

# Webinar: CTR pilot dossiers – time slots

Date 04.02.2021

## Before we start ...

- Please **mute** your **microphone** and **disconnect** your **video** to ensure a good connection.
- This presentation will take about one hour.
- Please use the **chatbox** to raise **questions**. At the end of the presentation, we will go through these questions. Untreated questions will be answered in a Q&A document published on our website.
- If you have additional questions after the presentation, please contact us at [CTRpilot@fagg-afmps.be](mailto:CTRpilot@fagg-afmps.be)



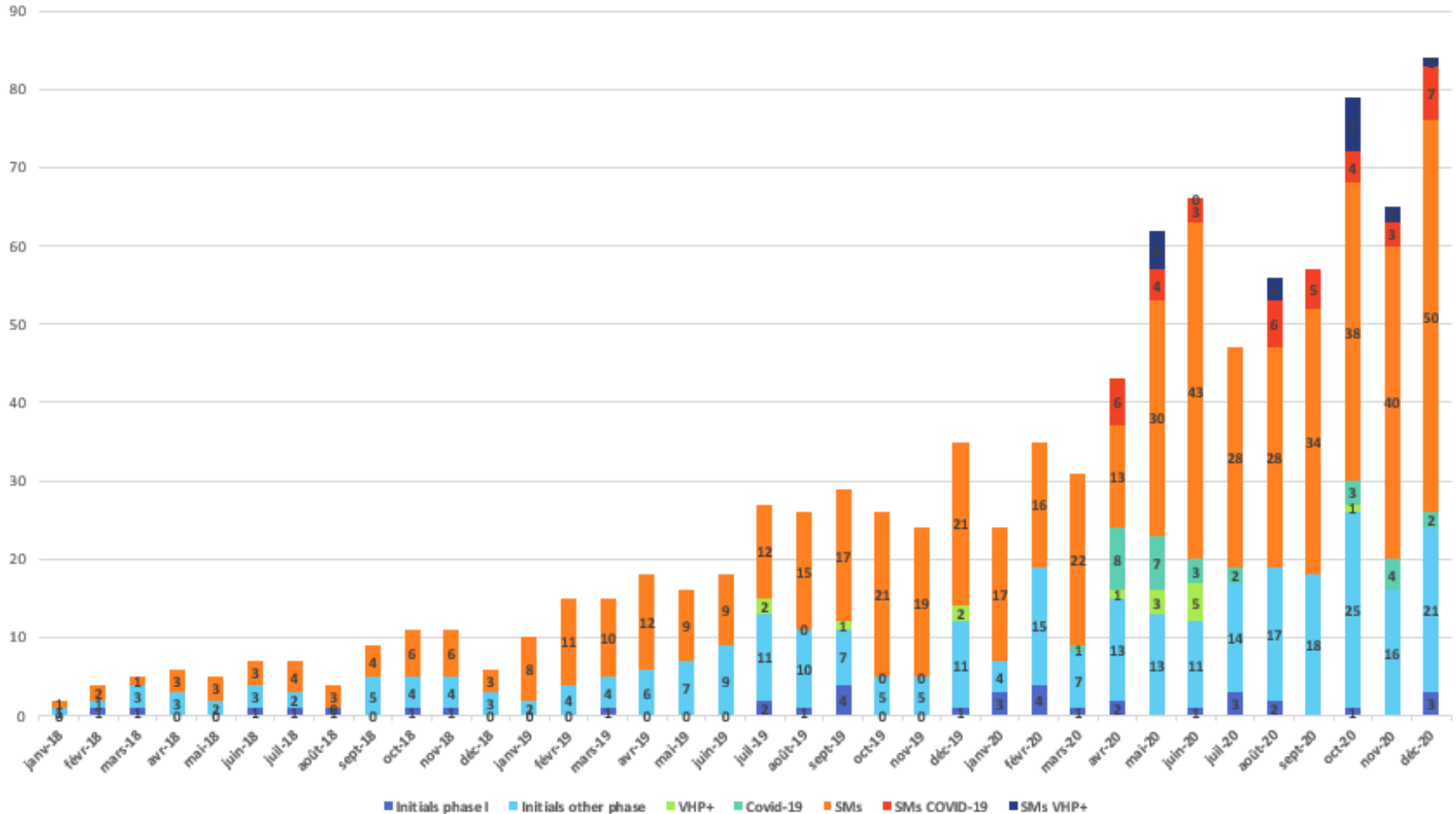
# Agenda

- Progress of the CTR pilot project
- Current situation and challenges
- Temporary procedure with time slots
- What if a sponsor/applicant cannot find a time slot ?
- How to book a time slot?
- How to book a time slot – example
- Conclusion

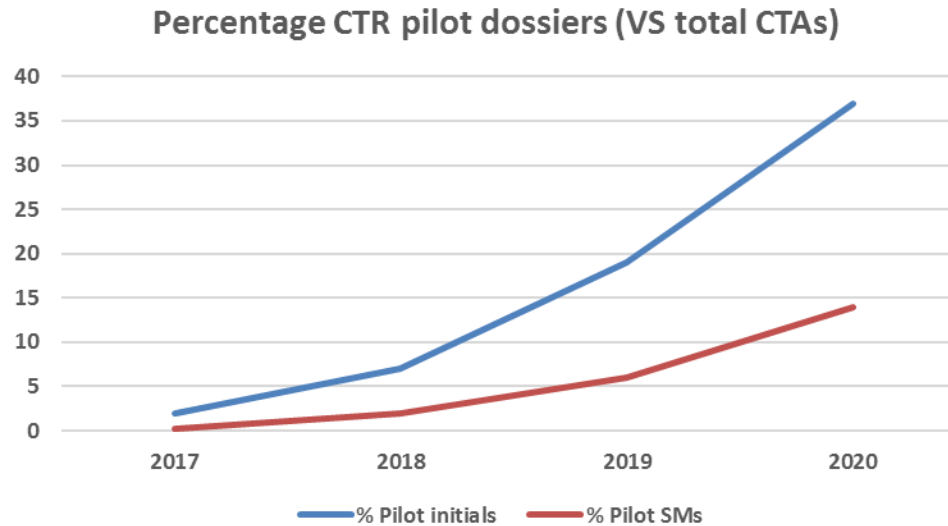


# Progress of the CTR pilot project

Nbr of dossiers received per month (TS)



# Progress of the CTR pilot project



Type of dossier	2017	2018	2019	2020
% Pilot initials	2	7	19	37
% Pilot SMs	0.2	2	6	14



# Current situation and challenges

- Around 40% of all initial CTA dossiers are now submitted through the CTR pilot project
  - Continuous progress of the CTR pilot 😊
- But second wave of the COVID-19 pandemic
  - Direct impact: increase of COVID-19 CTA dossiers
  - Indirect impact: decrease of our capacity for non-COVID-19 dossiers (Pilot and Directive)
  - Additional resources are foreseen but in the meantime we experience delays in handling a part of the CTA dossiers



# Temporary procedure with time slots

- Measures have been taken to reinforce the R&D teams, however not yet in place
- Temporary procedure: limit the number of CTR pilot **initial trials** accepted per period of time (2 per week) to stabilize the situation
- The procedure with time slots **does not apply** to COVID-related initial trials nor Substantial Modifications.



# Temporary procedure with time slots

- A web application with time slots will be available for sponsors/applicants from 8 February 2021 on our website.
- This will allow sponsors/applicants to book a time slot for the submission of an initial CTR pilot dossier as of 15 February 2021.





# What if a sponsor/applicant cannot find a time slot?

- At this moment, we are looking for a solution, i.e. a hybrid pathway, where sponsors who have prepared their application according to the CTR pilot project but no time slot is available anymore.
- Discussions are ongoing with the College and the ECs



# How to book a time slot?

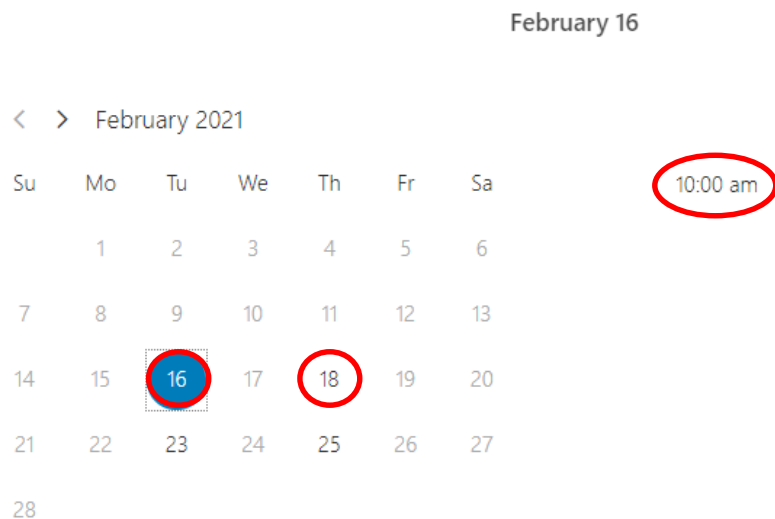


# How to book a time slot?



Federal agency for medicines and health products  
(FAMHP)

CTR Pilot Application Bookings  
4 hours



Every week, **two time slots** are available: on **Tuesday and Thursday at 10 AM.**

Please note: we expect you to submit your dossier the week that you have booked a time slot or the week after at the latest.

# How to book a time slot?



Federal agency for medicines and health products  
(FAMHP)

CTR Pilot Application Bookings  
4 hours



February 16

< > February 2021

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

10:00 am

Select the '10:00 am' time slot that is available.

# Federal agency for medicines and health products (FAMHP)

CTR Pilot Application Bookings  
4 hours



February 04

< > February 2021

Su	Mo	Tu	We	Th	Fr	Sa
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14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

There is no availability on this date. Please choose another one.

Above message will be shown if no time slots are available for that specific week

## Add your details

Name

Email

---

### Provide additional information

Sponsor

Applicant

EudraCT Number (optional)

Title of the clinical trial

Phase of the clinical trial (avec un dropdown: Phase I, Phase II, Phase III, Phase IV)

--select an option--



Names and addresses of sites involved in the clinical trial (please use the official name of the institution)



Is the IMP an ATMP

Is the IMP a GMO contained use product

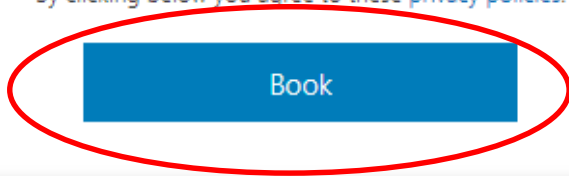
Therapeutic indication

Is the trial an extension trial from a previous trial

If yes on the previous question, please indicate the pilot number and EudraCT number (optional)

Don't forget to click on 'Book'

By clicking below you agree to these [privacy policies](#).



# How to book a time slot – example







# Federal agency for medicines and health products (FAMHP)

CTR Pilot Application Bookings  
4 hours



February 18, 10:00 am

< > February 2021

Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

10:00 am



## Add your details

Marleen Laloup

marleen.laloup@fagg-afmps.be

## Provide additional information

Sponsor

Sponsor X

Applicant

Applicant Y

EudraCT Number (optional)

1234567

Title of the clinical trial

fmoqsfoidsqhfidsqpfdsq

Phase of the clinical trial (avec un dropdown: Phase I, Phase II, Phase III, Phase IV)

Phase I



Names and addresses of sites involved in the clinical trial (please use the official name of the institution)

site 1: Victor Hortaplace 40/40, 1060 Brussels; site 2: Scientific lane 20, 2878 City A; Site 3: Study Avenue 3, 8749 City B



Is the IMP an ATMP

No



Is the IMP a GMO contained use product

No



Therapeutic indication

Oncology

Is the trial an extension trial from a previous trial

No



If yes on the previous question, please indicate the pilot number and EudraCT number (optional)

By clicking below you agree to these [privacy policies](#).

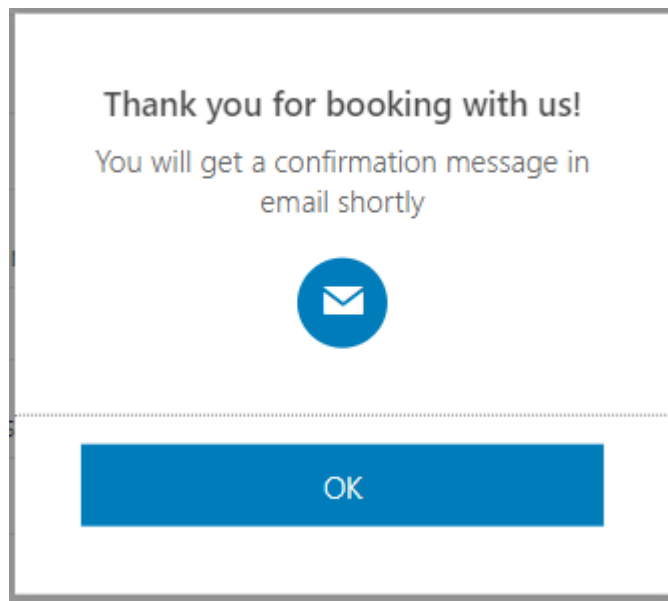
Book

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# How to book a time slot – example



# How to book a time slot – example

You will receive a booking confirmation at the email address you have provided



Confirmed booking for  
**Marleen Laloup**

CTR Pilot Application Bookings



Thursday, 18 February 2021

10:00 - 14:00

(UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm,  
Vienna

Have a conflict?  
[Change your appointment](#)

If you want to cancel your time slot, please **do not use this button.**

Send an email to [CTRPilot@fagg-afmps.be](mailto:CTRPilot@fagg-afmps.be) to cancel your time slot.

02-2021

# Conclusion

- CTR pilot project, including VHP plus process, remains the best way for all involved to train the future CTR conditions
- The CTR pilot project will continue until the implementation of the Clinical Trial Regulation
- The enthusiasm and massive participation to the CTR pilot is highly appreciated by the College and FAMHP, however, due to the particular circumstances, we need to introduce time slots, only for initial non-COVID-19 trials.
- We intend to return to our normal procedure with full acceptance of all proposed dossiers for the CTR pilot as soon as possible



**Your medicines and health products,  
our concern**