Union Controls

DG SANTE F5 Health Protection

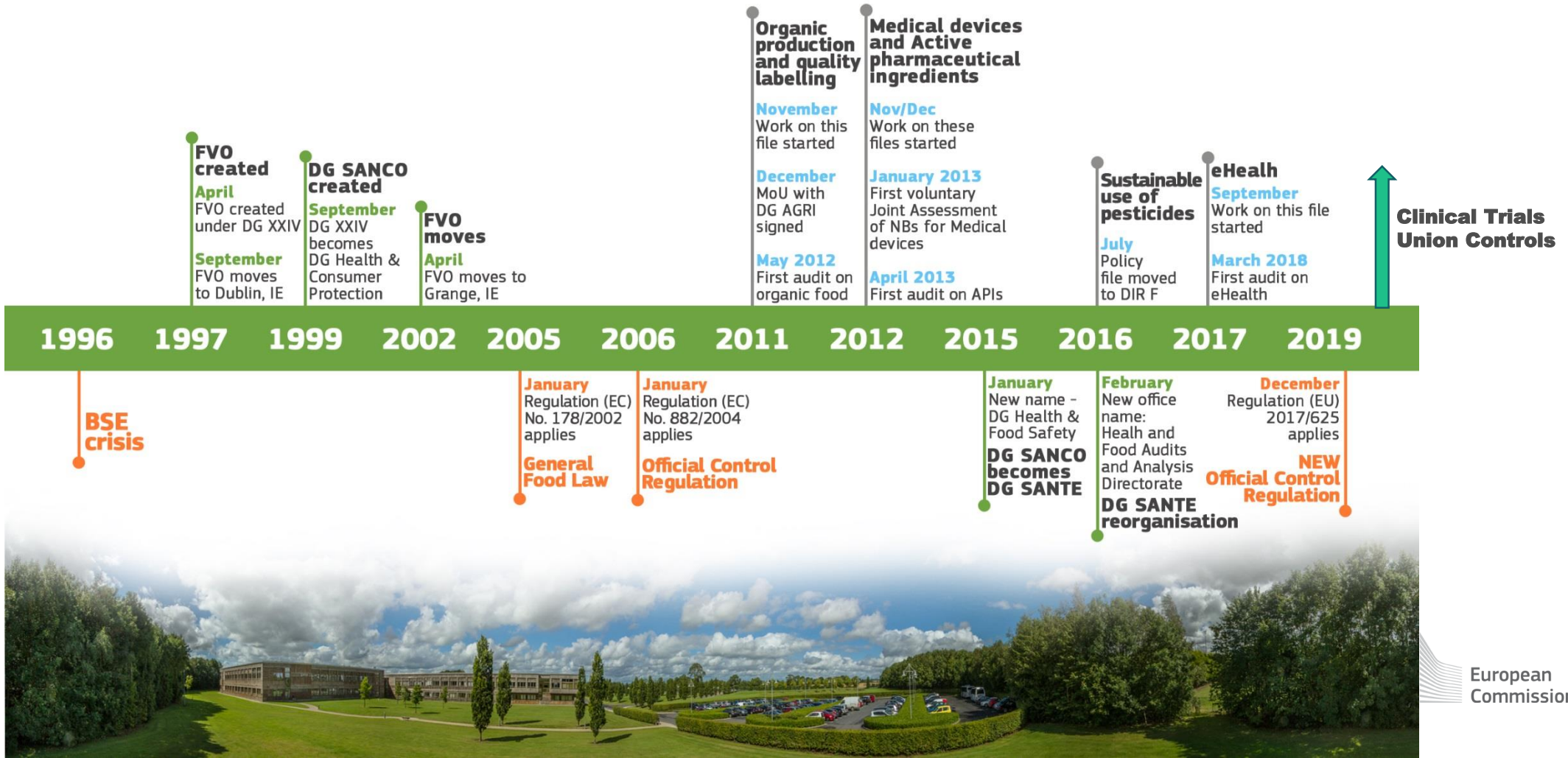
9 March 2021

Topics

- Directorate F Health Protection
- Union Controls
- Fact Finding Overview
- Q&A

European Commission

Health and Food Audits and Analysis Directorate



Directorate F areas of activity in Health

Active Pharmaceutical Ingredients

Clinical Trials

Medical Devices

Anti-microbial Resistance

European Commission

Union Controls

- Recital 65

The Commission should be able to control whether Member States correctly supervise compliance with this Regulation. Moreover, the Commission should be able to control whether regulatory systems of third countries ensure compliance with the specific provisions of this Regulation and Directive 2001/83/EC concerning clinical trials conducted in third countries

- Article 79 (1)

The Commission may conduct controls in order to verify:

(a) whether Member States correctly supervise compliance with this Regulation

(b) whether the regulatory system applicable to clinical trials conducted outside the Union ensures that point 8 of the Introduction and general principles contained in Annex I to Directive 2001/83/EC is complied with;

(c) whether the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of this Regulation is complied with.

Q&A 1 What are the new characteristics of the Clinical Trials Regulation (EU) No 536/2014 as compared to the Clinical Trials Directive 2001/20/EC?

- Union controls in Member states and third countries to ensure that clinical trials rules are being properly supervised and enforced.
- Clinical trials conducted outside the EU, but referred to in a clinical trial application within the EU, will have to comply with regulatory requirements that are at least equivalent to those applicable in the EU

Union controls - where are we in the process?

SANTE

- carries out Union controls to verify how Third Countries regulatory system complies with the Regulation
- carries out Union controls to verify how Member States correctly supervise compliance with the Regulation

Third Countries

- comply with regulatory requirements

Member States

- supervise compliance with the Regulation

Sponsors, CROs, Investigators

- apply the Regulation

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Fact Finding Studies Overview

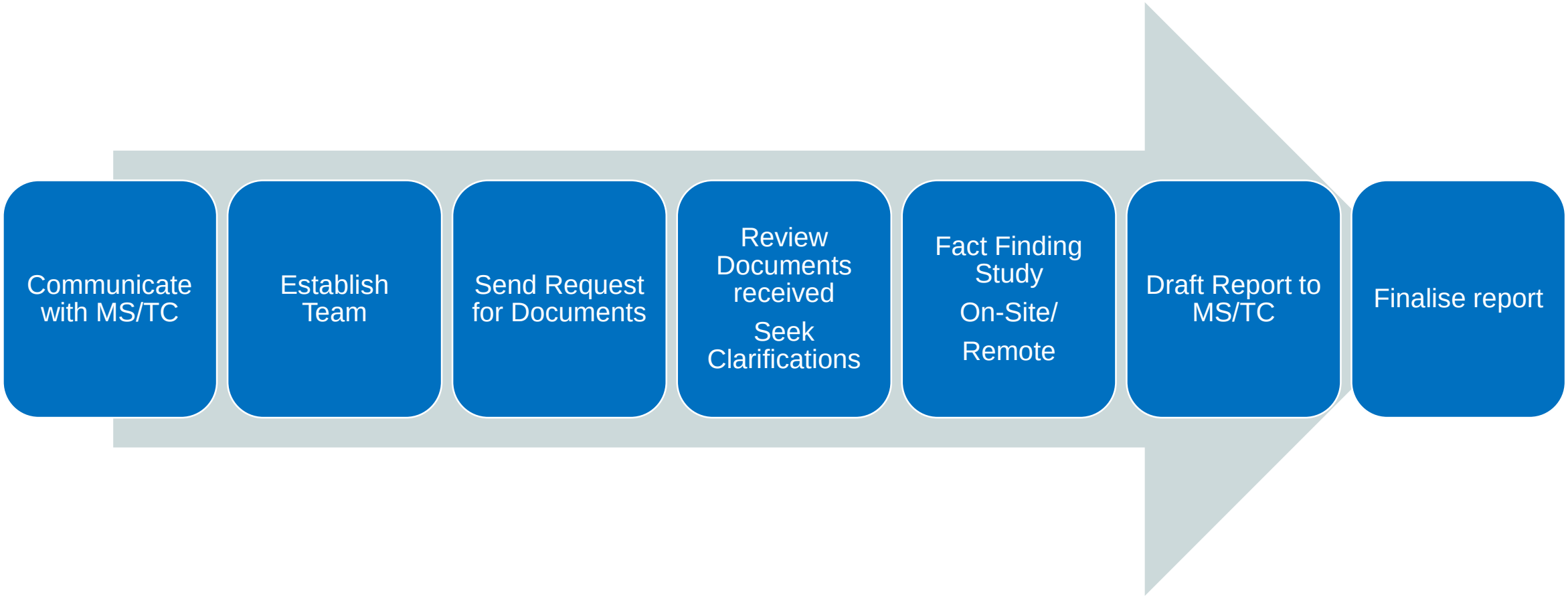
Fact finding studies – Why does the Commission need them?

- Test methodology
- Seek clarifications
- Open discussions

Fact Finding Studies – Why Participate?

- Shaping the future
- Shared learning experience
- Understand the process
- Raise points of interest

Fact Finding Study Process Overview



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Establish Teams

- Competent Authority and Ethics Committee(s)
- National Experts
  - CTEG expert
  - GCP inspector
- Commission auditors

Request for Documents

- Initiated 6-8 weeks in advance of the Fact Finding
- Documents received for review
- Missing documents or clarifications in advance of fact finding
- Feed into fact finding study discussions/meetings

Fact finding study – Scope

- Legislation enabling clinical trials
- Organisation of Authorities, Ethics Committees
- Processes for
  - Assessment, authorisation and substantial modifications
  - Assessment of safety reporting
  - GCP inspections, corrective measures and enforcement

Fact Finding Study Plan

- 5 – 7 days (On-site or remote)
- Opening meeting
- Meeting with Competent Authorities & Ethics Committees
- Daily de-briefing between the team and the authorities
- Closing meeting

Report

- A report on findings only (the Regulation not yet applicable)
- Opportunity for comment/correction (draft report)
- For MS only (not published)

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Fact Finding Study Progress

- First Fact Finding in April
  - Documents under Review
- Second Fact Finding in September
  - Team being established
- Third Country Fact Finding later in year
  - At the planning stage

Q&A

- Your Questions

- SANTE-F5-CLINICAL-TRIALS@ec.europa.eu

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Thank you

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