ACT EU Training for non-commercial sponsors:
Transitioning trials to CTIS

9 February 2024
Virtual event

TRANSITION OF CLINICAL TRIALS

THE ETHICS COMMITTEE PERSPECTIVE

Elena García Méndez

CEIm
COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS

SaludMadrid

Hospital Universitario La Paz
Hospital de Cantoblanco
Hospital Carlos III

Comunidad de Madrid

Ongoing clinical trials should complete transition from the Clinical Trials Directive to the EU Clinical Trials Regulation (Regulation (EU) No 536/2014) by the deadline of 30 January 2025

- What
- When
- How
- Our experience

What clinicals trials should transition?

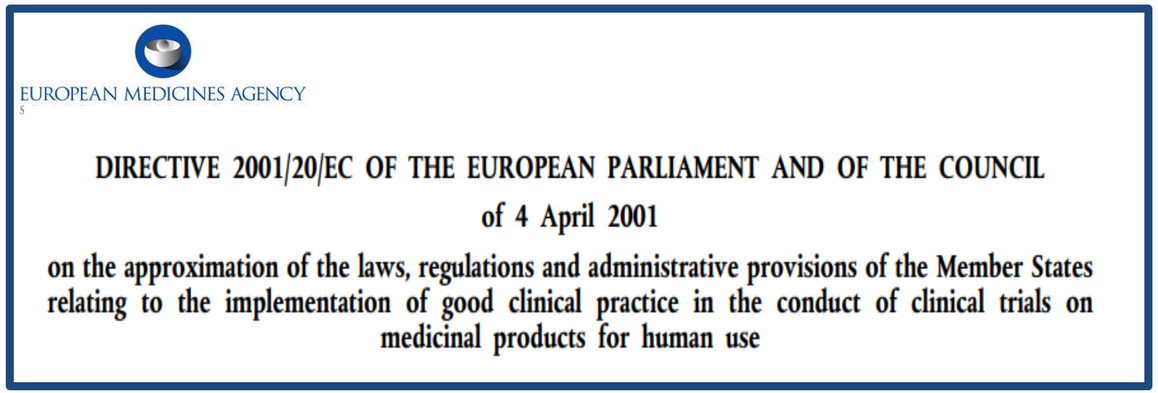
Ongoing clinical trials expected to continue beyond 30 Jan 2025, i.e. with at least one active site in the EU/EEA on 30 Jan 2025

- transition will be done only in those MSs where the trial has active sites
  - and only for the active sites

When should clinical trials be transitioned?

- At sponsor’s earliest convenience
- Provided that not SM is under assessment in any MSC
- Considering the maximum CTR timelines, the sponsor should start transition not later than 16 October 2024

How shall clinical trials be transitioned?


EUROPEAN MEDICINES AGENCY

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 4 April 2001

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

(Text with EEA relevance)

The transition should be an <u>administrative process</u>:

minimum assessment to ensure compliance with CTR

How

Part I + Part II = Conclusion

Initial application marked as a transitional trial

- **Form**
- **MSCs**
- **Part I**
- **Part II**
  - BE
  - CZ
  - FR
  - DE
  - IT
  - **ES**
- **Evaluation**
- **Timetable**

Country specific details (Part II - Spain)

Trial sites

Documents

- **Recruitment Arrangements**
- **Subject information and informed consent form**
- **Suitability of the investigator**
- **Suitability of the facilities**
- **Proof of insurance cover or indemnification**
- **Financial and other arrangements**
- **Compliance with national requirements on Data Protection**
- **Compliance with use of Biological samples**

How

Part II

What was already assessed will not be reassessed!

Validation procedure

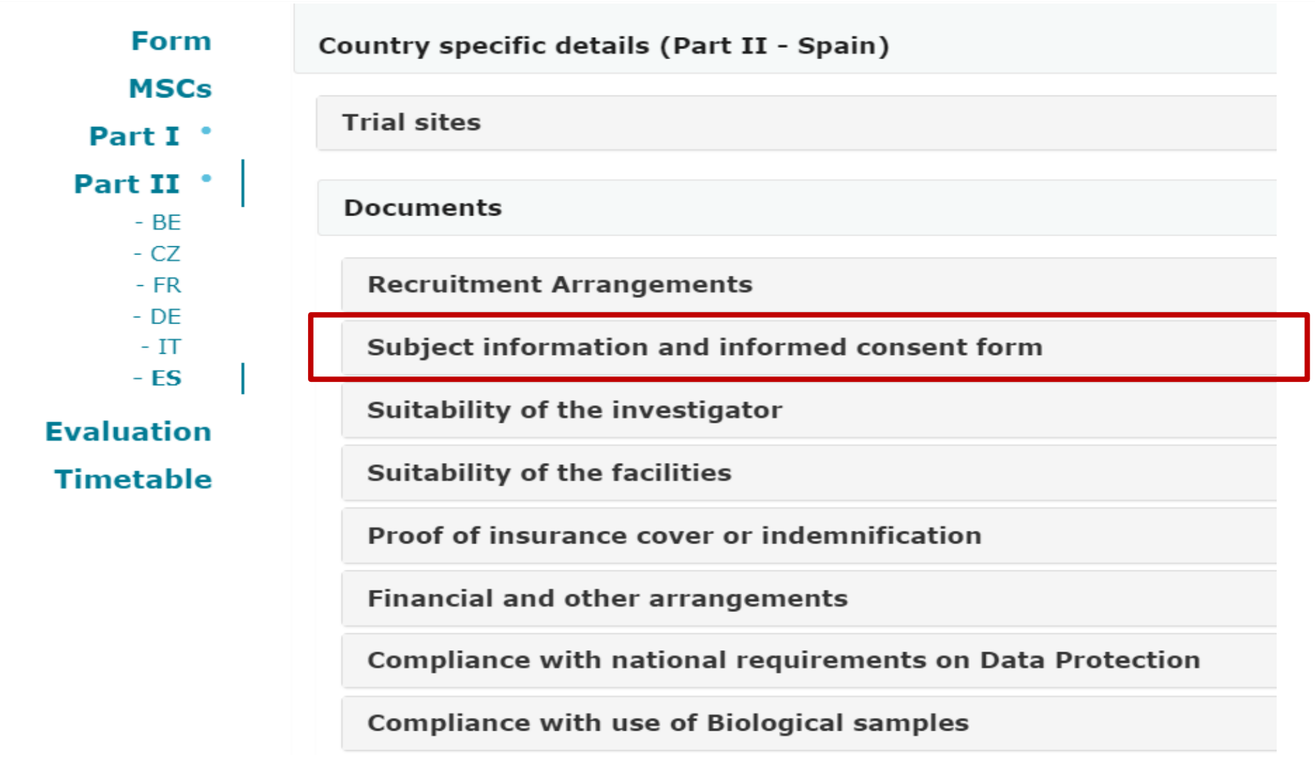
Minimum requirements

How

Part II

What was already assessed will not be reassessed!

Validation procedure



Latest authorized (under CTD) versions of the Subjects' Information Sheet/ICFs

Minimum requirements

How

Part II

What was already assessed will not be reassessed!

Validation procedure

For the other slots, upload a (blank) document confirming that this aspect was covered by the conclusion assessment under CTD

Minimum requirements

How

Part II

What was already assessed will not be reassessed!

Validation procedure

CTCG template cover letter

Only active sites

For the other slots, upload a document confirming that this aspect was covered by the conclusion assessment under CTD

Minimum requirements

How

Part II

What was already assessed will not be reassessed!

Validation procedure

CTCG template cover letter

Form

- Stating name of the EC which has given a positive opinion under CTD.
- Listing Part II documents approved under the CTD being submitted:

Member State	Type of document	Version and Date of the document approved per Member State	Date of approval		Comment
			National Competent Authority (if applicable)	Ethics Committee (if applicable)	

(add rows as appropriate)

Latest authorized (under CTD) version of the Subjects' Information Sheet/ICFs

If beyond minimum requirements, state it clearly in the cover letter

How

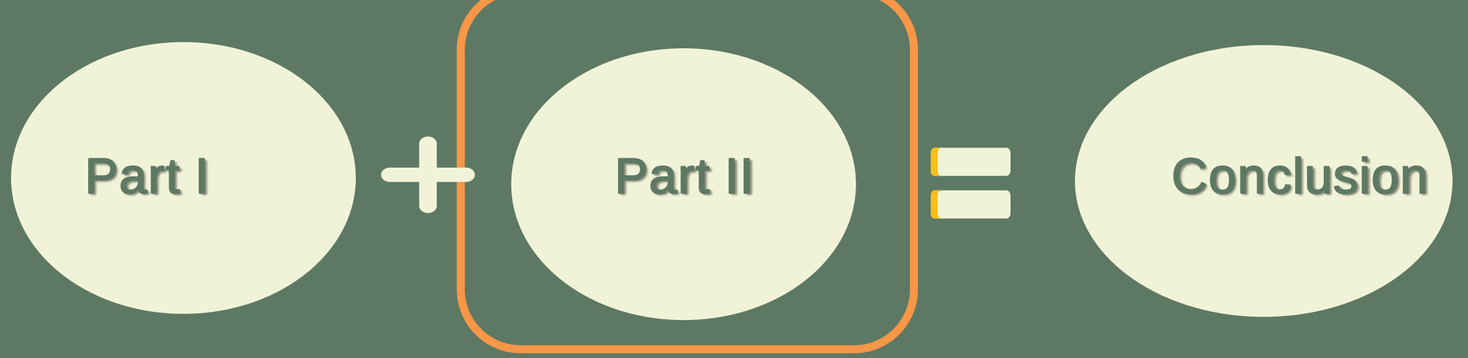
Part II

Most MSCs accept the transition minimum requirements

Information will be published shortly on the EU Commission website

In the meantime, check specific requirements with MS national contact

Next Substantial Modification



<u>At first Substantial Modification of Part II</u>, the sponsor should submit the authorized versions of the documents not uploaded at initial transition step

Clearly indicate in the Cover letter:

1. Documents which are new/amended due to the Substantial Modification
2. Documents uploaded to complete trial dossier

Next Substantial Modification

Part I + Part II = Conclusion

At first Substantial Modification of Part II, the sponsor should submit the authorized versions of the documents not uploaded at transition

The sponsor will provide the outstanding authorized documents

Next Substantial Modification

Part I + Part II = Conclusion

Form
MSCs
Part I •
Part II •
- BE
- CZ
- FR
- DE
- IT
- ES
Evaluation
Timetable

Check SM specific requirements with MS national contact

Country specific details (Part II - Spain)

Trial sites

Documents

Recruitment Arrangements

Subject information and informed consent form

Suitability of the investigator

Suitability of the facilities

Proof of insurance cover or indemnification

Financial and other arrangements

Compliance with national requirements on Data Protection

Compliance with use of Biological samples

✓ Only active sites

✓ If study recruitment has finished, NO need to upload recruitment material

✓ No need to retrospectively create a site suitability form

✓ New templates under CTR (not authorised under CTD) will be submitted

NO need to update templates of forms approved under CTD

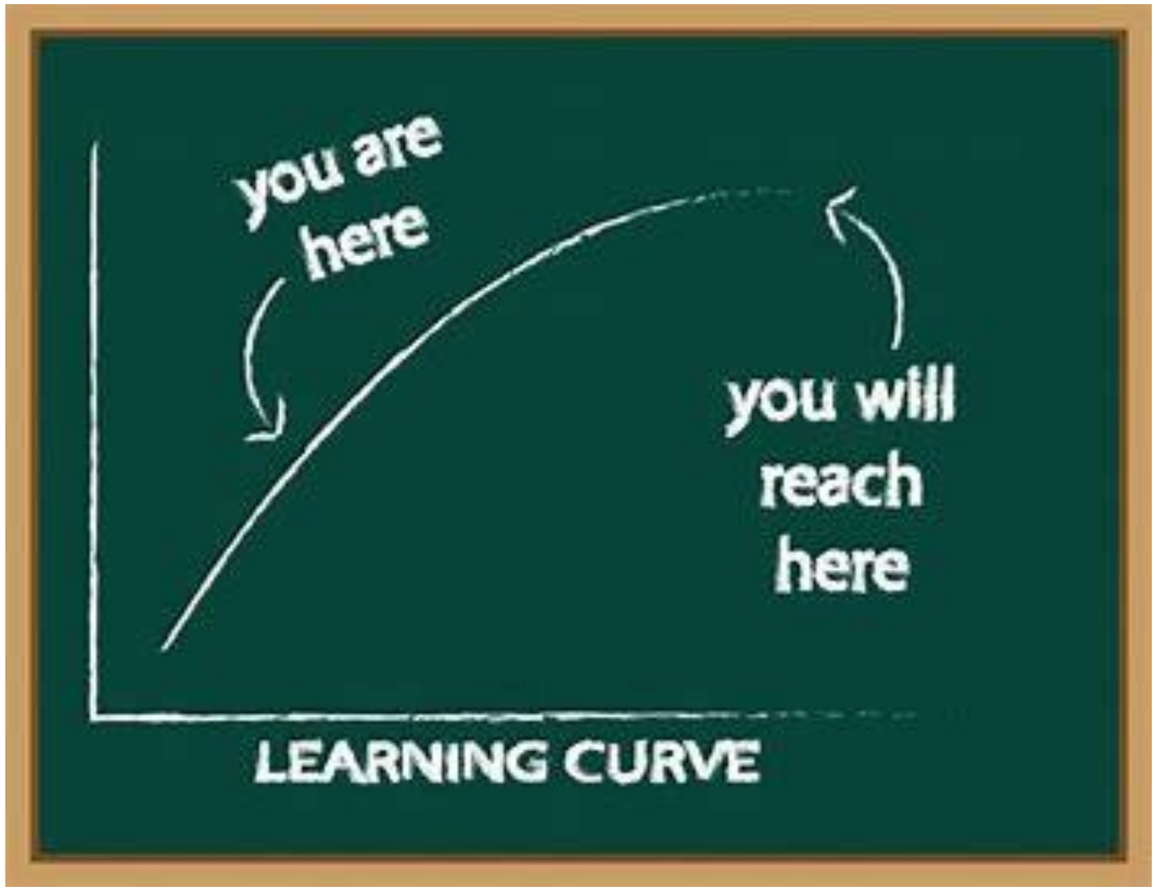
Our experience as EC in transition trials in Spain

- **So far, we were the Ethics Committee (CTD) of the trials transitioning**

- **Minor issues identified:**
  - Missing documents:
    - When multiple Subject Information Sheet/ICF have been authorized, some may be missing
    - When beyond minimum requirements, some sites documents may be missing
  - Errors in the cover letter (documents not well versioned; mismatch between cover letter and docs)

TO APPLY LEARNINGS

- To harmonize and simplify processes and criteria
- To be transparent on requirements
- Contact your MS contact point if and when required



IMPORTANT MESSAGE TO TAKE HOME

DO NOT EXHAUST TIMELINES:
TRANSITION TAKES TIME AND LAST-MINUTE UNEXPECTED SHOWSTOPPERS MAY ARISE

Start transition not later than 16 October 2024

Remember the two-week winter clock stop

THANK YOU!