FAST-EU:
Faciliating and Accelerating Strategic Clinical Trails in EU/EEA

Clinical Trials Coordination Group

MSP 20 March 2026

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Vision of the Member States

- **Increase the attractiveness of Europe for clinical trials**
  → access for patients to innovative treatments
  → developing and strengthening Europe as a hub for excellent reasearch
- **Maintain cooperative assessment by NCAs and Ethics Committees**
  → culture of scientific discussion and consensus
  → participation and inclusion of NCAs and Ethics
- **Create processes that allow scientific and ethical quality**
  → feasible timelines for NCAs and Ethics Committees
  → invest time/resources where they are most effectively used

Fundamental Concept

- 7-day-timelines
- Part I „global“ and Part I „national“/Part II dossier
- 70-day-timeline model with parallel validation and assessment in Part I

7-day-timelines

- Timelines will be based on **full weeks (7 days)** wherever possible
- Timelines will be based on the **submission date**
- Timelines will be **fixed** i.e. not dependent on previous steps.
- **Harmonisation of Part II with Part I** will be maintained.

Regulation (EEC, Euratom) No 1182/71 still applies, but 7-day-timelines…

- **avoid prolongation due to weekends.**
- **are resilient to holidays.**
- **are reliable and predictable to allocate ressources and to plan assessments.**
- **are intuitive and easy-to-handle from the start.**

The new Part I and Part II dossiers

Part I (scientific):

- **Cover letter** (English)
- **EU application form** (English)
- **Clinical trial protocol**
- **Protocol synopsis** (English)
- **Investigator's Brochure**
- **IMPD – Quality section**
- **IMPD – Non-clinical and clinical sections**
- **AxMP dossier** (quality / non-clinical / clinical)
- **GMP certificate or MIA** for IMP/AxMP manufacturer
- **Scientific advice summary** or **PIP decision**
- **IMP / AxMP labelling** statement (English)

Part I (national)/Part II:

- *Proof of payment (if applicable)*
- **Translation of cover letter**
- **Translation of protocol synopsis**
- **Translation of IMP / AxMP label text**
- **Translation of application-form information**
- **Translation of patient-facing documents**
- Collection, storage and future use of **biological samples**
- **Subject information sheet** and ICF
- **Recruitment materials**
- **Investigator CVs** and qualification evidence
- **Site suitability statement** or facility description
- **Insurance** / indemnity certificate
- Financial arrangements and site agreements
- Data-protection compliance statement

Challenges of the Pilot

- Recommendation to hold EC meeting in Week 4 (RMS) or Week 5 (MSC) after submission.
- Preparation for the EC meeting should start as early as possible, ideally after the submission of the CTA.
- The preparation should consider that national Part I documents and Part II documents will only be complete in Week 3.
- Running the pilot in current CTIS → explicit challenge for Ethics Committees BTA modified CTIS validation and assessment of Part II will be fully under the control of the Ethics Committees → earlier completion of Part II validation possible

Participating MSs

AT - Austria	x	DE - Germany	x	PL - Poland	x
BE - Belgium	x	EL - Greece	x	PT - Portugal	x
BG - Bulgaria	x	HU - Hungary	x	RO - Romania	x
HR - Croatia	x	IE - Ireland	x	SK - Slovak Republic	x
CY - Cyprus	x	IT - Italy	x	SI - Slovenia	x
CZ - Czechia	x	LV - Latvia	x	ES - Spain	x
DK - Denmark	x	LT - Lithuania		SE - Sweden	x
EE - Estonia	x	LU - Luxembourg		NO - Norway	x
FI - Finland	x	MT - Malta		IS – Island	
FR - France	x	NL - Netherlands	x	LI - Liechtenstein	

Experience from first EoI Rounds

- 26 EoI received in 2 rounds (3 re-submissions)
- 7 applications accepted → more than promised
- Striving for balanced workload (all MSs should be RMS at least once → publication of RMSs on website)
- Slight modification of approach after first round driven by practicalities and sponsor request:
  - 1 short EoI window per month → full picture
  - Sposor can select 1st or 2nd 2 weeks in the month following the EoI → modified submission ready requirement
  - RMS will communicate a CTIS submission date
  - Communication of acceptance still within 5 working days
  - Re-submission possible but no selection-guarantee

FAST-EU: Take Home

- HMA initiative to pilot the **accelerated assessment procedure proposed in the EU Biotech Act**
  - 70-day procedure (including RFI and Response Assessment)
  - Adapted approach for Part I (global vs. national)
  - Timelines based on submission date and full weeks
- Involves **most Member States**
- Public information available on the CTCG-Website

Heads of Medicines Agencies: Clinical Trials Coordination Group (CTCG)

- Updates on RMSs are published continuously

CTCG
Clinical Trials Coordination Group

Thank you for your attention

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