1. New rules on translations of patient-facing documents
2. New harmonised template on recruitment and informed consent procedure

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1. New rules on translations of patient-facing documents

Why new rules on translations patient-facing documents?

Background information:

- All patient-facing documents (EN and MS translations) were uploaded in the protocol section of CTIS (part I)
- This resulted in a high number of documents in the protocol section, and no clear overview
- Finding the authorised protocol versions can be a challenge in this long list of documents
- In case of partial submission, sponsor already had to submit a translated version in MS language with part I only, while trial may never start in these MS (financial and administrative burden; also due to the fact that many MS only accept certified/validated translations of patient-facing documents)
- MedEthicsEU conducted survey about the MS requirements and preferences for translations of documents
- MedEthicsEU drafted proposal to move MS translations to the part II and only have the EN version in the part I protocol section.
- Improved overview on the approved protocol versions and the MS translations patient facing documents; reduce burden/costs for sponsors in case of partial application (part I only)

- Proposal endorsed by CTAG November 2025

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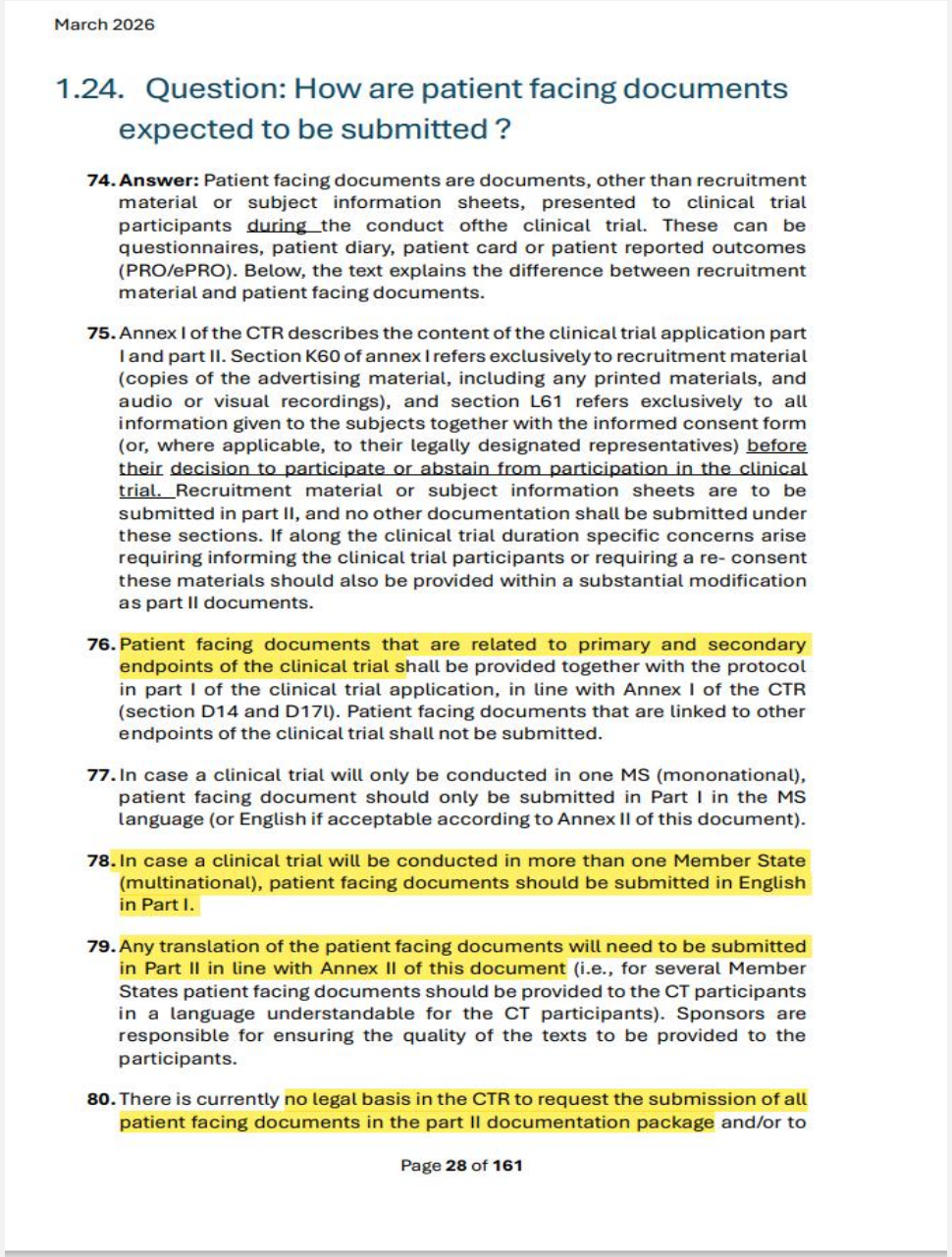
CTR Q&A 1.24

Version March 2026

Q1.24 updated as agreed by CTAG:

- Sponsor should submit only the patient-facing documents related to primary and secondary endpoints
- Translations in MS language of patient-facing documents to the part II (annex II with the MS requirements is updated)
- No legal basis in CTR to submit all patient-facing documents in the part II application package



March 2026

1.24. Question: How are patient facing documents expected to be submitted ?

74. Answer: Patient facing documents are documents, other than recruitment material or subject information sheets, presented to clinical trial participants during the conduct ofthe clinical trial. These can be questionnaires, patient diary, patient card or patient reported outcomes (PRO/ePRO). Below, the text explains the difference between recruitment material and patient facing documents.

75. Annex I of the CTR describes the content of the clinical trial application part I and part II. Section K60 of annex I refers exclusively to recruitment material (copies of the advertising material, including any printed materials, and audio or visual recordings), and section L61 refers exclusively to all information given to the subjects together with the informed consent form (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation in the clinical trial. Recruitment material or subject information sheets are to be submitted in part II, and no other documentation shall be submitted under these sections. If along the clinical trial duration specific concerns arise requiring informing the clinical trial participants or requiring a re- consent these materials should also be provided within a substantial modification as part II documents.

76. Patient facing documents that are related to primary and secondary endpoints of the clinical trial shall be provided together with the protocol in part I of the clinical trial application, in line with Annex I of the CTR (section D14 and D17l). Patient facing documents that are linked to other endpoints of the clinical trial shall not be submitted.

77. In case a clinical trial will only be conducted in one MS (mononational), patient facing document should only be submitted in Part I in the MS language (or English if acceptable according to Annex II of this document).

78. In case a clinical trial will be conducted in more than one Member State (multinational), patient facing documents should be submitted in English in Part I.

79. Any translation of the patient facing documents will need to be submitted in Part II in line with Annex II of this document (i.e., for several Member States patient facing documents should be provided to the CT participants in a language understandable for the CT participants). Sponsors are responsible for ensuring the quality of the texts to be provided to the participants.

80. There is currently no legal basis in the CTR to request the submission of all patient facing documents in the part II documentation package and/or to

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What are the new rules on translations patient-facing documents?

- English (EN) version of patient-facing documents in part I (CTIS protocol section)

- MS who require a translation in MS language(s): Translated version in CTIS part II section “Compliance with national requirements on data protection”

- Only for Mononational trials where patient-facing document are only available in MS language (other than EN): no EN version in part I is needed and the version in MS language can be submitted in the part I

What are the new rules on translations patient-facing documents related to primary and secondary endpoints?

- Date of implementation: **27 April 2026**

- **Applicable for new applications (initial, substantial modification related to patient facing documents, additional MS)**

- **Trials under evaluation, authorised trials but not yet started and ongoing trials**: **no corrective action is required**. Translations of patient-facing documents related to primary and secondary endpoints previously submitted and approved in Part I may remain in place and do not need to be relocated unless there is a SM on these patient facing documents.

Note: If there is a **SM with updates** on patient facing documents, see slide 8 and further for instructions

Annex II: Language for part I documents and translated Patient Facing Documents submitted in Part II

All Member States accept in Part I Patient Facing Documents in English (or in the national language in case the trial is mononational). Translated versions of Patient Facing Documents are to be submitted in Part II in the language as reported in the table below.

EU Member State	Cover letter	Protocol	Protocol synopsis	Translated Patient Facing Documents in Part II	Investigators brochure	GMP compliance	IMPD	AMPD	Scientific advice and PIP	Labelling	EN labelling is acceptable for an IMP that is only administered by the physician (or qualified health personnel) and not handed to the patient	Fields of the application form
Austria	EN or DE	EN or DE	EN and DE	DE	EN or DE	EN or DE	EN or DE	EN or DE	EN or DE	DE	Yes	EN and DE (1)
Belgium	DE or NL or EN or FR	DE or NL or EN or FR	DE and FR and NL. EN optional	NL and/or FR and/or DE (2)	DE or NL or EN or FR	DE or NL or EN or FR	DE or NL or EN or FR	DE or NL or EN or FR	DE or NL or EN or FR	DE and FR and NL. EN optional	Yes (3)	EN or DE or NL or FR
Bulgaria	EN and BG	EN or BG	BG	BG	EN	EN	EN	EN	EN	BG	Yes	EN and BG
Croatia	EN and HR	EN	EN and HR	HR	EN	EN	EN	EN	EN	EN and HR	Yes	EN and HR
Cyprus	EN	EN	EN and EL	EL	EN	EN	EN	EN	EN	EN and/or EL (4)	Yes*	EN
Czechia	EN or CZ	EN or CZ	CZ	CZ	EN or CZ	EN or CZ	EN or CZ	EN or CZ	EN or CZ	CZ	Yes**	EN or CZ
Denmark	EN or DK	EN or DK	EN or DK	N/A	EN or DK	EN or DK	EN or DK	EN or DK	EN	DK	Yes	EN or DK
Estonia	EN	EN	EN	EE	EN	EN	EN	EN	EN	EE	Yes	EN
Finland	EN or FI or SV	EN or FI or SV	EN or FI or SV	N/A	EN or FI or SV	EN or FI or SV	EN or FI or SV	EN or FI or SV	EN or FI or SV	FI (SV or EN (7))	Yes	EN or FI or SV
France	EN or FR	EN or FR	EN and FR	FR	EN or FR	EN or FR	EN or FR	EN or FR	EN	FR	Yes	EN and FR (5)
Germany	EN or DE	EN or DE	EN or DE	DE	EN or DE	EN or DE	EN or DE	EN or DE	EN or DE	DE	Yes (8)	EN or DE
Greece	EN and EL (6)	EN and EL (6)	EL	EL	EN or EL	EN or EL	EN or EL	EN or EL	EN or EL	EL	Yes**	EN and EL (6)
Hungary	EN and HU	EN or HU	EN and HU	HU	EN or HU	EN or HU	EN or HU	EN or HU	EN or HU	HU	Yes	EN and HU
Iceland	EN or IS	EN or IS	IS	IS	EN	EN	EN	EN	EN	IS	Yes	EN

Best practice guide naming of documents CTIS

- Version 3, February 2026

PART I

D. Protocol (*placeholder protocol information in CTIS*)
D1_Protocol EU CT number
D1_Protocol synopsis MS EU CT number (*include MS language code in title)*
D1_Master protocol EU CT number and name and sub-protocol name and specific number/ID *(only for CCT)*
D2_Protocol modification nr number EU CT number *(in case of SM as separate doc.*)
D3_DSMB Charter EU CT number
D4_Patient-facing documents e.g. questionnaire or diary *(ENG only*, if applicable*)

PART II

R. Compliance GDPR (*same placeholder in CTIS*)
R1_Compliance with the collection and use of personal data
R2_Patient-facing documents e.g. questionnaire or diary in MS language* (if applicable)

Initial application with PFD* related to primary and/or secondary endpoints

Example new initial application including Questionnaire_primendpoint (v1) – MSCs: **BE** (2 translations for this CT: DE, FR), **CZ** and **FI***

New situation: Part I - D4:
EN_Questionnaire_primendpoint_v1

New situation: Part II - R2
DE_Questionnaire_primendpoint_v1
FR_Questionnaire_primendpoint_v1
CZ_Questionnaire_primendpoint_v1

**FI does not require a translation (see annex II): no translated version in part II-R2 for Finland*

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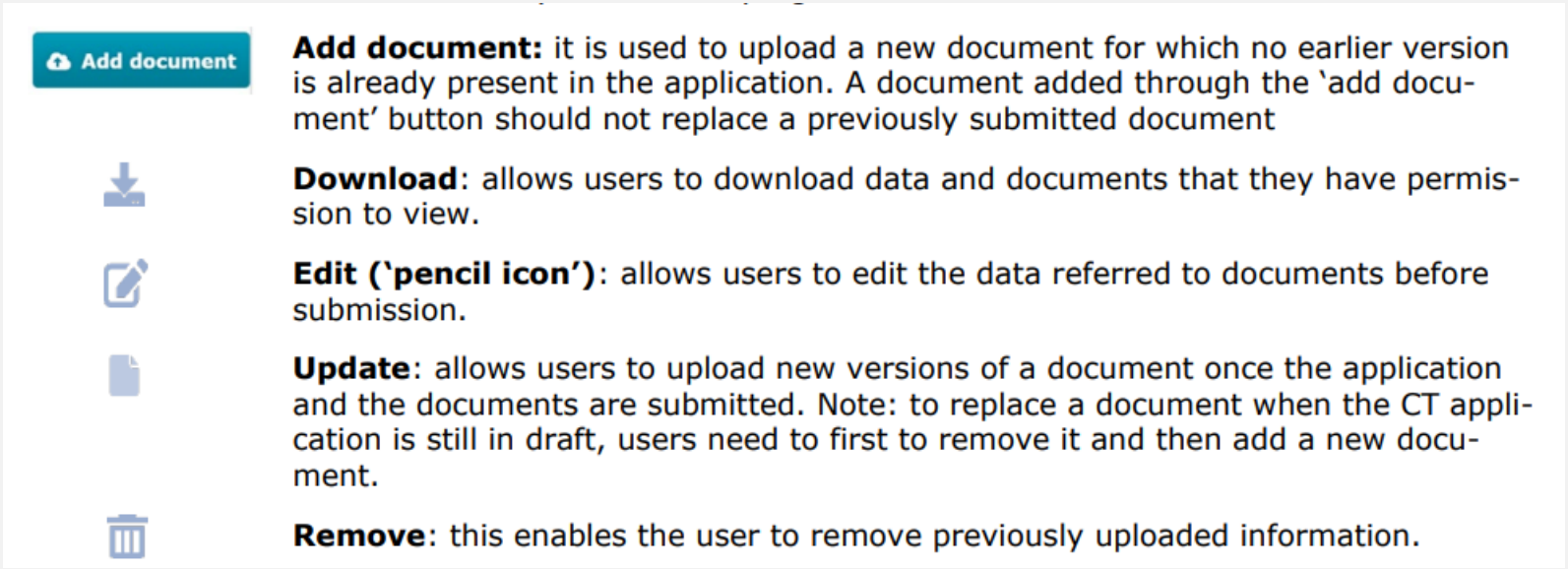
*PFD = patient facing document

Substantial modification PFD* related to primary and secondary endpoints in CTIS with the new rules

Example SM update on Questionnaire_primendpoint (v3 to v4) – SM part I/part II

- **Update** EN PFD (v3 → v4)
- **Remove** all old translated versions of PFD related to primary/secondary endpoints in D4 section by using the remove button (first v3, then v2, then v1) .
- **Add** new version (v4) of translated version of PFD related to primary/secondary endpoint in part II, section R2 (only for MS who require a translation).



Substantial modification PFD* related to primary and secondary endpoints in CTIS with the new rules

Example SM update on Questionnaire_primendpoint (v3 to v4) – SM part I/part II (MSCs: Germany and France)

- **Update** EN PFD (v3 → v4)
- **Remove** all old translated versions of PFD related to primary/secondary endpoints in D4 section by using the remove button (first v3, then v2, then v1) .
- **Add** new version (v4) of translated version of PFD related to primary/secondary endpoint in part II, section R2 (only for the MSs who require a translation).

Old situation: Part I - D4:

EN_Questionnaire_primendpoint_v3
v2
v1
DE_Questionnaire_primendpoint_v3
v2
v1
FR_Questionnaire_primendpoint_v3
v2
v1

New situation: Part I - D4:

EN_Questionnaire_primendpoint_v4
v3
v2
v1

New situation: Part II - R2

DE_Questionnaire_primendpoint_v4
FR_Questionnaire_primendpoint_v4

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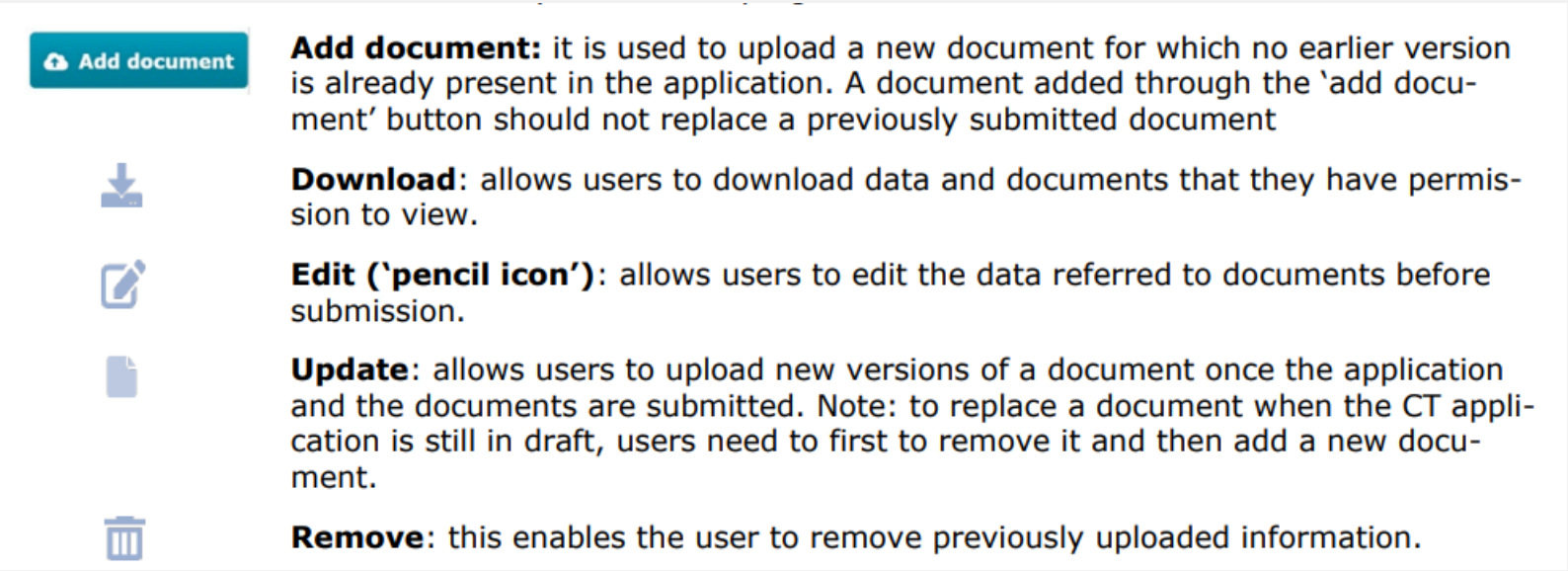
*PFD = patient facing document

What are the rules for Patient Facing Documents (PFD) not related to primary and secondary endpoints in CTIS

- PFD **not related to primary and secondary endpoints** should be **removed** with the **next SM part I**. Otherwise, these PFDs will continue to be included in all subsequent SMs (CTIS functionality).
- This is to prevent that outdated versions are included in a SM application
- All versions should be removed
- The version submitted previously in a CT application (IN, SM1, SM2, ...) remains visible in CTIS!



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*PFD = patient-facing document

PFD* not related to primary and secondary endpoints in CTIS with the new rules

Next SM part I – remove all versions of PFD not related to primary/secondary endpoints by using the remove button. See example for a Diary to measure an exploratory endpoint

Remove: this enables the user to remove previously uploaded information.

Old situation: Part I - D4:

EN_Diary_exploratory_v2
v1
DE_Diary_exploratory_v2
v1
FR_Diary_exploratory_v2
v1

New situation: Part I - D4:

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*PFD = patient-facing document

Additional MS: Spain

Example of Spain as additional MS and no other SMs submitted yet to move/remove translated versions in CTIS

- **Addition of Spain as MS, not possible to have other changes in CTIS (deleting existing Part I PFD* not possible)**

Old situation: Part I – D4

EN_Questionnaire_primendpoint_v3
v2
v1
DE_Questionnaire_primendpoint_v3
v2
v1
FR_Questionnaire_primendpoint_v3
v2
v1
EN_Diary_exploratory_v2
v1
DE_Diary_exploratory_v2
v1
FR_Diary_exploratory_v2
v1

New situation: Part I - D4:

EN_Questionnaire_primendpoint_v3
v2
v1
DE_Questionnaire_primendpoint_v3
v2
v1
FR_Questionnaire_primendpoint_v3
v2
v1
EN_Diary_exploratory_v2
v1
DE_Diary_exploratory_v2
v1
FR_Diary_exploratory_v2
v1

New situation: Part II – R2:

ES_Questionnaire_primendpoint_v3

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*PFD = patient facing document

Transition period

- **Transition period** is foreseen for **sponsors that are not ready on 27 April to comply with this new procedure due to** required changes in internal processes**,**

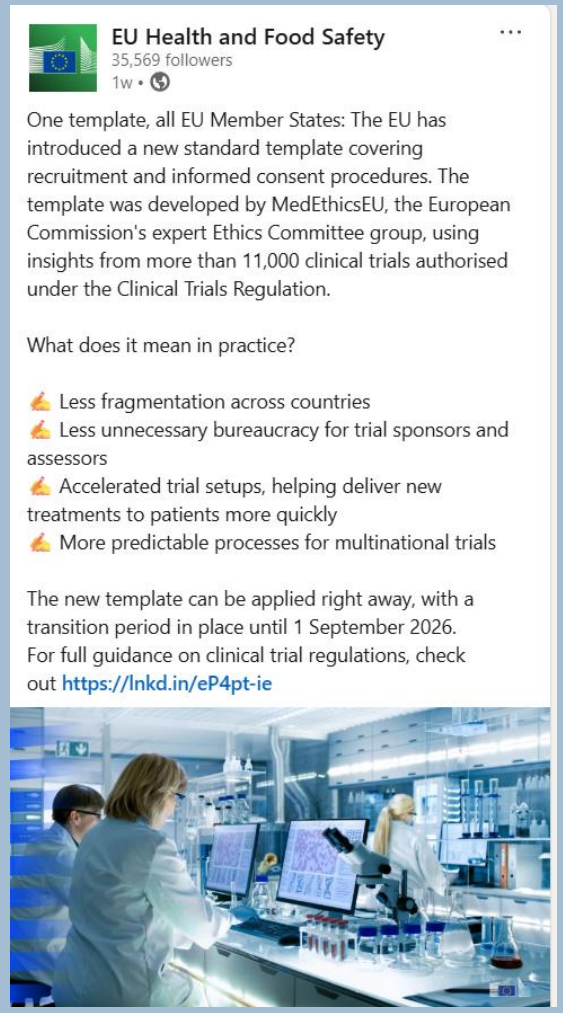
- Sponsor are requested to include **a justified request for exemption in the cover letter.**

- **Transition period of 3 months**
  - Translations of patient facing documents in MS language uploaded in part I will be accepted
  - If sponsors of applications submitted before 27 April 2026 have already implemented the new rules, this will be accepted as well

- **Except for article 11 (part I only submission): as of 27 April** only the **English (EN) version** of patient-facing documents should be included in a Part I only submission (no part II application)

2. New harmonised template on recruitment and informed consent procedure

[One template, all EU Member States: The EU has introduced a new standard template covering recruitment and informed consent procedures. The template was developed by MedEthicsEU, the European… | EU Health and Food Safety]



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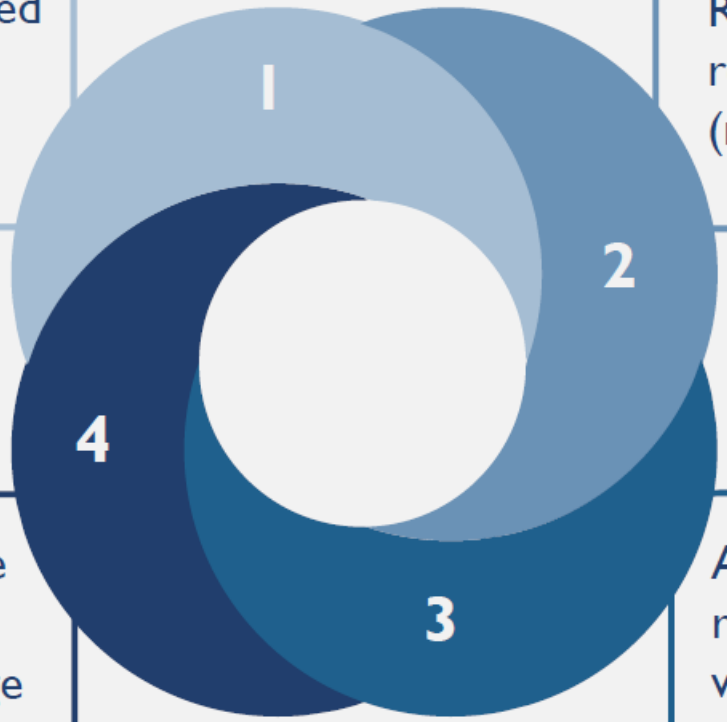
Core of the revision

Harmonisation

Create a template that can be used by all Member States – sufficient detail without generic answers

CTR requirements

Remove questions related to requirements outside CTR (national requirements)



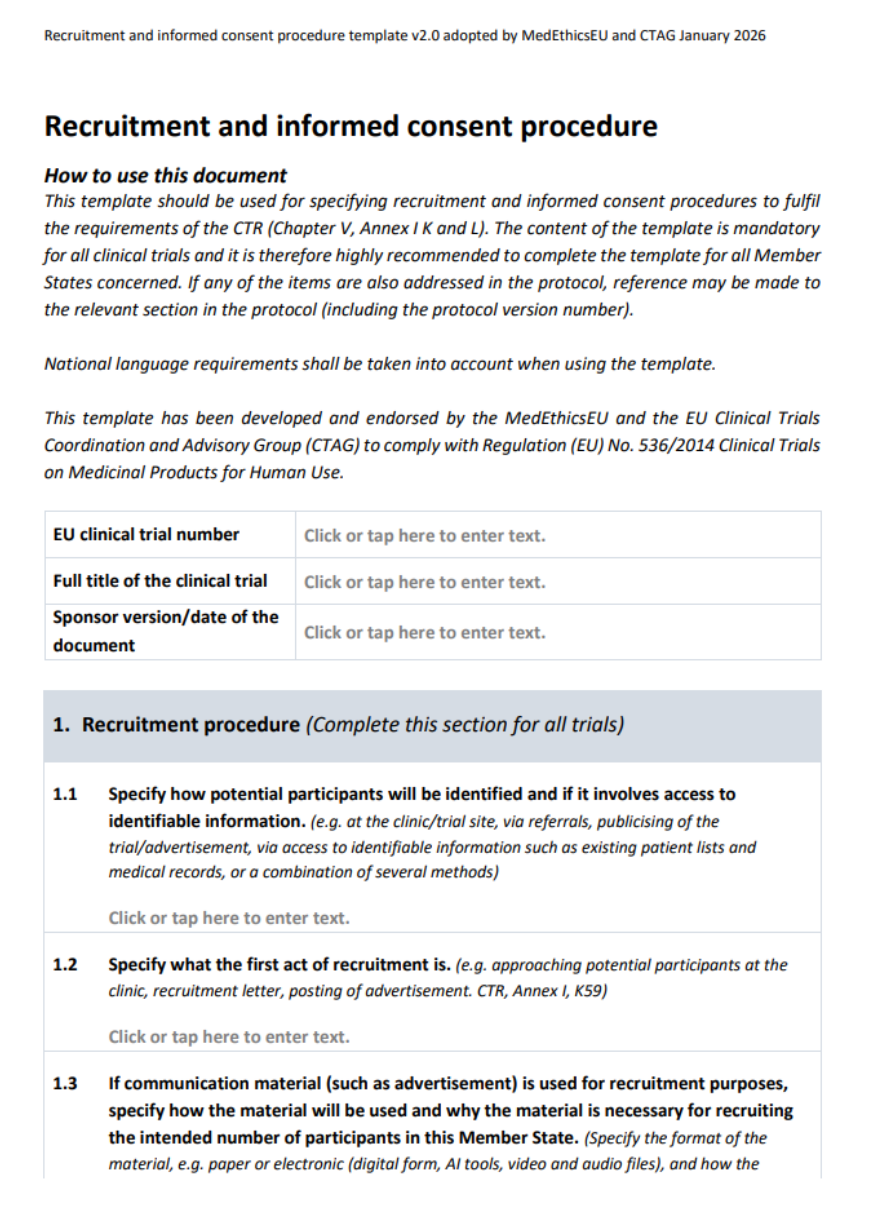
Logical and relevant

Create more logical order of the questions and sections and improve consistency and language

National context

Addition of sections for national requirements – harmonise where we can and be transparent when we can't.

Template on recruitment and informed consent procedure



Recruitment and informed consent procedure template v2.0 adopted by MedEthicsEU and CTAG January 2026

Recruitment and informed consent procedure

How to use this document

This template should be used for specifying recruitment and informed consent procedures to fulfil the requirements of the CTR (Chapter V, Annex I K and L). The content of the template is mandatory for all clinical trials and it is therefore highly recommended to complete the template for all Member States concerned. If any of the items are also addressed in the protocol, reference may be made to the relevant section in the protocol (including the protocol version number).

National language requirements shall be taken into account when using the template.

This template has been developed and endorsed by the MedEthicsEU and the EU Clinical Trials Coordination and Advisory Group (CTAG) to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use.

EU clinical trial number	Click or tap here to enter text.
Full title of the clinical trial	Click or tap here to enter text.
Sponsor version/date of the document	Click or tap here to enter text.

1. Recruitment procedure *(Complete this section for all trials)*

1.1 **Specify how potential participants will be identified and if it involves access to identifiable information.** *(e.g. at the clinic/trial site, via referrals, publicising of the trial/advertisement, via access to identifiable information such as existing patient lists and medical records, or a combination of several methods)*

Click or tap here to enter text.

1.2 **Specify what the first act of recruitment is.** *(e.g. approaching potential participants at the clinic, recruitment letter, posting of advertisement. CTR, Annex I, K59)*

Click or tap here to enter text.

1.3 **If communication material (such as advertisement) is used for recruitment purposes, specify how the material will be used and why the material is necessary for recruiting the intended number of participants in this Member State.** *(Specify the format of the material, e.g. paper or electronic (digital form, AI tools, video and audio files), and how the*

- **Published on Eudralex volume 10:** EudraLex - Volume 10 - Public Health - European Commission

- **The new version replaces** the previous version

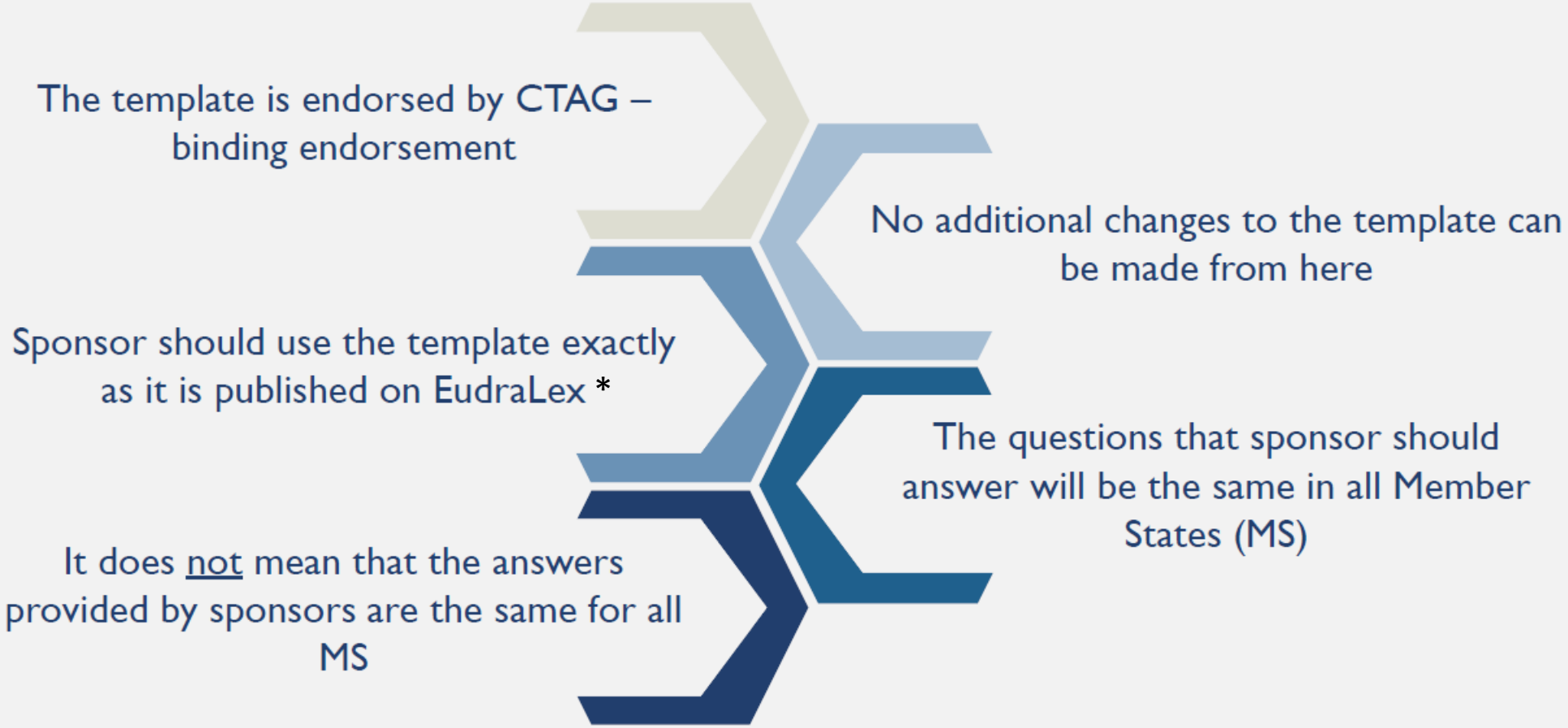
- **Highly recommended to use the new version**

- Transition period of **three months** (fully implemented on September 1st, 2026)

- Applicable for **initial Part II submissions** (initial, Add MSC, Art. 11)

- **No retrospective** implementation is needed

Important to remember



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**Translated version of template in MS language is acceptable (check MS website)*

Thank you for the attention!

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