CTIS Bitesize Talk: Part I-only applications and Part II requirements in CTIS

30 Aug 2023

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A few housekeeping rules

Questions were collected in advance on www.sli.do
With event code #bt30aug

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
CT Regulation 536/2014 (CTR) - Article 11

Article 11 provisions give the ability to the sponsor to submit an initial application in a sequential fashion to request for a decision to conduct the clinical trial.

Article 11

Submission and assessment of applications limited to aspects covered by Part I or Part II of the assessment report

Where the sponsor so requests, the application for authorisation of a clinical trial, its assessment and the conclusion shall be limited to the aspects covered by Part I of the assessment report.

After the notification of the conclusion on the aspects covered by Part I of the assessment report, the sponsor may within two years apply for an authorisation limited to aspects covered by Part II of the assessment report. In that application the sponsor shall declare that he is not aware of any new substantial scientific information that would change the validity of any item submitted in the application on the aspects covered by Part I of the assessment report. In this case, that application shall be assessed in accordance with Article 7 and the Member State concerned shall notify its decision on the clinical trial in accordance with Article 8. In those Member States where the sponsor does not apply for an authorisation limited to aspects covered by Part II of the assessment report within two years, the application on the aspects covered by Part I of the assessment report shall be deemed to have lapsed.
For a multiple member states application, the sponsor can prepare an application that includes Part I and II to some Member States concerned and limited to Part I only (on the basis of article 11) to other Member States concerned.

99. Therefore, in order to shorten the assessment and approval timelines and to avoid unnecessary rejections due to time-constraints, the submission of complete and high-quality applications is of particular importance.

European Commission Q&A – Q 2.7 (99)
122. The CTR foresees that an application can be limited to Part I of the assessment report. In this case:

123. The application for Part I will follow the process as laid down in art. 5, 6 and 7

124. The subsequent application for Part II will be assessed in accordance with art. 7 and notification of decision will happen in line with art. 8
Considerations:

- The sponsors can submit partial initial clinical trial applications, in line with the requirements of Article 11 of the Clinical Trial Regulation (CTR), by submitting an application with Part I to all Member States Concerned (MSC) and part II to none or some MSC.

- After the conclusion on part I is issued, the sponsor has the option to submit the outstanding part II to the MSC, enabling the MSC to issue a decision. This will be enabled for 2 years and from the reporting date of the conclusion to part I.

- The initial application will remain under evaluation in a Member State from the time the Part I is submitted and until a decision is issued in that Member State or for a period of 2 years, after which the application will lapse.

For more information, please consult Q 2.2 in European Commission Q&A
Considerations:

- A decision (proactively by the Member States or tacitly*) can only be issued once Part II has been assessed and concluded.
  *Article 8.6 of the Regulation No 536/2014

  6. Where the Member State concerned has not notified the sponsor of its decision within the relevant periods referred to in paragraph 1, the conclusion on Part I of the assessment report shall be deemed to be the decision of the Member State concerned on the application for authorisation of the clinical trial.

- When submitting the additional part II, the sponsor should declare that they are not aware of any new substantial scientific information that would change the validity of any item submitted in the application on the aspects covered by Part I of the assessment report.

- The submission of further applications of any type (substantial modification, non-substantial changes), can only occur after all MSC have issued a decision, i.e. after all MSC have received both part I and part II of the dossier.

For more information, please consult Q 2.2 - Q 2.5 in European Commission Q&A
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Considerations:

- In cases where the sponsor needs to submit a substantial modification (SM) while some MSCs have not yet issued a decision, the sponsor has the option to withdraw the application for those MSCs.

- Sponsor can start the trial in an MSC that has issued a positive decision (authorisation) the trial without waiting the authorisation of the trial to all MSCs.

- If no deferrals have been applied on CTA data, only the parts (Part I or Part II) that have been submitted and authorised are published.

For more information, please consult [Q 2.2 - Q 2.5 in European Commission Q&A](#)
How to complete the dossier in CTIS
Part I is (by default) submitted and sponsor decides which Part IIIs to submit. Sponsor cannot submit the third one, as it has not been completed (tick in box is deactivated).
Sponsor selects to submit the Part I and Part II just for one MSC, scheduling the submission of the other two MSCs’ Part IIs for later.
After partial submission, users can see in the overview page of the trial that Part I has been submitted for all MSCs and Part II only for one MSC.
Submit button appears after Part I conclusion submission and allows sponsor users to submit the remaining Part IIs.
Sponsor can submit the Part II for the second MSC, but not for the third MSC, as it has not been completed; documents or data might be missing (tick in box is deactivated).
In the CT overview, we can see the status for each Part of the application. Part I has been authorised for all MSCs. Part II has been authorised for one MSC (GR), is under evaluation for the second MSC (DE) and is pending for the third MSC (IS).

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No deferrals have been applied. Part I is published after one MSC (GR) authorises the trial (by submitting Part II conclusion and Decision). Pending Part IIIs or Under evaluation Part IIIs are not published.

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In the Full trial information tab, users could access all documents and data for Part I (authorised by all MSCs) and all documents and data of the Part II for which the MSC has made a decision.

If Part II is pending or is under evaluation (consequently, no decision has been made), their respective data and documents are not published.
Q&A session

For questions, go to www.sli.do & use event code #bt30aug
We ask for *your feedback* on this event

The feedback **poll is now open** in Slido

Go to [www.sli.do](http://www.sli.do) & use event code #bt30aug
or scan Slido QR code:
CTIS training environment Survey 4.0

Survey 4.0 remains open where new potential users of CTIS can express interest to access the CTIS training environment (CTIS Sandbox).

CTIS Sandbox Survey 4.0

For post-event survey, go to www.sli.do & use event code #bt30aug
CTIS upcoming events

- CTIS Walk-in Clinic – 20 Sep 2023 – 16:00 – 17:00 CEST
- CTIS Sponsor End-user Training Programme – 19-22 Sep 2023

For post-event survey, go to www.sli.do & use event code #bt30aug
### CTIS data fields for Part I application

<table>
<thead>
<tr>
<th>Part I section</th>
<th>Sub-sections</th>
<th>Required Fields</th>
</tr>
</thead>
</table>
| Trial Details  | Trial Identifiers | • Full title  
|                |               | • Public title |
|                | Trial Information | • If Low intervention trial (check box) / Justification for the low intervention trial  
|                |               | • Trial phase |
|                | Trial Category | • Add condition (button) / Medical condition(s)  
|                |               | • Therapeutic area |
|                | Medical condition | • Trial scope  
|                |               | • Main objective |
|                | Main objective | • Add inclusion criteria (button)  
|                |               | • Add exclusion criteria (button) |
|                | Eligibility criteria | • Add primary endpoint (button) |
|                | End points | • Estimated recruitment start date in EEA  
|                |               | • Estimated end of trial date in EEA |
|                | Trial duration | • Age range  
|                |               | • Gender |
|                |               | • Clinical trial group  
|                |               | • (if check box ‘Vulnerable group’ is clicked) Recruitment population group |
| Protocol Information | Clinical trial protocol | • Protocol |
# CTIS data fields for Part I application

<table>
<thead>
<tr>
<th>Part I section</th>
<th>Sub-sections</th>
<th>Required Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sponsors</strong></td>
<td>Contact point for Union</td>
<td>• Add contact point for Union (button)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Scientific Contact Point</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Public Contact Point</td>
</tr>
<tr>
<td><strong>Products</strong></td>
<td></td>
<td>• +Add (button)</td>
</tr>
<tr>
<td>Role: Test (example)</td>
<td></td>
<td>• +Add (button) / Authorised product (example)</td>
</tr>
<tr>
<td><strong>Dosage and administration details</strong></td>
<td></td>
<td>• Route of administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maximum duration of treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maximum daily dose allowed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Total dose unit of measure</td>
</tr>
<tr>
<td><strong>Information about the modification of the medicinal product</strong></td>
<td></td>
<td>• Has the medicinal product been modified in relation to its Marketing Authorisation? (check box)</td>
</tr>
<tr>
<td><strong>Investigator brochure for the medicinal product</strong></td>
<td></td>
<td>• Investigator brochure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Summary of product characteristics (SmPC)</td>
</tr>
<tr>
<td><strong>IMPD Quality</strong></td>
<td></td>
<td>• IMPD-Q</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Simplified IMPD-Q</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Justification for no IMPD upload</td>
</tr>
<tr>
<td><strong>IMPD - Safety and efficacy</strong></td>
<td></td>
<td>• IMPD - Safety and Efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Simplified IMPD - Safety and Efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Justification for no IMPD upload</td>
</tr>
<tr>
<td><strong>Content labelling</strong></td>
<td></td>
<td>• Content labelling of the IMP’s</td>
</tr>
</tbody>
</table>

* To view the required fields per IMP please refer to question 2.12 on the [Frequently Asked Questions document](#) of Module 10 of the **CTIS Online Training Modules**.

For more information on the language requirements for Part I documents, please consult [Annex II of the European Commission Q&A](#).

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### Annex III: Part II documentation - where sponsors can find national requirements

<table>
<thead>
<tr>
<th>Member State</th>
<th>Websites where sponsors can find important information to submit high quality Part II documents as part of their clinical trial applications.</th>
<th>Email address for enquiries related to Part I clinical trial applications</th>
<th>Email address for enquiries related to Part II clinical trial applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>• <a href="http://www.basg.gv.at">www.basg.gv.at</a></td>
<td><a href="mailto:clinicaltrials@basg.gv.at">clinicaltrials@basg.gv.at</a></td>
<td><a href="mailto:clinicaltrials@basg.gv.at">clinicaltrials@basg.gv.at</a></td>
</tr>
<tr>
<td>Belgium</td>
<td>• CTR page on the FAMHP website: <a href="https://www.famhp.be/en/regulation_5362014">https://www.famhp.be/en/regulation_5362014</a></td>
<td><a href="mailto:CTR@fagg-aflmps.be">CTR@fagg-aflmps.be</a></td>
<td><a href="mailto:CTR@fagg-aflmps.be">CTR@fagg-aflmps.be</a></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>• <a href="https://www.bda.bg/bg/62-business-info/clinical-examinations-biz">https://www.bda.bg/bg/62-business-info/clinical-examinations-biz</a></td>
<td><a href="mailto:clintrialsquestions@bda.bg">clintrialsquestions@bda.bg</a></td>
<td><a href="mailto:clintrialsquestions@bda.bg">clintrialsquestions@bda.bg</a></td>
</tr>
</tbody>
</table>
| Croatia      | • [https://zdjeljivje.gov.hr/o-ministarstvu/djelokrug-1297/ljekovi-i-medicinski-proizvodi/1349](https://zdjeljivje.gov.hr/o-ministarstvu/djelokrug-1297/ljekovi-i-medicinski-proizvodi/1349)  
  • [https://www.halmed.hr/O-HALMED-a/Usluge-i-cjenik/Cjenik-usluga-HALMED-a/](https://www.halmed.hr/O-HALMED-a/Usluge-i-cjenik/Cjenik-usluga-HALMED-a/)  | klinicka.ispitivanja@miz.hr                                         | klinicka.ispitivanja@miz.hr                                         |
  • [https://www.suk1.eu/medicines/klh-ctis-01](https://www.suk1.eu/medicines/klh-ctis-01) (English)  | ctis-dpo@suk1.cz                                                   | eticka.komise@suk1.cz                                              |
| Denmark      | • [https://nationalcenterforetik.dk/ansoegerguide/ansoegninger-til-vmnk/kliniske-forsog-med-laegemidler/anmeld-kliniske-forsog-aft-agnt](https://nationalcenterforetik.dk/ansoegerguide/ansoegninger-til-vmnk/kliniske-forsog-med-laegemidler/anmeld-kliniske-forsog-aft-agnt)  | kf@dkma.dk                                                        | kontakt@dvnk.dk                                                   |

Full list of national requirements for Part II documentation can be found [here](https://www.famhp.be/en/regulation_5362014)

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Additional resources

- Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation

- CTCG Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under the Directive 2001/20/EC that will transition to the Regulation (EU) No. 536/2014
Any questions?

Further information

For the CTIS Newsletter sign up at https://ec.europa.eu/newsroom/ema/user-subscriptions/3201/create

For upcoming CTIS events visit the EMA event page.

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