

CCI proposals in clinical documents - gap analyses

EMA Clinical Data Publication perspective

Presented by Silvia Garrido-Lestache and Radu Popescu

Clinical Data Publication Specialists – EMA, Transparency Department

24 March 2026



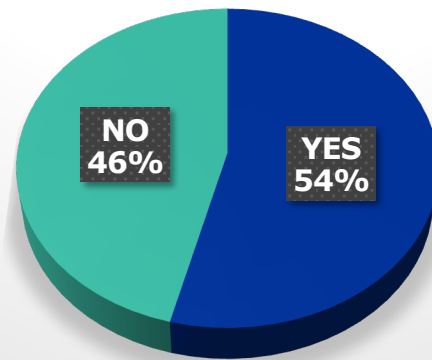
Outline

- 2025 CDP CCI Proposals in Numbers
- Observations and Recommendations
- Types of information not accepted as CCI
- Take home messages

2025 Clinical Data Publication CCI Proposals (1/4)

- 92 document packages were published on the CDP portal
 - 49 initial marketing authorisation application (MAA) procedures
 - 43 post-authorisation procedures
- Marketing authorization holders (MAHs) proposed CCI in 50 document packages

Document packages containing CCI proposals



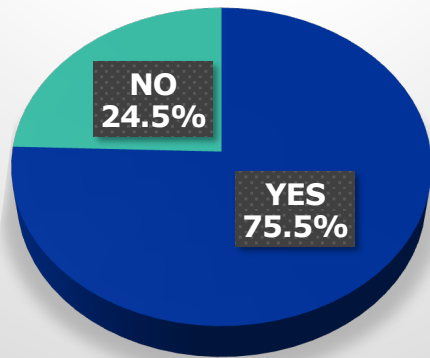
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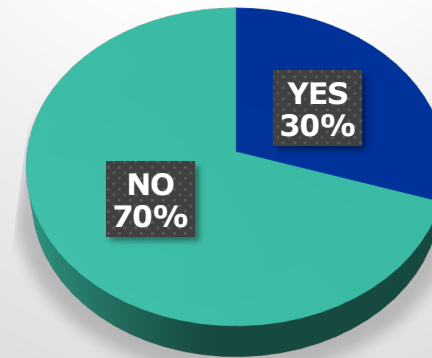
2025 Clinical Data Publication CCI Proposals (2/4)

- Applicants / MAHs proposed CCI in:
 - 37 (75.5%) initial MAA procedures out of 49
 - 13 (30%) post-authorisation procedures out of 43

CCI Proposals in Initial MAA Procedures



CCI Proposals in Post-Authorization Procedures



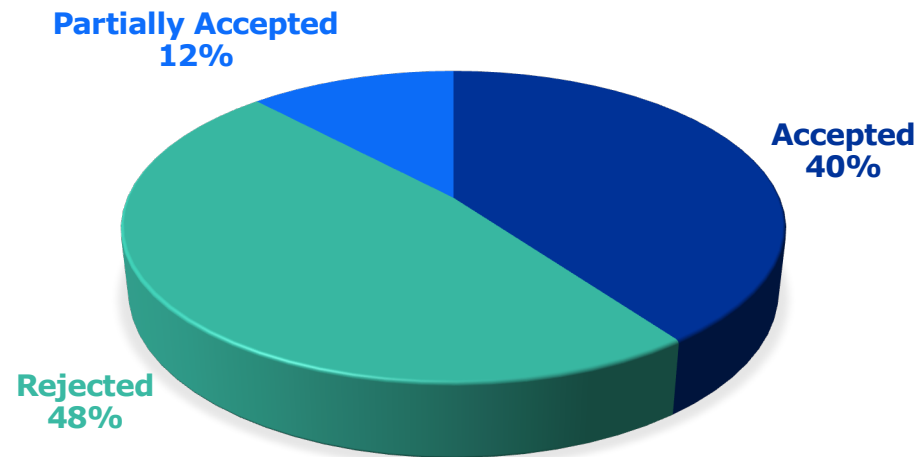
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2025 Clinical Data Publication CCI Proposals (3/4)

- Applicants/MAHs proposed CCI in 2192 instances
- EMA rejected the CCI proposals in 1056 instances and accepted in 889 instances

CDP CCI REJECTION / ACCEPTANCE RATES

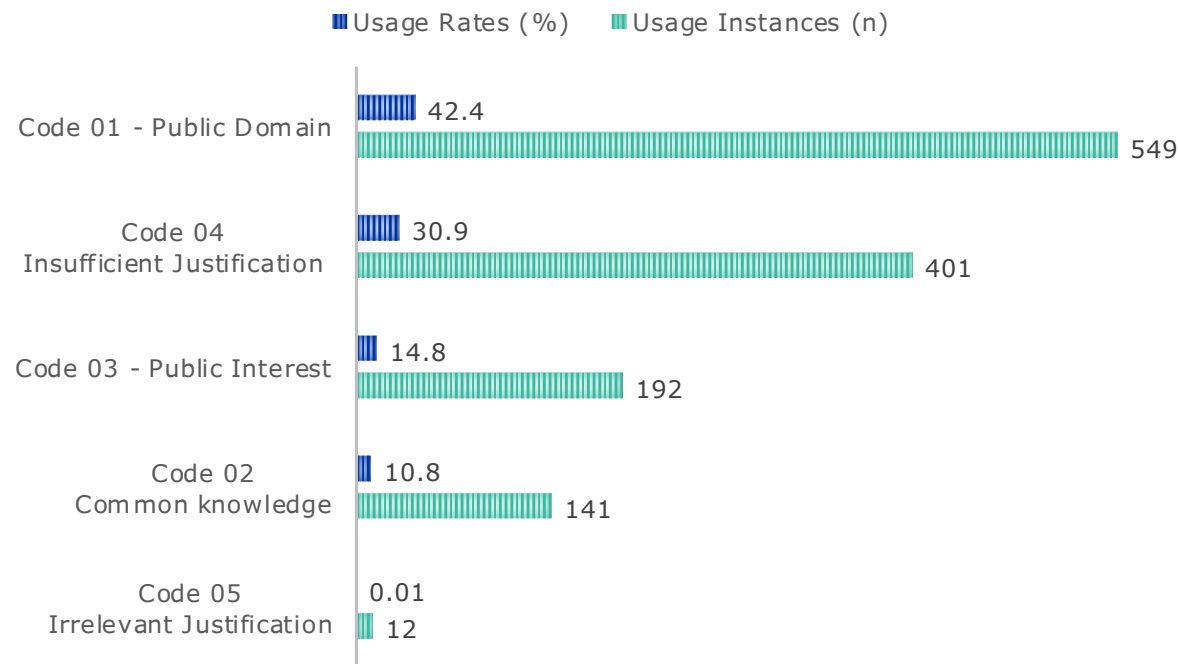


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2025 Clinical Data Publication CCI Proposals (4/4)

- 42% of the rejected CCI proposals based on Public Domain CCI rejection code



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EMA CDP CCI rejection codes

- Information is available in the **public domain** or publicly available – **Code 01**
- Information that **does not bear any innovative features** (common knowledge)- **Code 02**
- Disclosure of Information in **the public interest** - **Code 03**
- Information **lacking sufficient justification** – **Code 04**
- The justification provided is not **relevant for** the text proposed for redaction – **Code 05**



Observations and Recommendations

- More than 50% of the CCI proposals are not CCI
 - Avoid proposing for redaction general information
 - Target the proposals on what is innovative (if anything)
 - Consult the EMA on a representative subset of CCI redaction proposals (if any)
- More than 50% of rejections justified by publicly available information or common scientific knowledge
 - Know what information is frequently disclosed, when and where (e.g. scientific publications, congress posters, patent applications, published assessment reports)
 - Involve in-house multidisciplinary team before proposing any redactions
 - Know your product, the state of the art in the scientific research field (e.g scientific guidelines, therapeutic options)

Types of information not accepted as CCI (1/5)

- **Clinical study results**

- ☐ Efficacy
- ☐ Safety
- ☐ PK/PD including modelling and simulation

Rejection reasons

- Study results cannot just be used as such by competitors in support of their MAAs
- Competitors would need to run their own clinical development plans tailored to their molecules
- PK/PD modelling and simulation results are based on the developer's datasets generated with the product formulation available at that point in time (statements above do apply as well)
- Disclosure of study results would strengthen the scientific credibility of the clinical development towards partners, investors and payers
- **Information encompassing non-clinical and clinical development of the medicinal product and the subsequent assessment by competent authorities is not per se commercially confidential** – please see section 3.2 of the '[HMA/EMA Guidance document on the identification of CCI and personal data within the structure of the MAA – release of information after the granting of a MA](#)'

Types of information not accepted as CCI (2/5)

- **Dissolution methods**

- Rejection reasons

- Standard methods and materials defined in guidance documents, for example:
 - [Frequently Asked Questions](#)
 - [Dissolution Testing of Immediate Release Solid Oral Dosage Forms](#)
 - [Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations](#)
 - Available in the public domain (e.g. United States Pharmacopeia (USP) or published on regular basis by FDA at: [Dissolution Methods](#))

- **Dissolution curves and results**

- Rejection reasons

- Support the bridging/ comparability exercise between formulations or products
 - Dissolution results are not transferable in any way to a competitor's product, cannot be used as such
 - Competitors must generate their own data, specific to their product

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Types of information not accepted as CCI (3/5)

- **Exploratory end points / analyses**

Rejection reasons

The vast majority of them are not confidential, quite the opposite:

- Known exploratory end-points used by all developers
- Choice justified scientifically, driven by well known considerations such as the pathophysiology of the disease, mechanism of action of the molecule, measurement feasibility and reliability, studied population, etc.
- Not CCI just because they are called exploratory or because they can potentially lead to hypothesis-generation, or to inform future studies

- **Biomarkers**

Rejection reasons

- Biomarkers listed in the CSRs/ study protocols are typically known within the scientific community
- Choice driven by biological, physiological or pathological disease considerations, therapeutic area

Types of information not accepted as CCI (4/5)

- **Statistical considerations or calculations that feed-into**

- ☐ Sample size calculation
- ☐ Timing of/trigger of interim analyses or unblinding
- ☐ DMC decisions

Rejection reasons

- Widely known statistical and methodological concepts
- Statistical concepts are not product specific nor innovative
- Documented in published scientific guideline(s) and guidance document(s)
- Competitors would have to calculate (for example) the sample size for each clinical study, based on the scientific knowledge available at the time of the study initiation
- Sample size considerations are driven by scientific knowledge specific to the therapeutic area, disease, molecule and its behaviour

Types of information not accepted as CCI (5/5)

- **Bioanalytical methods**

- Rejection reasons

- Reflect general functioning principles of the immunoassay platform (e.g. MSD ECL)
 - Functioning principles - known within the scientific community and available in the public domain

- **Bioanalytical methods performance parameters' values**

- Rejection reasons

- Performance parameters (e.g. assay sensitivity, LLQ) confirmation of assay's reliability
 - Calculated based on sound scientific considerations, disease / product relevant and well-established methodology
 - Performance parameter's values are specific for the product and the studied population
 - Competitors would need to develop their own assay and validate it based on the data available to them

Take home messages

- Information not available in the public domain $\neq$ CCI
- Redaction proposals should not target the standard, well known statistical methods, methodological considerations, clinical research principles, clinical practice guidance and bioanalytical platforms/principles
- Make yourself acquainted to what is already disclosed by researchers / sponsors/ applicants in scientific articles and at scientific congresses
- Do not feel compelled to propose CCI – no Policy 0070 requirement
- Applicants/MAHs did not propose a single CCI redaction in 25% of initial MAAs and 70% of post authorisation procedures – testimony that clinical data is not CCI
- Take advantage of discussing with EMA any multiple / repetitive CCI proposals prior to the submission of the redaction proposal document package



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Thank you

silvia.garrido@ema.europa.eu

radu.popescu@ema.europa.eu

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