Reducing Bureaucracy in Clinical Trials

HCPWP-PCWP Joint Meeting

March 2022

‘Reducing Bureaucracy in Clinical Trials’

- **cross-disciplinary coalition of medical societies and patient advocates**
- Coalition statement, 27 signatories
- BioMed Alliance + European medical societies + ECPC
- broad patient involvement via societies’ patient WGs
- Campaign web site: **https://bureaucracyincts.eu/**

- **Coalition Recommendations (Nov. 2021)** as basis for:
  - Advocacy (EU regulatory/data frameworks, global guidelines)
  - Ongoing dialogue with policymakers and stakeholders
  - Inviting additional endorsements from patients and investigators

The Coalition

27 signatories

Expert groups:

WG1 – Safety Reporting

WG2 – Informed Consent

WG3 – Regulatory Guidelines

Support WGs: Patient Engagement, Policy

Coordination: EHA, BioMed Alliance TF on Clinical Trials

GOAL	• short/medium-term pragmatic solutions to reduce bureaucratic burden
AT STAKE	• **quality** of studies + **patient safety**
REQUIRES	• a simplified, more adaptable and less bureaucratic regulatory environment

KEY ISSUES:

Safety reporting

- Needed: simplification, proportionality (CROs)

Informed consent and re-consent

- Needed: clear & concise procedures; ethics committees 'relevance check'; co-design by patients

Regulatory guidelines

- Needed: clear and proportional regulatory guidelines that prevent over-interpretation and contribute to better, patient-centered trial designs