful tool for the membership
- Surveys are working well but need to be managed effectively with respect to roll-out – let's try and avoid "Survey fatigue"!
- Membership needs to be reminded that each member company can generate "pre-competitive" questionnaires at any time
- Suggestion to survey academic centres who are actively participating in PGx research to assess their feedback on the key current topics of interest within the field of PGx

I-PWG Marketing:

- Need to develop I-PWG promo slides for use with various external partners/new companies/internal member colleagues
- Need to engage with Japanese-based Pharmas (i.e. Takeda., Mitsubishi) to assess their interest in joining the I-PWG. Proposed that this should be done via the network of existing members companies

Session 2 – I-PWG Plans for 2023

I-PWG external engagement plans:

The following organisations/groups were suggested to be approached by the I-PWG to either present at our Monthly Meetings or for us to assess (informally) future collaborative discussions:

- FDA
- EMA
- HGRAC
- UK Biobank
- Genomics England
- PI academic networks
- Patient Advocacy Groups (i.e., Genetic Alliance etc.)

Session 2 – I-PWG Plans for 2023

I-PWG external engagement plans:

- Global Alliance for Genomics and Health (GA4GH)
- PGRN
- Genomics Roundtable
- IQ Consortium
- Healthcare payors
- Roundtable of National Academic Science, Engineering & Medicine

Session 2 – I-PWG Plans for 2023

Guidance Document Responses:

- There was a general recognition that the I-PWG have been very successful in previously generating response documents to a range of groups/authorities (i.e. Israel MOH, NIH, EMA etc…)
- Recognised that the membership needs to proactively to identify which guidance documents need responding to and on an ongoing basis
- Need membership advocates to lead small groups (LDWG's) to formulate the responses on behalf of the I-PWG
- This is an important area where the I-PWG can play a pivotal role to support our membership

Session 2 – I-PWG Plans for 2023

Other general recommendations:

- I-PWG to take a leadership position regarding patient diversity in clinical trials
- Develop a “ROR Terminology Guide”
- Investigate the opportunity for understanding utility of PRS in clinical trials
- Opportunity of having I-PWG members become members of other consortia (e.g. CPIC)
- Further promotion of I-PWG activities needs to occur within member companies in order to expand the breadth of membership within existing companies

Greetings from Boston!