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THE COALITION FOR
REDUCING BUREAUCRACY
IN CLINICAL TRIALS

REDUCING BUREAUCRACY IN CLINICAL TRIALS

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Comment

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Reduce bureaucracy in clinical trials now

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 Check for updates

Clinical trials in Europe must become far more efficient to support the needs of investigators and their patients. The way trials are designed, conducted and regulated should be attuned first and foremost to the needs of patients, to ensure timely and equitable access to safe, effective and innovative treatments.

Since 2020, European medical societies and research organizations that represent investigators and patient advocates across a broad range

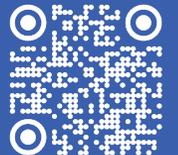
aligned and harmonized rules and guidelines. (Both documents as well as an overview of Coalition members can be found at <https://bureaucracyincts.eu>.) Now, the Coalition has updated and expanded its recommendations, after consulting regulators, policymakers, sponsors and members of ethics committees.

The recommendations were developed jointly by investigators and patient advocates in thematic drafting groups. They incorporate key lessons from the implementation of the EU Clinical Trials Regulation (CTR)¹, which has been in effect since January 2022. They are concrete and pragmatic, rooted in real-life experiences and draw insights of those directly involved in the conduct of clinical trials. The document is available [online](#).

We are convinced that the Coalition's proposals for deregulation

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Read the full set of
recommendations
here:



Reducing Bureaucracy in Clinical Trials – why?

The problems

- Administrative burdens overwhelm investigators at the expense of focus on patients
- Workforce shortages – bureaucratic burdens important factor
- Conducting clinical trials in Europe is complex, inefficient, and costly

The causes

- Lack of a harmonized, efficient regulatory framework
- Implementation of CTR incl. CTIS comes with technical challenges and operational constraints
- Regulatory framework disconnected from the realities of clinical research

At stake

- **Quality** of clinical trials
- **Safety** of patients
- **Access** to innovative treatments

Reducing Bureaucracy in Clinical Trials – how?

The goal

- Pragmatic short- and medium-term solutions to improve the clinical trials regulatory framework and reduce unnecessary administrative burden

The approach

- Coalition Recommendations based on the needs of investigators and patients
- Alignment with key stakeholders incl. regulators, sponsors, Ethics Committees

The Coalition Recommendations for 3 problem categories

- **EU regulatory framework** – Fragmented across Member States with a lack of proportionate, clear guidelines – leading to inconsistent implementation and regulatory over-interpretation
- **Safety reporting** – Overly complex, lacking proportionality, creating unnecessary burden without improving patient safety
- **Informed consent forms** – Lengthy, overly technical, not designed with patients' understanding or engagement in mind

Regulatory recommendations

- **Streamline and align clinical trial assessments**

Promoting the alignment of Competent Authority and Ethics Committee reviews in Member States requiring dual assessment, expanding the Reporting Member State (RMS)-led model to include common elements of Part II, and supporting effective RMS leadership through targeted training and adherence to its decisions.

- **Align informed consent form (ICF) requirements**

Implement a two-part structure for ICFs: one standardized across the EU for efficient assessment by Ethics Committees, the other containing country-specific requirements. A reporting Member State-led process should assess the standardized part.

- **Extend the definition of non-interventional clinical studies**

Expand the definition of non-interventional trials to include studies with minor therapeutic or invasive procedures that pose no significant safety risks or involve randomization. Oversight should be limited to national Ethics Committees, with an EU-wide platform – similar to CTIS – established to streamline communication with sponsors during application and oversight.

- **Harmonise contract writing and negotiation**

Implementing a mandatory EU contract template with predefined, limited modifications.

Safety Reporting recommendations

- **A unified EU online platform**

A single EU platform for adverse event reporting between investigator and sponsor/CRO with standardized templates and MedDRA nomenclature.

- **Exempt disease-related SAEs from immediate reporting**

Sponsors should outline in the protocol all anticipated events that are efficacy endpoints, consequences of the underlying disease, or commonly occurring in the study population, ensuring they are exempt from expedited reporting.

- **Optimizing SUSAR reporting to investigators**

Sponsors/CROs should provide investigators with periodic safety profiles, including Suspected Unexpected Serious Adverse Reaction (SUSAR) line listings and DSURs, particularly during Phase III and IV trials, rather than sending individual SUSAR reports.

- **Optimizing AEs reporting to investigators**

Sponsors/CROs should provide biannual line listings of severity-graded adverse events or biannual/annual DSURs that compile all key safety information, instead of sending individual reports, to keep investigators informed about adverse events not classified as SUSARs.

Informed Consent Form recommendations

- **Use appendices for non-essential information**

Keep the main ICF focused on essential content – such as study purpose, previous use of the investigational treatment, screening and study procedures, alternative care options, key side effects, potential benefits, study duration, and contact details. Less critical details, such as rare side effects, data protection, and sample storage, should be moved to appendices.

- **Simplify information on side effects**

Include only the most common side effects in the main body, using clear, patient-friendly language. Avoid technical terms (e.g., “Neutrophils: $<1.5 \times 10^3/\mu\text{L}$ ”) and replace them with understandable alternatives (e.g., “increased risk of infections”).

- **Incorporate visual aids**

Use infographics to illustrate study design and treatment arms, helping patients grasp (at a glance) the study’s structure and options.



CROSS-DISCIPLINARY APPEAL FOR LESS BUREAUCRACY, IMPROVED PATIENT SAFETY, AND BETTER TRIALS

THE COALITION FOR REDUCING BUREAUCRACY IN CLINICAL TRIALS

In September 2020 a broad cross-disciplinary coalition of medical societies and patient advocates issued the joint statement 'Reducing bureaucracy in clinical trials: now is the time!'. The [statement](#) calls for urgent action to make clinical trials less bureaucratic and more patient-centred, efficient and cheaper. At stake are the quality of clinical trials, access to innovative treatments and, crucially, patient safety. The Coalition calls on regulators, policymakers, sponsors, ethics committees and other stakeholders to collaborate

Thank you for your support!
<https://bureaucracyincts.eu>



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