German Association of Applied Human Pharmacology (AGAH e.V.) - Points for clarification concerning the EU Single Portal

- Convince all MSs to accept English as the common language used for the Single Portal (except for documents intended for trial subjects‘ use).
- Foresee that each party concerned (e.g. CA, Ethics Committee, Sponsor) defines the person(s) responsible for portal access for the specific clinical trial by themselves.
- How will the system reliably identify authorised users?
- Foresee that authorised users can be changed any time by the parties concerned.
- Keep user profiles as flexible as possible, differentiating between „read only“ and „read and write“ access rights for the specific parts of the application dossier.
- Define how corrections of wrong entries into the portal will be handled including an appropriate audit trail.
- Foresee automatic consistency checks within the application dossier and establish a process to discuss and agree the checking criteria.
- Foresee warning flags regarding national holidays to facilitate timely validation and assessment of the application dossier in the respective MS (all timelines are based on calender days, irrespective of Sundays or holidays)
- Foresee that the portal acknowledges receipt of the application dossier, provided all requested entries have been completed.
- Foresee that the portal allows to enter the information required for the full application dossier in separate parts and keeps all entries in case of e.g. computer crash or break-down of internet access.
- In case of computer crash and problems to re-establish within 24 hours, define which date will be seen as valid for the submission: the date of the first entries or the date of the last entries into the dossier?
- The EU Regulation 536/2014 foresees that the application dossier can be amended by the Sponsor in case of requests for additional information by the CA and /or Ethics Committee(s) within the 12 days Sponsor response time following the 26 days of CTA assessment.It is essential that this also refers to changes in e.g. protocol and subject information performed during the Sponsor response time; a restart of the entire application process in case protocol / subject information require adaptations is absolutely impractical. This is particularly relevant with respect to European competitiveness.
- Define which sponsor-owned information will be considered confidential in early drug development (e.g. until proof of concept) and how this can be ensured in the application dossier. This is crucial to keep Europe attractive as a place to perform early phase clinical trials.
- Foresee a simplification of the required entries into the portal for monocentric and/or single country trials.

- There is a need to define contents and electronic formats of the assessment reports Parts I and II (set up templates within the portal, identical for all MSs).
- Which information has to be entered into the portal for a long-term clinical trial that was approved according to the EU Directive 2001/20 and continues across the transition period into the period when the EU Regulation 536/2014 is valid only? It is essential to avoid a full application dossier has to be set up.