# GCIG Harmonization Meeting, Chicago – June 2016

# GCIG Clinical Trial Agreement Template

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# GCIG Clinical Trial Agreement Template

- GCIG Clinical Trial Agreement Template was developed by Harmonization Committee members to facilitate and foster collaboration between the collaborative groups.

- The first template was drafted in April 2005. Revisions were made to template in 2013 based on feedback from groups.

- Over the course of last few meetings feedback/comments have been received from groups based on their experience of using revised template.

- As a result of the feedback/comments received, we've made some further changes to agreement.

# GCIG Clinical Trial Agreement Template – Summary of changes (1)

In summary the following main changes have been made:

- **Page 2 Order of Parties switched in line with title page. Page 2 Parties to the agreement. Text added to note to highlight if legal entity acting on behalf of group is not the sponsor details needed to be recorded explaining this and detailing who the sponsor is.**

- **Section 2 Conduct of the Study , Clause 2.1 Additional text added to note to highlight this clause may need amended appropriately where lead group is not sponsor to clarify the sponsor has delegated certain sponsor responsibilities to lead group and to participating group.**

- **Section 3 Duties, Clause 3.1.12 Suggested amended text which is to release lead group/sponsor from insuring all parties involved in trial and reflect it is responsibility of each participating group to be insured appropriately for all aspects of running trial and lead group/sponsor must ensure each participating group holds appropriate insurance cover for their participation**

# GCIG Clinical Trial Agreement Template – Summary of changes (2)

In summary the following main changes have been made:

- **Clauses 3.2.6, 9.1, and 9.2 : the changes made to these clauses were previously presented by Nathalie and Bénédicte last year. All were in agreement with changes.**

- **Section 9 Project Intellectual Property as Study Data, Clause 9.3 amended text for this clause has been provided to make clause more general and remove reference to fees.**

- **Section 11 Biological Material, Clause 11.5 Note added to instruct in case of future additional research/analysis on biological material collected for a study it would be required for consent to have been given to cover samples being used for additional research purposes and for approval to be given by relevant authorities and to note this clause may need amended to cover this**

# GCIG Clinical Trial Agreement Template – Summary of changes (3)

- In summary the following main changes have been made:

- **Section 11 Biological Material, Clause 11.7 Clause slightly reworded to make clearer and note added to instruct in case of transfer of samples between groups, additional contractual arrangements would be required, In these instances it is recommended the GCIG template material transfer agreement is used.**

- **Appendix 1, Roles and Responsibilities Checklist – Minor updates/additions made throughout**

  [Check with groups R&R Section 5, Point 11 Tracking proof of submission of SL's/ISLs to ECs we've assumed this related to Safety Letters/Investigator Safety Letters)

- **Minor changes/clarifications and corrections of inconsistencies made throughout the agreement template.**

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- As in previous revision we have been cautious in the changes made to the template.

- Template is starting point for agreements which can be modified/adapted by groups to suit each trials requirements and to take into account the regulations of countries involved.

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- Keen to receive feedback from groups today on the changes which have been made.

- Thank you to  Anastassia, Bénédicte, Kathy and Nathalie for their help and input .

- Thank you for your time.