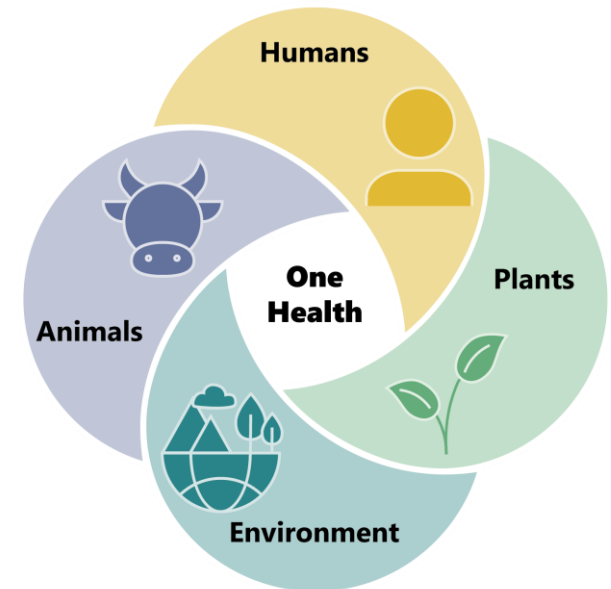


Facilitating and Accelerating Strategic Clinical Trials in the E FAST-EU update

Stefan Strasser (AGES)



What is FAST-EU?

Facilitating and Accelerating Strategic Clinical Trials



- HMA initiative to pilot the **accelerated assessment procedure proposed in the EU Biotech Act**
 - 70-day procedure (including RFI and Response Assessment)
 - Parallel workflows for Validation, Part I assessment and Part II assessment
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 - Timelines based on submission date and full weeks
- Focused on a limited number of multinational trials as a **training and information gathering exercise** → scale-up and formalisation in JA HS-25-27 in 2027
- Public information on **CTCG-Website** since January 2026
- **Go-live on 30.01.2026**

Member States Overview

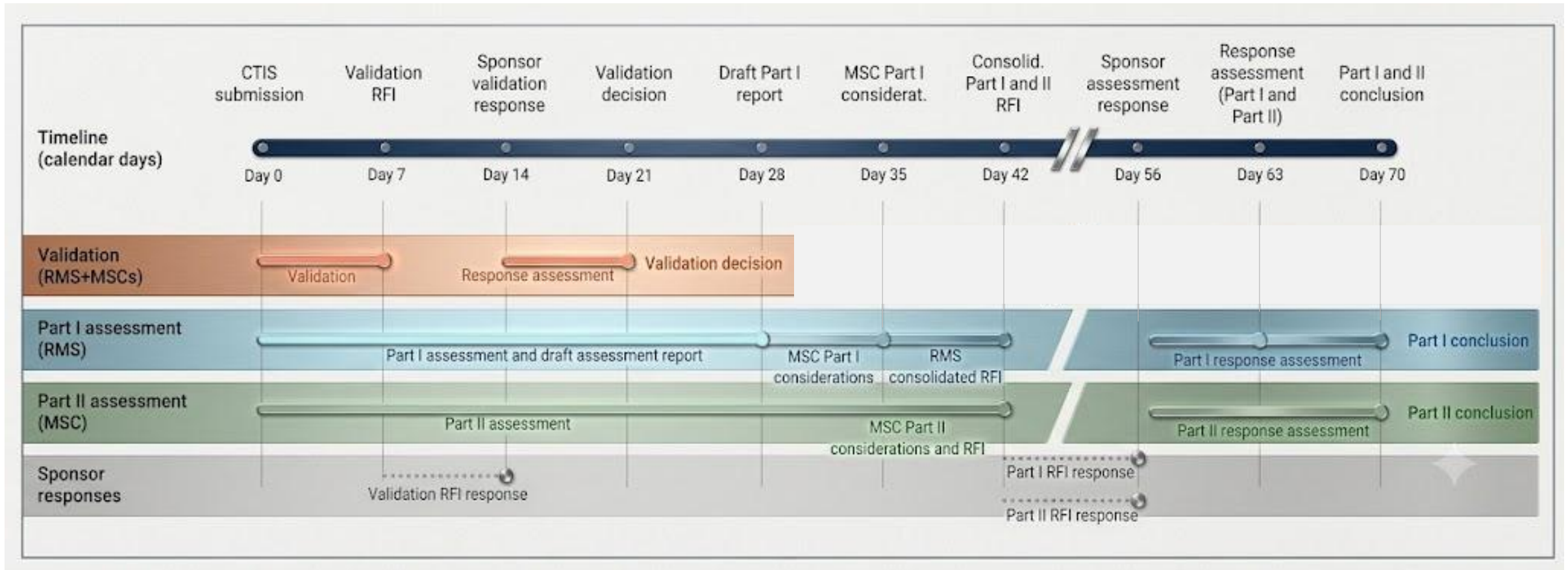
Who is participating?



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	<u>x</u>
DK - Denmark	x	LT - Lithuania	x	SE - Sweden	x
EE - Estonia	x	LU - Luxembourg		NO - Norway	x
FI - Finland	x	MT - Malta		IS – Island	
FR - France	<u>x</u>	NL - Netherlands	x	LI - Liechtenstein	

How does FAST-EU work?

A manually coordinated process within CTR and CTIS



How to submit to FAST-EU?



<https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html>

- Dossier must be **completed and ready** for submission
- **Expression of Interest (Letter of Intent)** via e-mail to FAST-EU@hma.eu
- Guidance and Lol template on the **CTCG website**
- Response within 5 working days:
Slot confirmation + final RMS + submission date
- Submission in CTIS within the allocated slot (at the earliest 2 working days after confirmation) → **please declare as FAST-EU in the cover letter!**
- If no slot can be allocated → info to sponsor and **switch to the standard CTR procedure** - no disadvantage for the study

Has it worked so far?

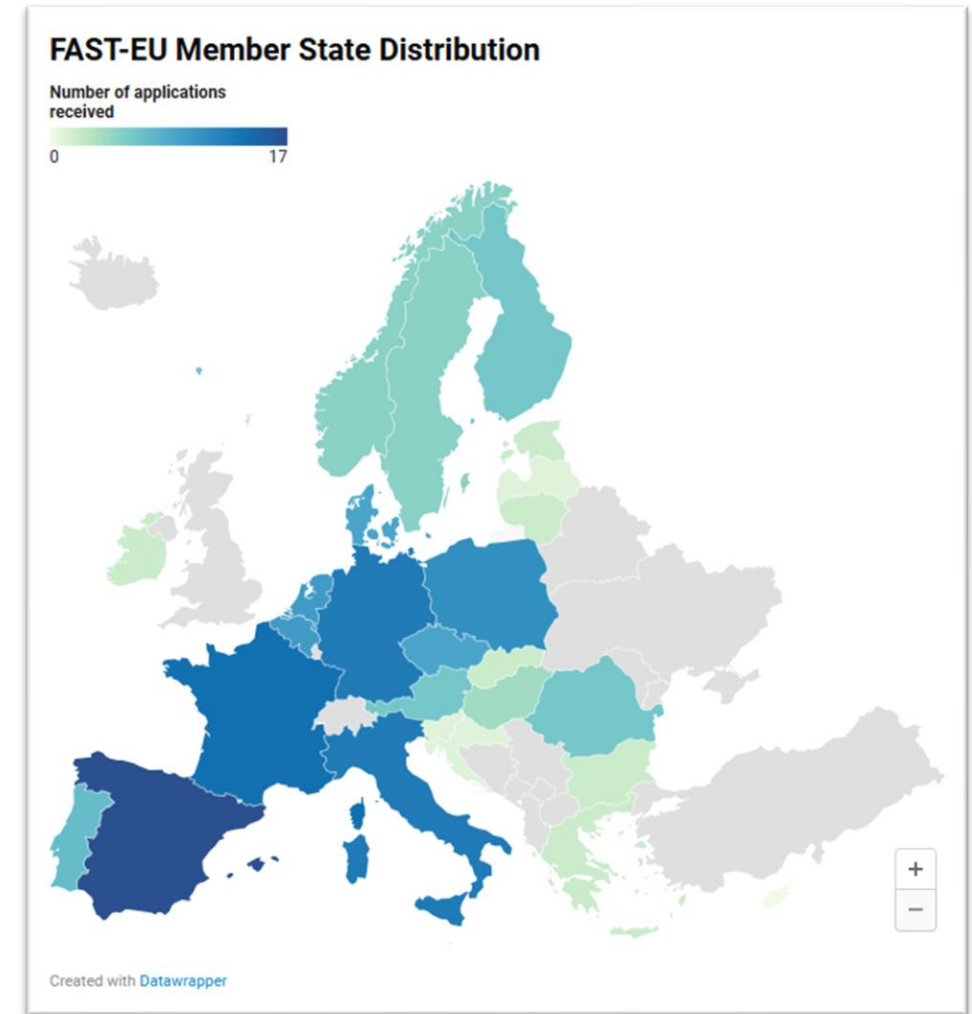
Results of the first procedures

Metrics:

- 83 expressions of interest ([January] – May)
→ 15-20 per month
- 19 procedures selected → 4 per month
- 17 RMS countries and 18 sponsors!**
- Average of 8.4 MSCs per trial (2-22)

Milestones:

- Completed: 7
- Under assessment: 3
- Under validation: 6
- Awaiting submission: 3





Fotos: Christina Fink, Asvola, Monkey Business Images, malshkoff/Shutterstock.com

Austrian Medicines and Medical Devices Agency

Classified as internal/staff & contractors by the European Medicines Agency