FINAL

QUALITY ASSURANCE WORKING GROUP
WEDNESDAY, MAY 30, 2018, 8:30AM – 9:00AM
MONROE ROOM, PALMER HOUSE HILTON HOTEL, CHICAGO
CHAIR: J. BRYCE CO-CHAIR: A. BRAND
LIAISONS: VOTAN/BERGER (OPS)

MINUTES

Welcome & Introductions: **Brand**

COI declarations: None declared

Present: Alison Brand ANZGOG, Smitha Udagani PMHC, Leora McCullough ISGO, Regina Berger AGO-AU, Benedicte Votan GINECO, Adriana Chavez Blanco GICOM, Yusuke Kajimoto GOTIC, Tatsuo Kagomura JGOG, Juan Pablo Melina Observer CR, Carien Creuitzberg DGOG, Vanda Salutari MITO, Elena Biagioli MANGO, R Fossati MANGO, Bette Stonebraker GOG-F, Ruth Perets ISGO, Anuja Jhingran G-GOC, Radoseaw Riadry Observer PGOG, Eva Gomez GICOM, Wanda Lawson Patient Advocate ANZGOG, Maren Keller NOGGO, Stefan Kommass AGO De, Pernille Strom NSGO, Nicole Gower NCRI, Vanda Salutari MITO, Ana Levin GEICO, Israel Diaz Observer Cuba

APPROVAL of MINUTES/REPORT: Novebmer 2017 (posted on GCIG website)
Motion: ____A. Chavez Blanco_____ Seconded: ___A. Hiltz_____

Follow up from brainstorming session in Vienna.

3 issues were discussed:

- Regulatory session for recommendationsVendor Assessment
  - Draft assessment has been circulated
  - Comments should be emailed to Karen Carty (k.carty@clinmed.gla.ac.uk)
  - Group Assessment should move forward with the expectation that it can be modified to be group/trials specific as needed.
  - The generic assessment for trials needs more development. Volunteers: Adriana, Laura, Karen will continue to work on this.
- Minimum requirements for central monitoring:
  - Document was circulated.
  - Can it be accepted? It is generic and a starting point. It tells groups what we would expect from them in terms of their monitoring plan but that is ultimately up to each group.
  - Yes, it will be accepted and sent to board of directors
- Regulatory session recommendations:
  - Anastasia, Mary McCormick and Adriana presented at brainstorming.
  - Main issue thus far that has been identified is insurance and indemnity.

- Especially an issue in Latin America. It is very expensive to buy insurance and if there is no funding available from the trial, this can be impossible.
- A document for Latin America outlining this issue was drafted and circulated. There are some ideas for how to handle this and also for how to potentially obtain funds for this. A similar document was going to be written for European sites (Anastasia). We request that the same thing be written for India, Singapore, etc. Some feedback and examples of how this was handled for previous studies. The point is to be informative for other groups to read when new studies are started.
- Difficult for all issues to be in one document.
- We perhaps should be contacting each Harmonization rep who has actually accrued in those countries and ask how they have overcome the issue of insurance and indemnity.
- Some studies have accrued in Latin America without requiring insurance.
- It is part of Mexico's interpretation of GCP that insurance is always provided.
- Adriana to send a list of particular details regarding insurance and indemnity that we would like to know for each group.

- Can the QA working group become a sub committee of the harmonization group? Is the regulatory part going to CCRN? Jane spoke to Bette about it. All agree that this will be a sub-committee of harmonization. The Harmonization group will nominate members.