Good Clinical Practice:
patient-centered, investigator-friendly

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EHA initiative: Increasing patient safety and reducing bureaucracy in clinical trials

Following a bottom-up initiative, EHA is working with key stakeholders to find solutions to the challenges posed by bureaucratic obstacles in clinical trials, mainly:

1. Excessive safety reporting
2. Comprehensibility of Informed Consent Forms
3. Regulatory ambiguity

Reducing Bureaucracy in Clinical Research: A Call for Action

Safety reporting

- **Leave safety reporting with the (medical) experts**
- **Simplify and (partially) standardize safety reporting forms**
  - prevent sponsors from making their own reports
  - devise the process as a ‘friendly request’; no unnecessary steps or signatures (Australasian experience as inspiration)
- **Clear definition of SAE with grading** is necessary. Without serious and effective modifications, it will be impossible to **reduce the amount of work** due to overinterpretation of SAEs.

Informed consent forms (ICFs)

- ICFs should be **short and understandable,** as stated in ICH E6

  However, **the list of items in 4.8.1 is excessively long**.

- **A two-step document with 1 or 2-page summary** plus explanations, including biologic assessment, could be helpful.

- **Patient organizations** must be involved.

Sponsors and CROs

- ICH E6 recommends to **“avoid unnecessary complexity, procedures, and data collection”** (addendum 5.0 Quality Management). What is lacking: clear guidance for implementation
- Good idea: a **risk-based process** with SOPs that are shared with the investigator
- Transfer of all duties to the CRO by the sponsor is a risk (section 5.2) Safety-related responsibilities should not be transferred and should be agreed **between the sponsor and the investigator.**

How to implement these recommendations?

Over-interpretation of Good Clinical Practice guidelines, mainly by CROs, perverts the initial aim of optimizing patient safety.

Therefore, **more clarity** about how, who, where, when to implement these recommendations would be helpful.

Could abbreviated guidelines, alongside the revised full version, be a solution?