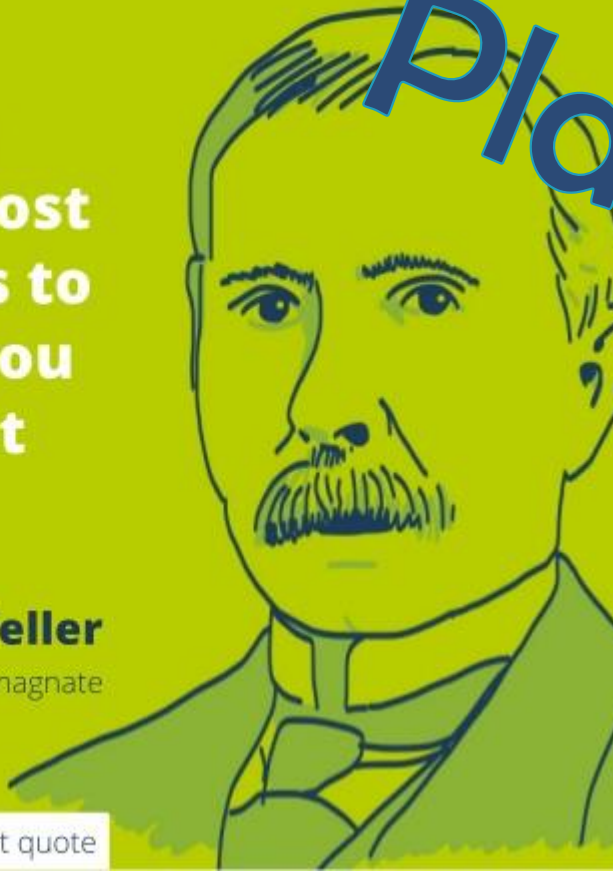


Communication Plan

Next to doing the
right thing, the most
important thing is to
let people know you
are doing the right
thing.

John D. Rockefeller
Business magnate



COMMUNICATION

PURPOSE

- ▶ Strong, effective and frequent communication between all involved partners is KEY for the success of the study
- ▶ No communication = no success

COMMUNICATION

A clear communication plan should be elaborated by the leading 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

GCIG Harmonization Group Objective

❖ To draft a GCIG communication plan template

- The purpose of this document is to define primary contacts, roles and responsibilities communication pathways including status reporting and issue escalation for the **GCIG Study**
 - Document should be kept simple
 - To avoid redundancies with other GCIG tools (intergroup agreement, group specific appendix



Fist draft proposal (1/3)

1. Paragraph with a list of the participants involved in the global conduct of the trial :

- ✓ Sponsor of the trial
- ✓ Lead Group *if different from the sponsor*
- ✓ GCIG Participating Groups
- ✓ Drug Supply Company
- ✓ CRO involved in the conduct of the trial *if any*
- ✓ Local CRO *if involved in the global conduct of the trial*
- ✓ Drug Supply management *if applicable*



Fist draft proposal (2/3)

2. Communication at the global level with a table specifying meeting/TC organisation

- ✓ Trial Steering Committee (definition of TSC needed)
- ✓ Trial Management Team *in case of pharmaceutical sponsored trial*
- ✓ GCIg Participating Groups
- ✓ Global CRO *if any*
- ✓ Others *if relevant*



Fist draft proposal (3/3)

3. Communication at the Site level

- ✓ Investigator Communication and Questions
- ✓ Serious Adverse Events (relevant ?)

4. Other Communication tools

- ✓ Frequently Asked Questions (Q&A)
- ✓ Status Reports/Newsletters

5. Issue Escalation and Resolution

6. Appendix : List of all primary contacts

- ✓ In the different organisations involved



Next Steps

- ▶ **To validate the draft by the working group ie**
 - Laura Farelly, Anastassia Negrouk, other volunteer ?
- ▶ **Final draft in circulation in September 2016**
- ▶ **To be adopted at our next Harmonization meeting (Lisbon, October 2016).**

