

Clinical Trials Symposium – Bucharest, Romania

Dr. Barbara Schug

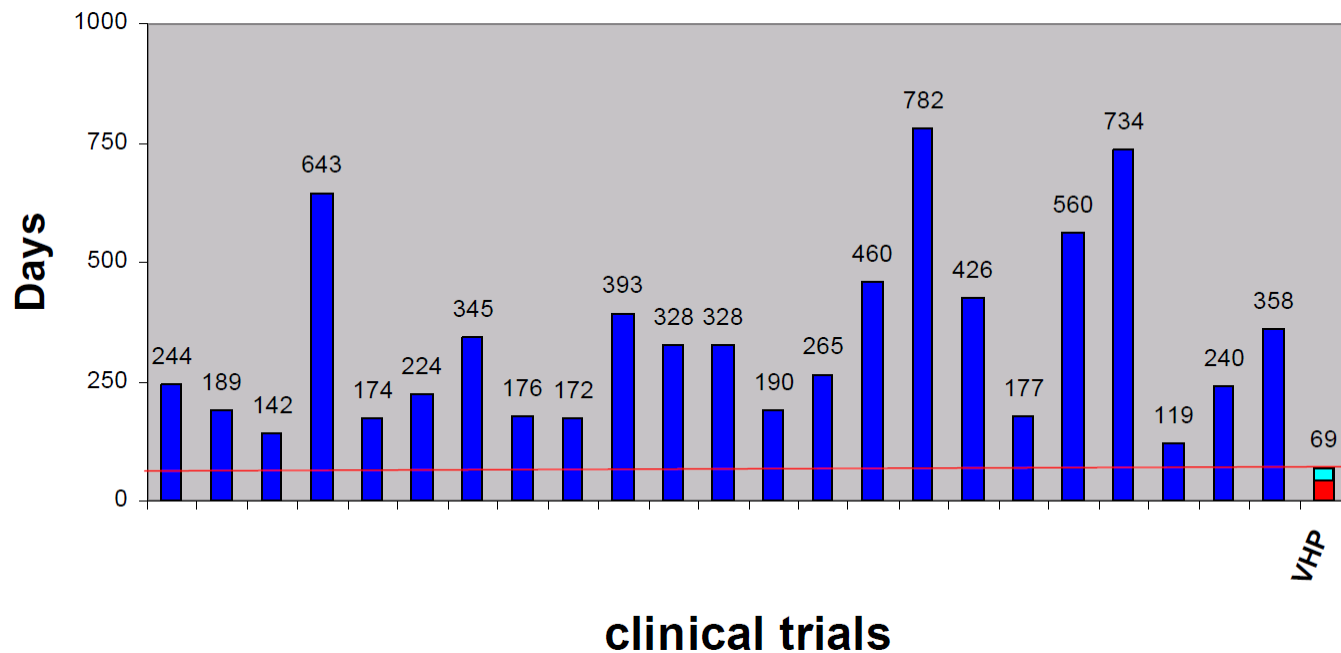


Objectives

- Harmonisation
 - Directly applicable, no implementation in national law
- Simplification
 - One electronic submission, one decision
- Transparency
 - Public access via EU database



Benefit of Harmonisation



Timeline



Minimum duration	10 days	45 days	5 days	60 days
Maximum duration	25 days	76 days	5 days	106 days

Advanced therapy & Biologicals

Advanced therapy:

- Gene therapy
- Somatic cell therapy
- Tissue engineered product

+ 50 days



20
years of
excellence
1998-2018

standards excellent
SocraTec

Application Dossier – Part I

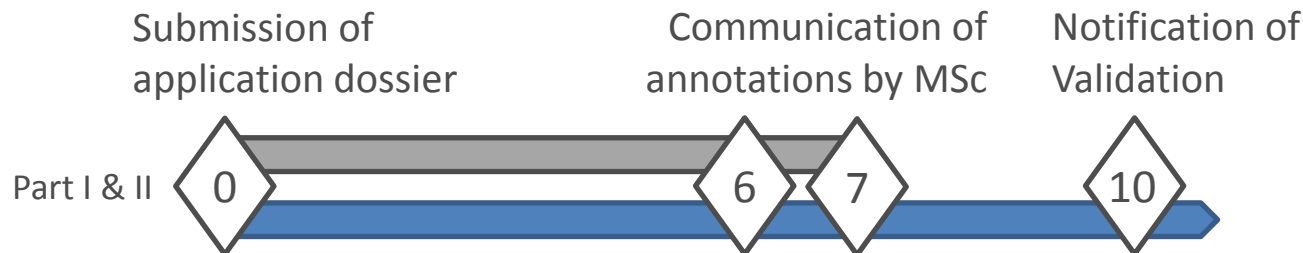
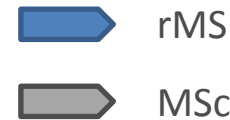
- Common scientific information
 - Clinical trial protocol
 - Investigator's brochure
 - IMPD, AMPD (= auxiliary medicinal product dossier)
 - Scientific advice, paediatric investigation plan
 - Labelling content
- Assessment by reporting Member State

Application dossier – Part II

- Country-specific information
 - Recruitment arrangements
 - Subject information, informed consent form/ procedure incl legal representative for subjects not able to provide IC
 - Suitability of investigator & facilities
 - Insurance / Liability in case of damages
 - Financial and other agreements
 - Proof of payment of fee & compliance with data protection
- Assessment by each member state concerned



Application Process – Validation



- Sponsor proposes rMS
- Other MSs may propose themselves as rMS until day 3
- Agreement among MSs
- No agreement: Sponsor's proposed rMS = rMS

Decision upon reporting MS

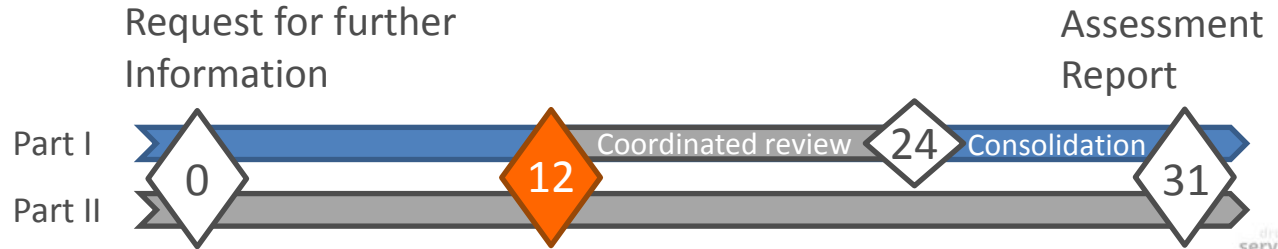
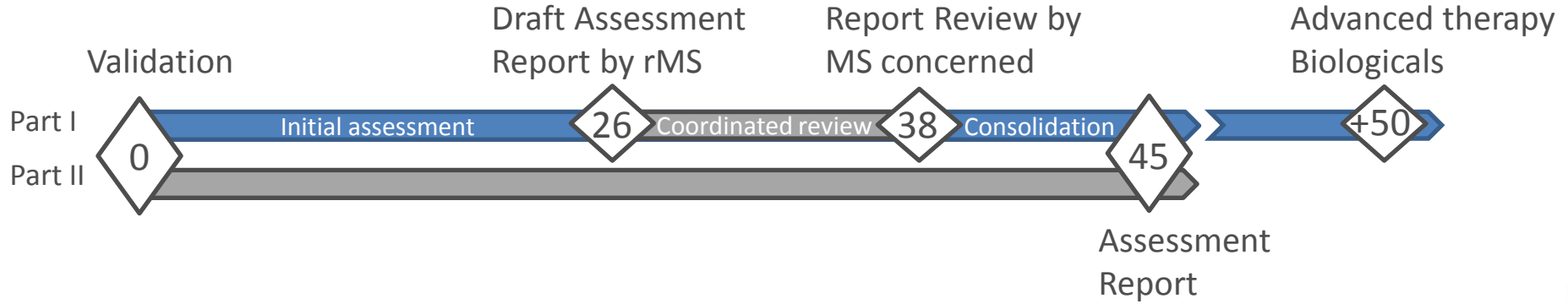
Request for further Information

Notification of Validation



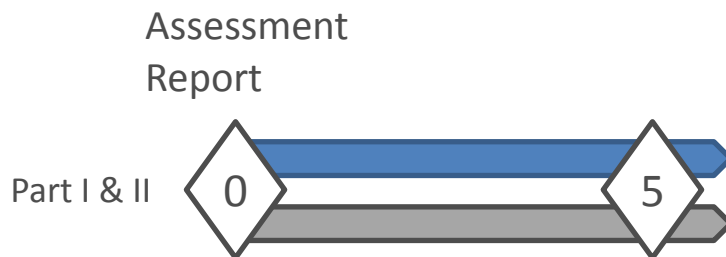
Sponsor's Answer

Application Process – Assessment



Sponsor's Answer

Application Process – Decision



National notification whether

- The trial is authorised
- The trial is authorised subject to conditions
- Authorisation is refused

Clinical Trials Information System

EU Portal

- Communication system
- Upload of all study related documents
 - Sponsor: Application dossier, study status, result summary (also for laypersons), report
 - Member States: Assessment reports, inspection reports, notifications

EU Database

- Storage of documents
- Public access to all data except for
 - Protection of personal data
 - Protection of commercially confidential information
 - Communication between MS

Low-intervention clinical trials

- For authorised products only:
 - Used in accordance with terms of the marketing authorisation
 - Or use is evidence- based and supported by published scientific evidence on the safety and efficacy
 - Minimal additional risk by diagnostic/ monitoring procedures
- Advantages:
 - Less obligations regarding monitoring, master file, traceability of IMPs
 - Damage compensation system not mandatory

Co-sponsorship

[...], where a clinical trial has more than one sponsor, *all sponsors shall have the responsibilities of a sponsor* set out in this Regulation, unless the sponsors decide otherwise in a written contract setting out their responsibilities. Where the contract does not specify to which sponsor a given responsibility is attributed, that responsibility shall lie with all sponsors.

Relevant for networks of scientists / academic institutions

National „challenge“: EC

- Cooperation between NCA and EC:
 - So far, NCAs and ECs act completely independent in most MS
 - New processes to be established in all MS (not only RMS)
- Responsibility for Part I documents:
 - Primarily with the RMS
 - For MS concerned review sets focus on Part II documents
 - But ICH-GCP does not release EC from its responsibility of reviewing the trial protocol either

Serious breaches

- Likely to affect to significant degree
 - Safety and rights of subjects
 - Reliability and robustness of data generated
- Consequence:
 - To be reported by the sponsor through EU portal within 7 days
- Challenge:
 - Difficult decision in case of grey-zone events



Promising development

- Bringing European countries closer together
 - To foster clinical research in Europe
 - And to facilitate multi-state clinical trials
- Open questions:
 - Ethic's committees' role not harmonised
- And of course:
 - What's with Brexit? Hopefully not a huge drawback for clinical trials in UK and all other countries of EU ...



Many thanks to ...

- Frauke John (SocraTec R&D) for her support preparing the presentation
- André Warnke and Maria Anschütz (SocraTec R&D) ...
... and Ingrid Klingmann (Pharmaplex)
... for fruitful discussions

