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
**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

**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