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Directorate-General PRE authorisation/Research and Development Division
(human use)

Q&A Information Session on Time Slots for CTR pilot initial dossiers

1) Temporary procedure with time slots, is this also applicable for COVID-19 initial dossiers?

No, only for usual initial CTR pilot dossiers, outside the COVID-19 indication.

2) For how long do you anticipate this temporary solution will apply?

We hope for as short time as possible, but as the recruitments to reinforce the Division R&D should still be initiated, it is difficult to provide a clear endpoint.

3) Does it apply to VHP-plus dossiers as well?

No, but we still ask to send us a letter of intend for VHP plus dossiers and we currently cannot accept more than 1 or maximum 2 VHP plus dossiers per month.

4) Do we receive a confirmation e-mail when the booking is finalized?

Yes, you can see how it looks in the presentation slides.

5) Does this apply for all submissions or only for the submissions we do in CTR pilot?

This only applies to submissions in the CTR pilot.

6) Should the person that books also perform the submission, or can a colleague do the submission?

No, we will be able to identify the trial with the Eudra-CT number even if this is not the same person who submits the dossier. However, it must be clear that it is not allowed to book for a specific trial and to submit another one.

7) If we have 2 sister studies (same product), can we use one slot for both?

When two studies are very similar, only one time slot needs to be booked. You can accomplish this by mentioning in the box 'Title of the trial' both titles and in the box 'EudraCT number' both numbers. However, we would like to ask you to send us an email explaining the differences between both trials when this booking has been done. As such, if we conclude that the differences are too important, you will be asked to book two time slots.

8) I am also interested to receive answer to the previously asked question about sister studies. We will also submit 2 very similar studies. Only 1 a few differences in the protocol (1 exclusion criteria is different), same study design, same product, same patient material and same sites is used. So review of submission package should best be done in one shot. Can we use 1 timeslot for both studies?

We can accept that only one time slot is used for both studies. But studies must be really similar. Same indication, little difference (see also Q7).

9) Will all timeslots be opened as of 08Feb2021 - or will they be opened one month at a time for instance? In other words, how long in advance can we book our submission?

At the start of the time slots, which will be for submissions starting from the 15th of February 2021, bookings until the end of March will be possible. April will be opened on the first Friday of March, May on the first Friday of April and so on until the end of this temporary solution.

10) How long upfront can we book - limitation?

See Q9: you will be able to book until the end of the next month.

11) Is there a limitation per CRO to book time slots?

There will be no limitation applied, however, we will check every booking that has been done to avoid duplications of the same trial and to rule out any misuse of the system.

12) Would it be possible to set a limitation of number of timeslot reserved by a given sponsor or CRO (for example for the coming 2-3 months) to give the opportunity to other companies to use a timeslot as well?

No, there won't be any limitations, however, there will be a close monitoring to avoid misuses.

13) I don't agree with limiting submissions for CROs. We have many sponsor and many studies. However I can promise that we will not book slots if we don't think we will be able to meet that deadline for the submission. Whether a sponsor decides to submit himself, or works with CRO for this, it shouldn't limit his possibilities to choose a time slot.

The limitation of 2 time slots per week applies to all sponsors/applicants, no difference is made whether or not the sponsor is a CRO.

14) Will there be any costs for the review of the dossiers?

No, these dossiers are CTR pilot initial dossiers. The submission of these dossiers is free of charge. However, when no time slot is available and the sponsor/applicant decides not to delay the submission, this needs to go via the Directive, for which a fee applies.

15) Is it correct that you book a timeslot but the submission is still via CESP?

Yes, this is correct. The purpose of the system is to limit the number of initial CTR pilot dossiers accepted per period of time. But once accepted, the CTR pilot process, as usual, is followed.

16) Can we just mention a company as applicant?

Yes, you just need a name (person or company) and an e-mail address (personal or generic) where you will receive the confirmation of booking.

17) Could you please briefly described the pilot submission for COVID-19 clin trial?

The limitation doesn't apply to Covid-19 CTR pilot dossiers.

Applicants who want to submit a Covid-19 dossier through the pilot process are asked to send an e-mail to **CTRpilot@fagg-afmps.be** with the following information:

- Eudra-CT number
- Title of the trial
- Phase
- Sites involved in BE
- ATMP or GMO contained use trial ?
- Foreseen submission date ?
- Protocol synopsis (if possible)

18) For VHP trials we want to go through the pilot, does the booking system also apply?

No, for VHP plus trials please see answer to Q3

19) What if all sites aren't confirmed yet? Best to mention all possible sites?

Yes, in order to allow the College to select an independent EC, even if not all sites are selected at the end of the day.

20) How many dossiers will you treat per timeslot?

One CTR pilot initial dossier per time slot and two time slots per week (2 dossiers per week).

21) Not relating to CTR directly: but if we need to register a new compound with EMA, it may take up to 10 days now… this could already take up the 2 weeks of the booking and does not simplify the process as documents required for this (final IB) not always available on time

Yes, that's why the time slots procedure allows this 2 weeks flexibility. However, we must keep this flexibility reasonable to allow us to keep a clear view on our planning.

22) **what about studies submitted in Dec 2020 where we still did not receive a T0? do we need to reserve a timeslot?**

No, already submitted studies will be processed in the usual way. Little by little we will resorb our back log. We do all our possible to send you a T0 e-mail as soon as possible.

23) **If there is no timeslot and we will submit via the old way, what delays do we expect?**

Usual 7 May 2004 delays can be expected for initial CTAs submitted via the old way.

24) **Is this temp solution also applicable for submission of amendment to trials already ongoing in the frame of the pilot?**

No, only applicable to CTR pilot initial dossiers.

25) **Is it better to have an account a sponsor or an account a person ?**

Both are possible and accepted. See answer to question 16).

26) **A general question on the ECTR pilot, the guidance document indicates that the pilot project is limited in time. It will not continue once the CTR regulation is implemented. Is it expected that studies submitted in the pilot will continue in the ECTR or would there be other options available?**

Even if submitted and assessed in the CTR spirit, the current legislation is still the law of 7 May 2004 (transposition of the Directive 2001/20/EC into BE national law). So all approved dossiers before implementation of CTR will de facto not yet been considered as CTR dossiers but as Directive dossiers.

- ⇨ either the CTR pilot trial will end before the transition period is finished (3 years after implementation of CTR) or the dossier will have to be switched from the Directive to the CTR. However in the meantime (before switch) SMs will be accepted in the CTR pilot process until the end of the transition period,

27) **Do you have any news on the actual entry into force of the CTR?**

The CTR will enter into force in December 2021

28) **Wouldn't it be better to allow only booking of submissions which are almost ready for submission like it is done in the CWOW pilot in UK?**

This would imply a huge amount of work for the management of the proposed dossiers, the submission of which being only confirmed when almost ready. Moreover this kind of system would not allow us to have a good distribution of the submitted dossiers in the month.

29) **If we did not yet receive T0 for SM submitted in Jan 2020 via CTR pilot due to backlog, how long will it take before we receive T0?**

We currently have 3 to 4 weeks delay for giving the T0. The time slots system will allow us to work on the backlog and to come back as soon as possible to a situation where we stick to the CTR pilot process timelines, as foreseen in the CTR pilot guidance for sponsors available on our website.

30) **And how to handle with e.g. a dear investigator letter, which must be submitted within 24 hours?**

A Dear Investigator Letter is a notification and can be directly submitted via CESP. The time slots system does not apply to notifications and to substantial modifications, only to initial non Covid-19 dossiers and non-VHP plus CTR pilot dossiers.

31) **An example. If I book for June 1 (Tue), I have up until June 15 to submit? Is this correct? If I submit my application on June 1, when will it be reviewed.**

Submissions will be accepted from the Monday of the time slot week until the Sunday of the week after.

E.g.: if reserved time slot is Thursday 18/02/2021, submission of the dossier will be accepted from Monday 15/02/2021 until Sunday 28/02/2021.

E.g.: if reserved time slot is Tuesday 23/02/2021, submission of the dossier will be accepted from Monday 22/02/2021 until Sunday 07/03/2021.

Once our backlog will be resorbed, timelines as foreseen in the CTR pilot guideline for sponsors will be again respected.

32) **If timeslots are cancelled and re-open for other sponsors, how fast will the system show the new possible timeslots ?**

It is important to send us an e-mail to **CTRpilot@fagg-afmps.be** if this is really not possible to submit the dossier following the time slot reserved. In this way, we will be able to free the time slot on the same day (if e-mail sent in the normal work hours).

33) **If the timeslot we want to book is already saturated, will we get a refusing e-mail for our booking?**

No, you will not be able to book. You will directly see a message that there is no available time slot at that date (see info session presentation slides).

34) **Is the timeslot procedure applicable for USM and EoT notifications?**

No, these notifications can be submitted directly via CESP

35) **If you are not able to submit the dossier within 1 week of the reserved timeslot, do we need to reserve a new timeslot or will a new date be discussed via e-mail/tel?**

See answer to question 31). You will have 2 weeks from the time slot date to submit the trial. If not possible within these 2 weeks, yes, a new time slot will have to be reserved.

36) **Could you please provide us with more details on the hybrid solution ? Does it mean that the dossier will be submitted by the sponsor to all the ECs ? Will they accept it without their local requirement s (e.g. additional forms) ?**

Discussions are ongoing with the College and the ECs on this matter as there are some hurdles to be taken.

37) **If we prepared for a Pilot submission but there are no timeslots left, are we allowed to submit the dossier for CA with the pilot structure when we submit via the old directive?**

Yes

38) **Do we need to book another timeslot in case we need to provide missing documents to validate a submission?**

No, once the dossier is submitted, the normal CTR pilot process will apply

39) **How many initial non-COVID-19 trials per month have been submitted the last few months?**

It was variable. More dossiers were submitted during the waves. Some months we received up to 10 Covid-19 dossiers (CTR pilot or Directive). We also receive a lot of substantial modifications /amendments for these dossiers.

40) **How will this allow you to have more time? The dossiers that are not submitted via the pilot will need to be submitted via the directive.**

Management of CTR pilot dossiers, for which the FAMHP is the National Contact Point, is much more time consuming than management of Directive dossiers.

41) **Will pilot studies be prioritised compared to studies submitted via directive or hybride way?**

No

42) **What happens if not all documents are available at the time of the booked slot, can the sponsor already submit what is available?**

There will be no change compared to the current process : a dossier should be complete at the moment of the submission.

43) **How many dossiers are usually submitted via the CTR pilot on a weekly basis (before the time slots were in place)?**

The time slot system will limit the acceptance of new initial dossiers in the CTR pilot to around a half of the number of dossiers we currently receive.