

Harmonization Committee Operations

June 2, 2016

Harmonization Committee

- ▶ **Seven slide presentations:**
- ▶ **Budgeting in Intergroup trials** – detailed presentation on overview and costing, including detailed template
- ▶ **Presentation on AGO–AU Model** for budgeting

Action Item

To produce template draft 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

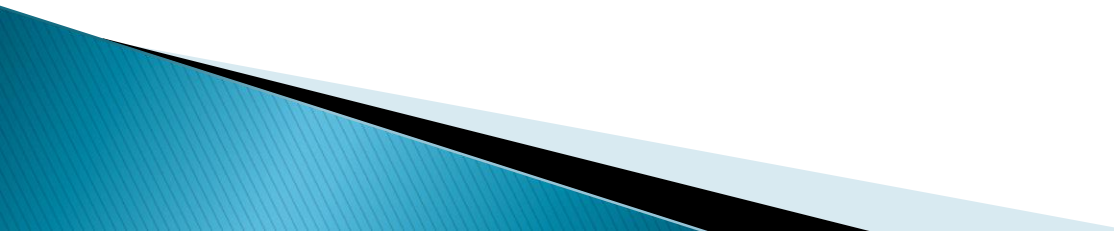
A clear communication plan should be elaborated by the lead group – It should define:

- ▶ The communication between the lead group and the participating groups (TC, emails, Newsletters..)
- ▶ Escalation and resolution of issues
- ▶ The safety flow and queries flow

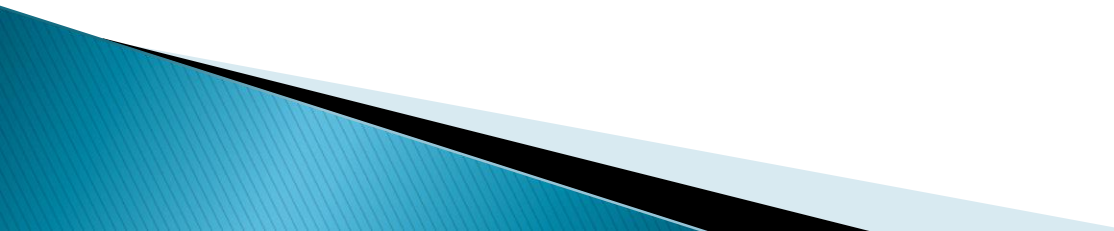
- ▶ Plan to circulate final draft by September and adopt in Lisbon

Harmonization Committee

- ▶ **GCIG Clinical Trial Agreement Template**
 - ▶ Updates and wording clarification presented

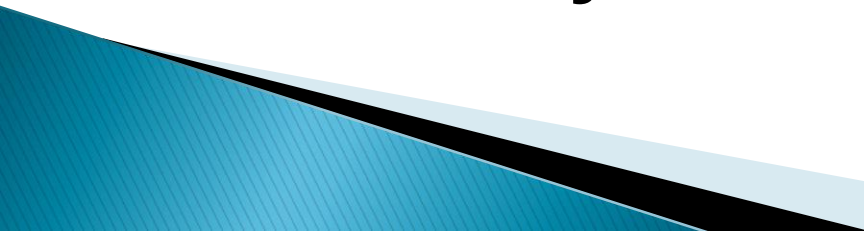
 - ▶ **Mentoring and Welcome Package**
 - ▶ Updated Mentoring Assignments
 - ▶ Need to have Updated Welcome package posted to the Website
- 

Harmonization Committee

- ▶ **Essential Documents**
 - ▶ Updates to the Essential Documents Checklist presented
 - ▶ Discussion took place regarding the international differences of what constitutes “Essential”
 - ▶ Working group will continue to define these parameters
- 

Harmonization Committee

- ▶ **ENGOT Liaison Report**
 - ▶ Updates presented
 - ▶ Network Monitoring in Intergroup Trials to be further discussed in Lisbon in collaboration with the QA WG

 - ▶ **Updates on status of Insurance/indemnity and Group Contacts and Summaries**
 - ▶ **Lead Group Participation Matrix** – Karen Adema for Julie
- 

Harmonization Committee

OPS and Stats

- ▶ To be held this afternoon at 3:30 in this very room