MEDIZINISCHE UNIVERSITÄT
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Essential documents checklist

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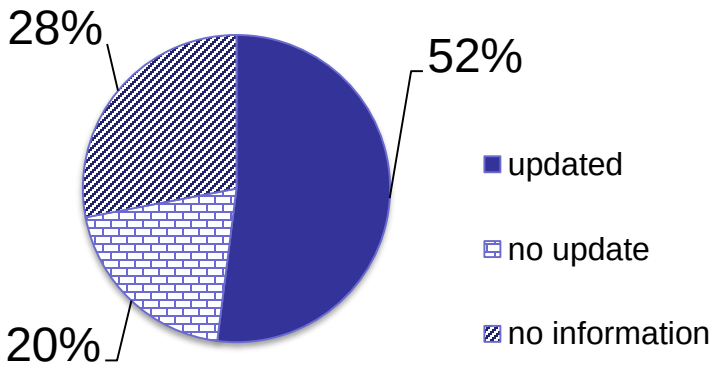
History - Updates

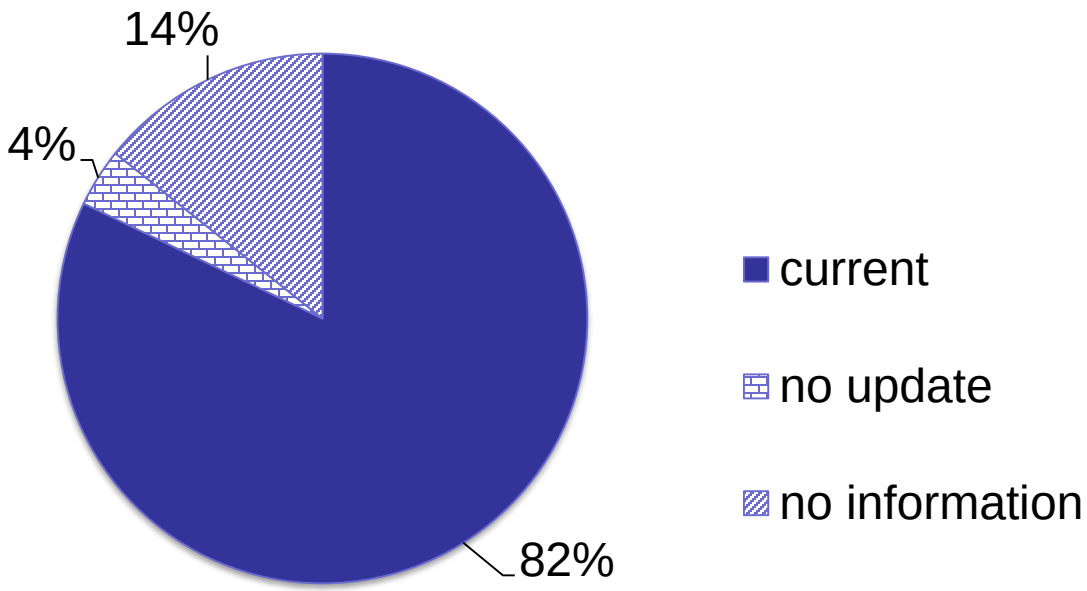
Harmonization Guide Book Appendix 4

To assess which documents are considered essential documents within each group and which are necessary to start a trial within this group.

- Revised May 2009 - Incl. Information from 12 groups
- Update October 2014 – 13 groups
- Update April 2016



Group responses



- Current information received from 23 groups:
- Information missing from 5 groups:
  - No initial information: ACRIN, DGOG, RTOG, SGOG
  - No update: GOG

Update April 2016 - results

- We now have information on 24 of 28 groups.
- Some documents mandatory for GCIG studies are not required within the group/country
  - CA approval
  - Insurance
  - Protocol signature page
- The following documents are required within all of the groups
  - EC/IRB approval
  - Contract with Hospital/Site
  - Principal investigator‘s CV

Update April 2016 - results

- Some documents are mandatory with the exeption of few groups/countries
  - CA approval – not required in 3 groups
  - Delegation of duties and sample signature sheet – 1 group

- Several documents are needed in few groups
  - SC/CRA´s CV (3)
  - IRB SUBMISSION DOCUMENTS (COPY) (3)
  - MOH APPLICATION/APPROVAL (2)
  - IRB ROSTER AND MOH ACCREDITATION (3)
  - SITE´S MOH LICENSE (2)

Appendix 4 Guidebook

What next?