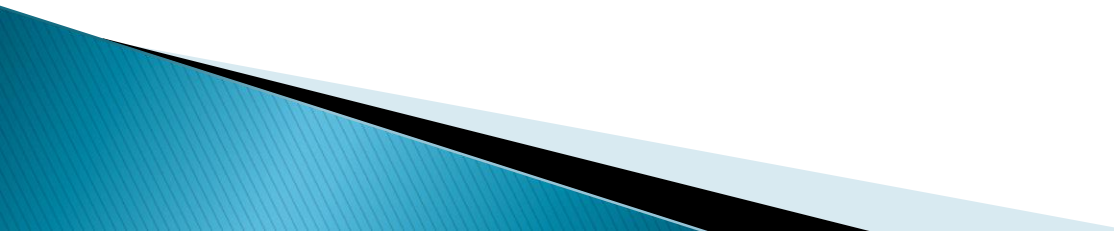


Harmonization Committee Operations

October 26, 2016

Harmonization Committee

- ▶ Opened Meeting with a tribute to Eriko Aotani
 - ▶ Presentation by Ros Glasspool from the Mega Data Working Group
 - ▶ Harmonization will actively participate in the Working Group, with focus on the Data Sharing Agreement
- 

Harmonization Committee

- ▶ **Budgeting in Intergroup trials** – presentation of current version of template
- ▶ Discussion ensued regarding noted differences between countries, regions, and groups in budgeting procedures and whether there could be an alternative tool to aid in the process

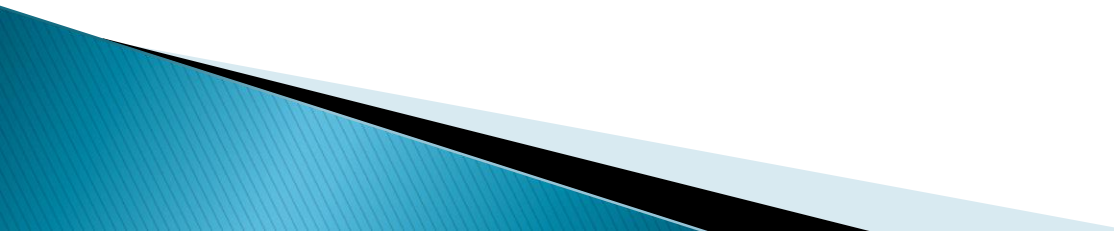
Action Item

To produce a **Checklist** for circulation to the Committee with ultimate goal to include in the Harmonization Guidebook.



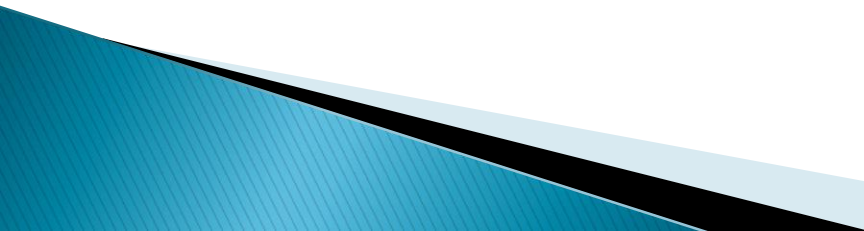
Harmonization Committee

- ▶ **Communication in Intergroup Trials**
 - ▶ A communication plan is paramount in the success of Intergroup protocol collaboration and participation
 - ▶ Current draft is being circulated among the members
 - ▶ Final draft expected to be completed by December

 - ▶ **Harmonization Guidebook**
 - ▶ Completed, posted on the Website
- 


Harmonization Committee

- ▶ **GCIIG Clinical Trial Agreement Template**
 - ▶ Version 3-22Jul2016 is posted and available for Groups' use

 - ▶ **Mentoring and Welcome Package**
 - ▶ Updated Mentoring Assignments-ongoing process
 - ▶ Welcome package posted to the Website
 - ▶ Checklist to be created to aid the mentoring process
 - ▶ Plans to hold a Mentoring session just prior to June Harmonization meeting
- 

Harmonization Committee

- ▶ **Essential Documents**
 - ▶ Essential Documents Checklist presented
 - ▶ Checklist ready for posting pending updates by a couple of Groups

 - ▶ **Lead Group Matrix Activity**
 - ▶ Matrix indicating GCIG accrual is being updated following a 2 year lapse
 - ▶ New columns to be added to include disease site and protocol accrual by group
- 

Harmonization Committee

- ▶ **ENGOT Liaison Report**
 - ▶ Updates presented
 - ▶
 - ▶ **Other New Business**
 - ▶ Rules and Responsibilities document for Harmonization Rep and Liaisons to be created
- 

Harmonization Committee OPS and Stats

- ▶ To be held following this meeting