Bundesamt für Sicherheit im Gesundheitswesen

BASG / AGES
Institute Surveillance, Department Clinical Trials
Traisengasse 5, A-1200 Vienna, Austria

PILOTPROJECT CLINICAL TRIALS 536/2014 – Executive Summary

Objective and purpose

The objective of the pilot is to develop and test practical scenarios to reach the "single decision" of National Competent Authority (BASG) and Ethics Committees (IEC) that is required by Regulation (EU) 536/2014. The practical needs and limitations will be communicated to the Federal Ministry of Health and Women (BMGF) which is responsible for the National process.

Benefits

Currently applicable legislation will not be overruled by the pilot and the procedure will result in a valid legal decision. An application will not be delayed or have to be resubmitted due to the pilot!
The goal primarily for BASG and IEC is to adhere to the timelines of the regulation 536/2014. It is equally recommended for the applicant. If a timeline cannot be adhered to, the fallback positions are current legal timelines.
The BASG will serve as the single contact point during the procedure for responding to validation requests and considerations.

Opportunities

Applicants will gain the opportunity to prepare for responding to validation requests and considerations within the competitive timelines of the regulation. They will further benefit from the flexible and individual handling of problems during the pilot. Extension of timelines for the applicant will not violate the pilot. During the pilot there will be a contact point for questions and problems.

Limitations

The first step of the pilot is limited to the IEC Medical University Graz and therefore trials with this leading IEC. The initial submission needs to be timed with the meeting dates of this IEC. Parallel, but separate submission to BASG and IEC is currently necessary. It is planned to remove these limitations in later steps of the pilot.

Process steps

- Applicant sends a letter of intention to clinicaltrials@ages.at at least one week before the planned submission.
- After participation was confirmed the applicant submits in parallel to BASG and lead IEC.
- BASG and lead IEC perform a coordinated validation.
- BASG sends a validation request to the applicant.
- After the request has been resolved a confirmation of valid submission is issued by the BASG which starts the legal timeline (35 days) and the pilot timeline (26 days)
- Within 26 days the applicant receives a combined list of considerations from BASG and lead IEC (if applicable) which results in a clock-stop.
- The applicant responds to questions within 12 days (an extension possible on request).
- BASG and lead IEC review questions within 12 days.
- BASG issues a written decision within 5 days. To comply with current legislation the lead IEC also issues an IEC opinion.

Milestones

- Phase 0 (single trial) ..... **August 2016 (for IEC meeting 12.09.16)**
- Phase I (several trials) ..... **until December 2016 (3 IEC meetings)**
- Phase II (involvement of further IECs) **2017**

Contact

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