

EUROPEAN
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CTIS Bitesize Talk: IMPD-Q-only submission

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A few housekeeping rules

Questions were collected in advance on www.sli.do
With event code **#bt10may**

Tips for optimal screen viewing



- ❖ Make use of the instructions under the embedded video in the event page and connect directly to the **IBM channel** *for the full-screen experience*
- ❖ Increase the *video quality* from the **HD button** on the right bottom of the screen setting it to 720p (or 1080p).
- ❖ Have a *stable internet connection*

CTIS Bitesize Talk - Panellists



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Glossary

IMPD-Q : quality part of the Investigational Medicinal Product Dossier

PO: Product Owner

RFI: Request for Information

CT: clinical trial

IMPD-Q-only application

Background:

- The sponsor of a clinical trial who is not the product owner (PO) of the IMP, may not have access to the quality IMPD (IMPD-Q).
- The clinical trial application associated with the IMP should include the IMPD-Q or reference the IMPD-Q from another application to enable the assessment.
- In the event of no access to the IMPD-Q, the associated considerations/RFI should not be directed to the sponsor who will not be able to respond.

For more information, please consult [Q 2.15 in European Commission Q&A](#)

IMPD-Q-only application – What are the options?

What are the options available to sponsors:

- 1) PO is sponsor of another clinical trial (CT) with same IMP authorised under the CT Regulation: reference should be made between the 2 trials
- 2) PO is sponsor of another CT with same IMP authorised under the CT Directive: the trial should be transitioned first to the CT Regulation and reference to it can be made as per point 1).

3) “IMPD-Q-only application”

- **For product owners that are not trial sponsors**
- For all situations where a quality RFI should go only to the PO

“IMPD-Q-only application” preparation process

- Product owner (PO) should be registered to **access CTIS** (either with sponsor admin or simply via trial centric approach)
- Create a DRAFT initial application including **Part I only** including all MSC included in the sponsor initial CT application
- The IMPD-Q application to include:
 - ✓ **Cover letter** with reference to the planned “sponsor trial”
 - ✓ **IMPD-Q** for the product associated to the application as per Annex I, section G of the Regulation
 - ✓ MIA and GMP certificates may be provided also in this application*
 - ✓ Placeholder documents for all mandatory documents for the other part I sections are not required and should be completed with a blank document
 - ✓ Mandatory structured data should be completed with the text “IMPD-Q” and mandatory dropdown should be completed as the sponsor trial (e.g. phase II)

*Sponsor of the trial may also submit the GMP and MIA

CTIS data fields for the IMPD-Q application

Field	Purpose
Trial Information	
Title	<i>IMPD-Q application</i>
Medical Condition	<i>IMPD-Q application</i>
Therapeutic area	<i>Corresponding to the sponsor trial</i>
Trial scope	<i>Corresponding to the sponsor trial</i>
Main objective	<i>Corresponding to the sponsor trial</i>
Eligibility criteria	<i>IMPD-Q application</i>
Primary endpoint	<i>IMPD-Q application</i>
Trial duration	<i>Corresponding to the sponsor trial</i>
Age range	<i>Corresponding to the sponsor trial</i>
Clinical trial group	<i>Corresponding to the sponsor trial</i>

CTIS data fields for the IMPD-Q application

Field	<i>Purpose</i>
Product Information	
Product and Substance	PO medicinal product selected from xEVMPD
Pharmaceutical form	PO medicinal product selected from xEVMPD
Mode of administration	Planned "sponsor trial"
Maximum dose	Planned "sponsor trial"
Maximum treatment duration	Planned "sponsor trial"
Sponsor Information	
Contact details	<i>PO contact details</i>

CTIS application for the sponsor trial

The information related to the product should match the information included in the IMPD-Q only in relation to structured data.

Reference should be made to the “IMPD-Q-only application” in the cover letter, stating the EU-CT number of the “IMPD-Q-only application”

Instead of the IMPD-Q, a letter of access document should be uploaded referring to the “IMPD-Q only application”

Full cooperation between PO and trial sponsor is expected

Procedural rules for initial application (1/2)

- PO submits “**IMPD-Q-only application**” (initial application for Part I only) at the same time sponsor submits the initial application of the trial for which the IMP is intended (“**sponsor trial**”). It is recommended that both submissions are **not more than 24 hours apart** to all MSC.
- “IMPD-Q-only application and “sponsor trial” are assessed in parallel:
 - same RMS and MSC must be selected
 - same timelines apply (*coordinated by RMS*)

Full cooperation between PO and trial sponsor is expected

Procedural rules for initial application (2/2)

- In order to apply the same assessment timelines, RFI are to be raised for both applications
 - RFI related to the Q-IMPQ are submitted to the PO to respond, RFI submitted to the sponsor are to be responded by the sponsor: *no access to each other application*
- **IMPQ-Q only application is not approved but concluded** (acceptable or not acceptable)
- The decision submitted by each MSC to the sponsor trial is based on the assessment of both applications
- **Lifecycle of IMPQ-Q via further initial applications:**
In case the IMPQ-Q is to be used for another application (subsequent addition of a member state, substantial modification for the trial) then the procedure described above needs to be repeated.

Procedural rules for Substantial Modification (IMPD-Q) (1/2)

- PO submits “**IMPD-Q-only SM application**” (initial application for Part I only) at the same time sponsor submits a **Substantial Modification (SM)** application of the trial for which a change to the IMPD-Q is needed (“**sponsor trial**”). It is recommended that both submissions are **not more than 24 hours apart** to all MSC.
- “IMPD-Q-only SM application” and “sponsor trial” **SM** are assessed in parallel:
 - same RMS and MSC must be selected
 - same timelines apply (*coordinated by RMS*)

Full cooperation between PO and trial sponsor is expected

Procedural rules for Substantial Modification (IMPD-Q) (2/2)

- In order to apply the same assessment timelines, RFI are to be raised for both applications
 - RFI related to the Q-IMPD are submitted to the PO to respond, RFI submitted to the sponsor are to be responded by the sponsor: *no access to each other application*
- **IMPD-Q only SM application is not approved but concluded** (acceptable or not acceptable)
- The decision submitted by each MSC to the sponsor trial is based on the assessment of both applications

Procedural rules for Additional MSC application (IMPD-Q only) (1/2)

- PO submits “**IMPD-Q-only AMSC application**” (initial application for Part I only) at the same time sponsor submits an **additional MSC application** to the trial (“**sponsor trial**”). It is recommended that both submissions are **not more than 24 hours apart** to all MSC.
- “IMPD-Q-only AMSC application” and “sponsor trial” **AMSC** are assessed in parallel:
 - same RMS and MSC must be selected for the “IMPD-Q-only AMSC application”
 - same timelines apply (*coordinated by RMS*)

Full cooperation between PO and trial sponsor is
expected

Procedural rules for Additional MSC application (IMPD-Q only) (2/2)

- In order to apply the same assessment timelines, RFI are to be raised for both applications
 - RFI related to the Q-IMPD are submitted to the PO to respond, RFI submitted to the sponsor are to be responded by the sponsor: *no access to each other application*
- **IMPD-Q only AMSC application is not approved but concluded** (acceptable or not acceptable)
- The decision submitted to the sponsor trial is based on the assessment of both applications by the AMSC

Benefits of CTIS use for IMPD-Q submission



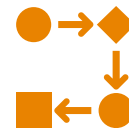
All in one system



User management &
confidentiality



RMS and MSC selection
tool



Workflow support
(validation &
assessment, RFI module,
timelines, etc.)

Any questions?

Further information

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