



Submissions and Agencies
Workstream

**Commercially Confidential
Information in clinical data
publishing**

Parveen Kumar

www.GenInvo.com

North America | UK | Europe | Asia



An abstract graphic on the left side of the slide, consisting of a network of light blue lines and dots that resemble a circuit board or a digital data flow, extending from the top to the bottom.

Company's Confidential Information (CCI) Confidential Business Information (CBI)

An abstract graphic on the right side of the slide, consisting of a network of light blue lines and dots that resemble a circuit board or a digital data flow, extending from the top to the bottom.

Definitions

EMA	CCI shall mean any information contained in the clinical reports submitted to EMA by the applicant/MAH which is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH.
PRCI	"confidential business information", in respect of a person to whose business or affairs the information relates, means - subject to the regulations - business information: • that is not publicly available, • in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and • that has actual or potential economic value to the person or their competitors because it is not publicly available, and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

EMA acceptance and justifications

Product Development Rationale, Overview, Study Objectives	• Clinical Development Programme – Exploratory endpoint not part of submissions • Regulatory guidance outside EU • Formal advice documents
Overview of Biopharmaceutics	Detailed assay information/quantitative composition/lot numbers
Overview of Clinical Pharmacology	Stereochemistry Issues - Competitors could gain a detailed understanding of the stereoisomers and three-dimensionality of the molecule.
Benefits and Risks Conclusions	Implications of any deviations from non-EU regulatory advice or guidelines.
Pharmacology studies	Information about specifications on company assays and immunogenicity assays
Determination of sample size	Analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates)
Method of PK/PD determination	Method of PK/PD determination

PRCI acceptance and justifications

C.08.009.2 (2)(a)	Clinical information that was not used by the manufacturer in the drug submission or supplement, or medical device application to support the proposed conditions of use or the purpose for which the drug or medical device is recommended
C.08.009.2 (2)(b)	Clinical information that describes tests, methods or assays used exclusively by the manufacturer

EMA Rejection reasons

Rejection 01	Information already available in the public domain or publicly available
Rejection 02	Common knowledge
Rejection 03	Disclosure due to public interest
Rejection 04	Insufficient justification
Rejection 05	Irrelevant justification

An abstract pattern of white lines and dots on a dark teal background, resembling a circuit board or a network diagram, located on the left side of the slide.

Experience with Rejections

An abstract pattern of white lines and dots on a dark teal background, resembling a circuit board or a network diagram, located on the right side of the slide.

Vendor Details as CCI/CBI

Vendor Names as CCI/CBI

Justification

This information concerns the identity of third-party fabricators and service providers and does not constitute clinical trial information falling within the scope of that term as per C.05.001. Economic value to competitor etc.

Regulatory response

The name of vendors involved in trial related duties are to be released. Addresses could be redacted as personal information



www.GENINVO.com
North America | UK | Europe | India

IP lot/batch numbers as CCI/CBI

Batch/Lot number of study drug as CCI/CBI

Justification

This method does not constitute clinical trial information falling within the scope of that term. This information may be of economic value to a competitor (for generating a biosimilar)

Regulatory response

Lot numbers are clinically relevant for consistently following information and outcomes of clinical trials and must remain unredacted unless they are at high risk for identifying participants



www.GENINVO.com
North America | UK | Europe | India

References section as CCI/CBI

External or internal references as CCI/CBI

Justification

Not clinical trial information. References searched, used and analyzed are of Economic value to competitor

Regulatory response

References are in scope for release and can not be redacted



www.GENINVO.com
North America | UK | Europe | India

Code snippet as CCI/CBI

SAS code snippet for analysis model used as CCI/CBI

Justification

Test methods or assays that could be of Economic value to competitor

Regulatory response

Model code does not meet the qualifying exemption for regulations selected



www.GENINVO.com
North America | UK | Europe | India

Questionnaires as CCI/CBI

Study specific questionnaires used as CCI/CBI

Justification

This information describes tests, methods or assays that are used exclusively by the manufacturer, and must not be disclosed

Regulatory response

Unique tests, assays, and methods does not include questionnaires, surveys, or case report-forms



www.GENINVO.com
North America | UK | Europe | India

Limit values as CCI/CBI

LLOQ, BLQ from PK analysis as CCI/CBI

Justification

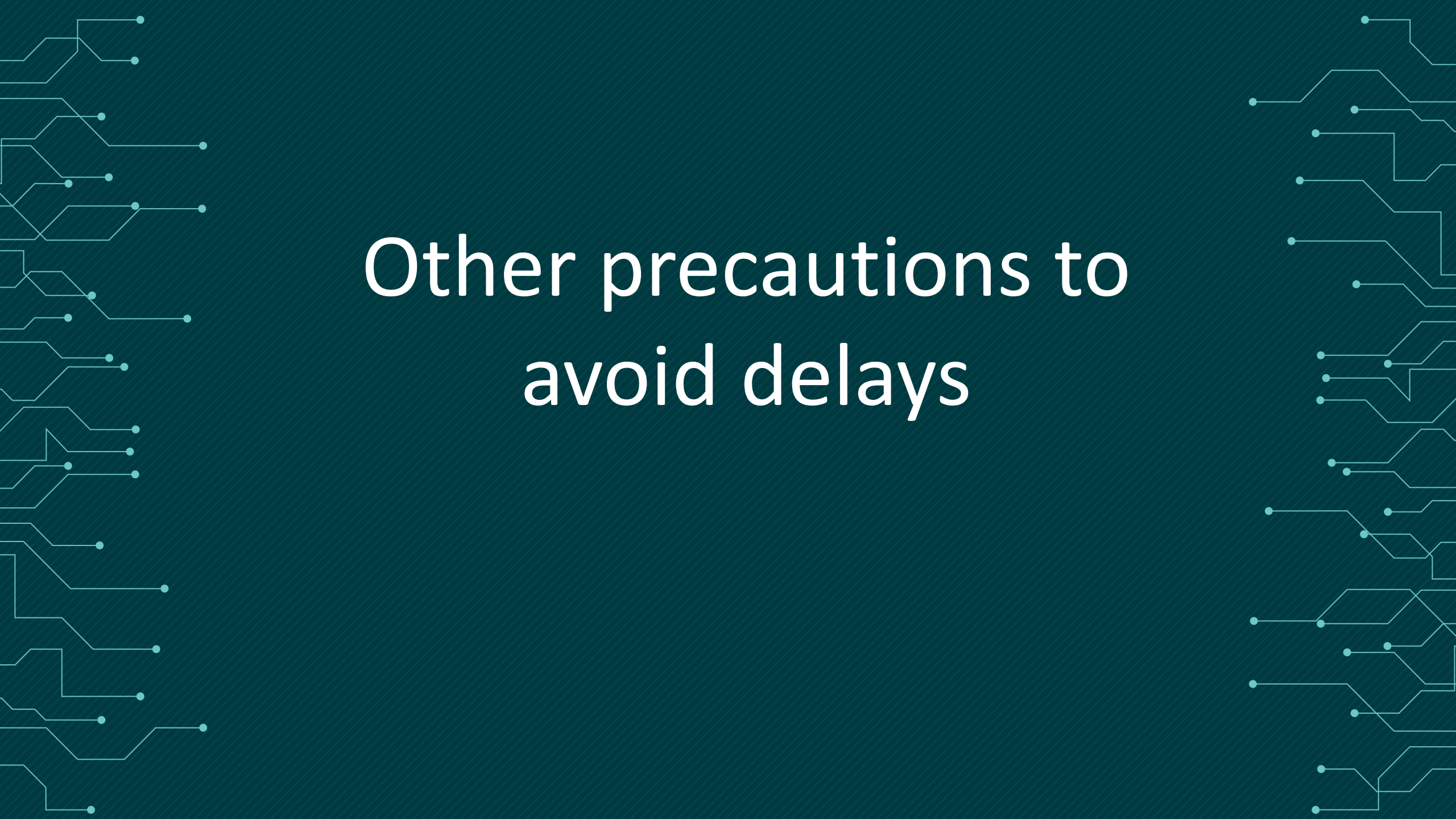
This information describes the lower limit of quantitation of Teva's tests, methods or assays that are used exclusively by sponsor

Regulatory response

Lower limit of Quantification are a common metric in statistical analysis, and must be included to allow for analysis of clinical data



www.GENINVO.com
North America | UK | Europe | India

The background is a dark teal color with a subtle, repeating pattern of light teal circuit lines and dots, resembling a stylized electronic board or data network. The pattern is most prominent on the left and right sides, framing the central text.

Other precautions to
avoid delays

Submission Package

PRCI

- Once submitted, number and order of rows in redaction control sheet shall not change
- Detailed justification column shall be updated for revised justification with Sentence starting with ORIGINAL for original justification and REVISED for updated justification

	G	H
n	Detailed Justification of Proposed Redaction	Health Canada's Response to Proposed Redaction
	REVISED: The manufacturer agrees with Health Canada's rationale. ORIGINAL: The information in these records concerns non-clinical information falling outside the scope of the definition of "information in respect of a clinical trial" as defined in C 000 000 1, as it concerns non-business data including non-business	

- Anonymisation report shall not include any details on CBI redactions
- Pages removed shall be mentioned in the redaction control sheet.

Process Related

- **Publicly available information:** Regulatory emphasize on information which is already in public. Sponsors shall have clear information on reports and protocols which are already available in public for particular project. It saves time for anonymization and regulatory bodies
- **Logical Justification:** Justification for CBI/CCI redactions shall be more logical and not only related to economic value to company. For example, if vendors name is redacted then it can be justified if there is any agreement between vendor and sponsor to not reveal vendor's name in public.
- **Standardize CBI redactions:** Standardize the CBI redactions across the company for publishing purposes CT.gov, other registries, and publications.



Ideas Delivered Intuitively

Thank You!

(309) 807-5006 | parveen.k12@geninvo.com | www.GenInvo.com

