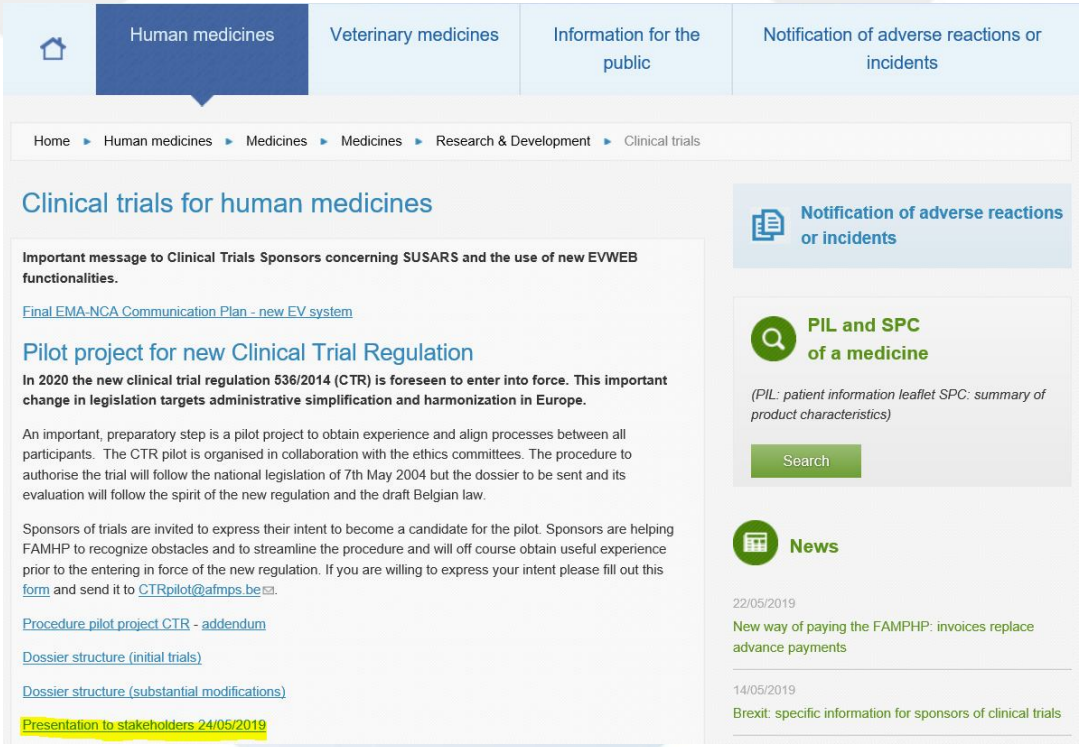
CTR / Pilot info session for sponsors

DG pre, R&D

24/05/2019



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Agenda

A. BE CTR pilot

1. Pilot project procedure updates
2. Pilot figures
3. Our feedback on submitted dossiers
4. Answers to feedback received from sponsors
5. Safety reporting clarifications
6. Additional information and clarifications
7. Conclusion on pilot and questions

B. CTR Pilots: Belgium versus other EU member states

C. EUPD + demo

BE CTR pilot

DG pre, R&D

24/05/2019

Anne Lenaers

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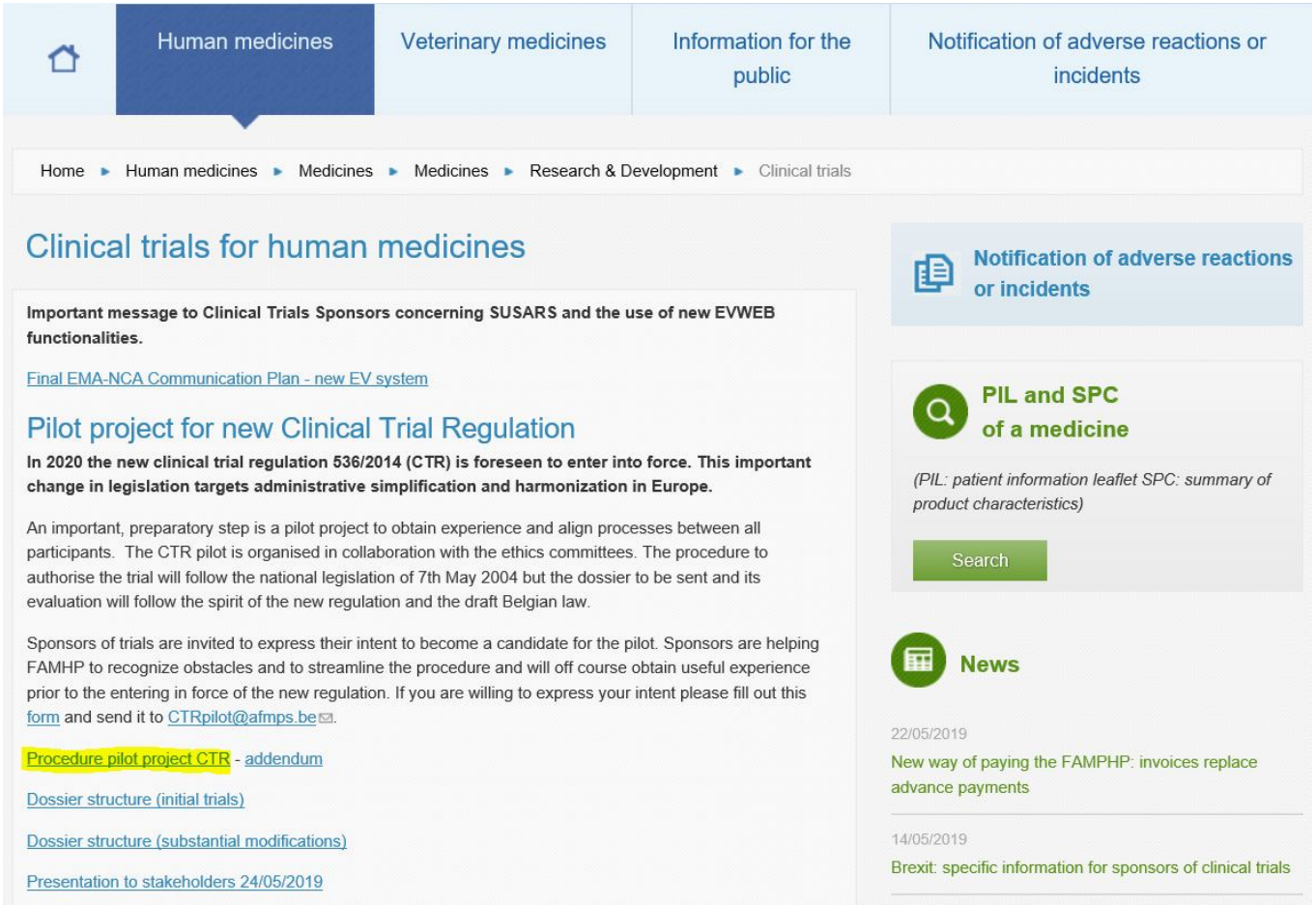
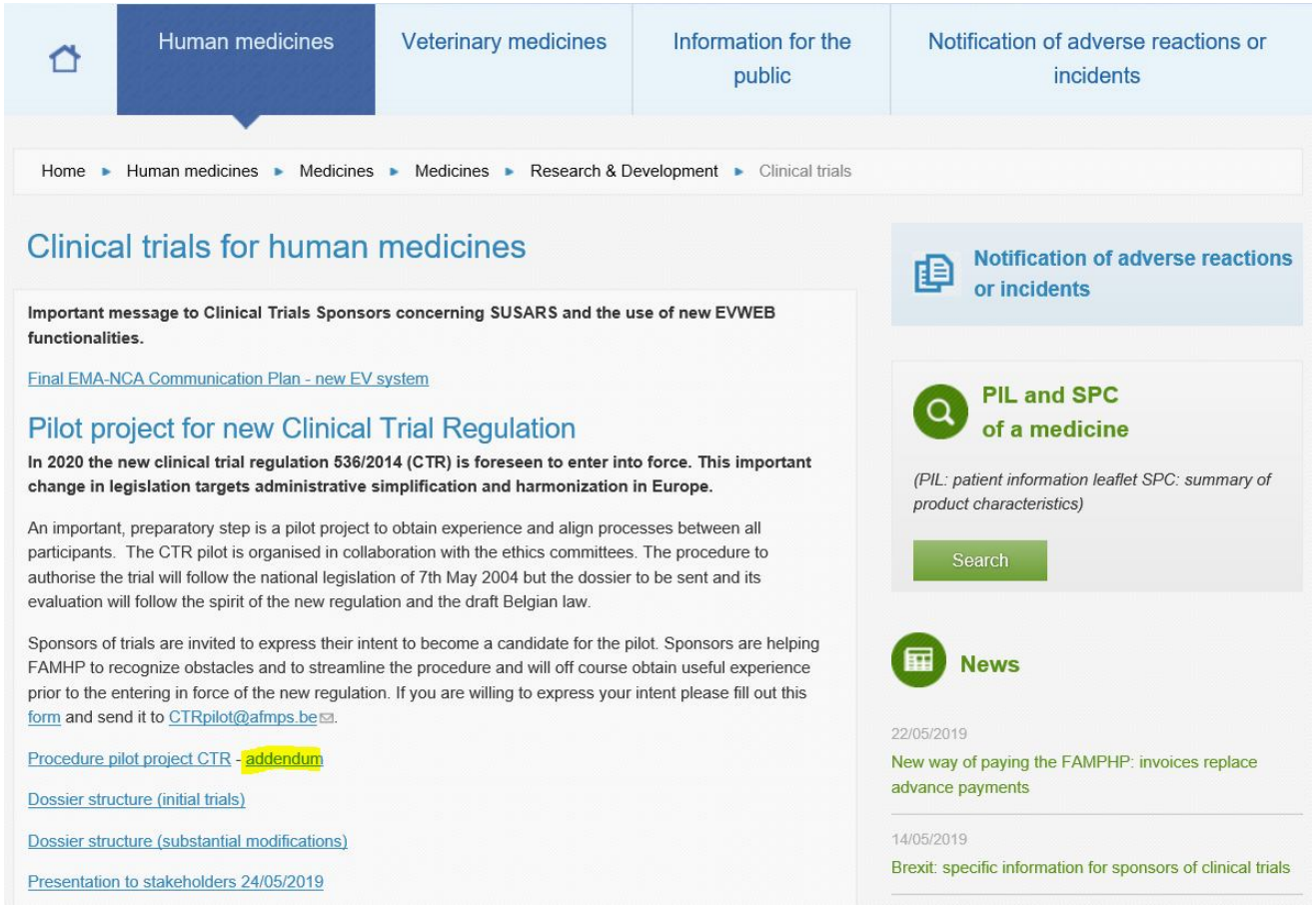
1. Pilot project procedure updates

- **Sixth version** of the CTR pilot guidance for sponsors available on FAMHP website:



1. Pilot project procedure updates

- **Addendum introducing the VHP plus process :**



1. Pilot project procedure updates

Main changes/clarifications in V6 of the pilot guidance :

- Introduction of the VHP plus process
- Clarification on substantial modifications and examples in a table
- From 1st March 2009, all proposed CTAs accepted in the CTR pilot project
- Importance to provide a copiable list of documents (and versions) in the initial submission but also after each change of versions (after RFI, after condition, in a substantial modification)
- Clarification on ICF languages and translations
- Clarification on GDPR requirements

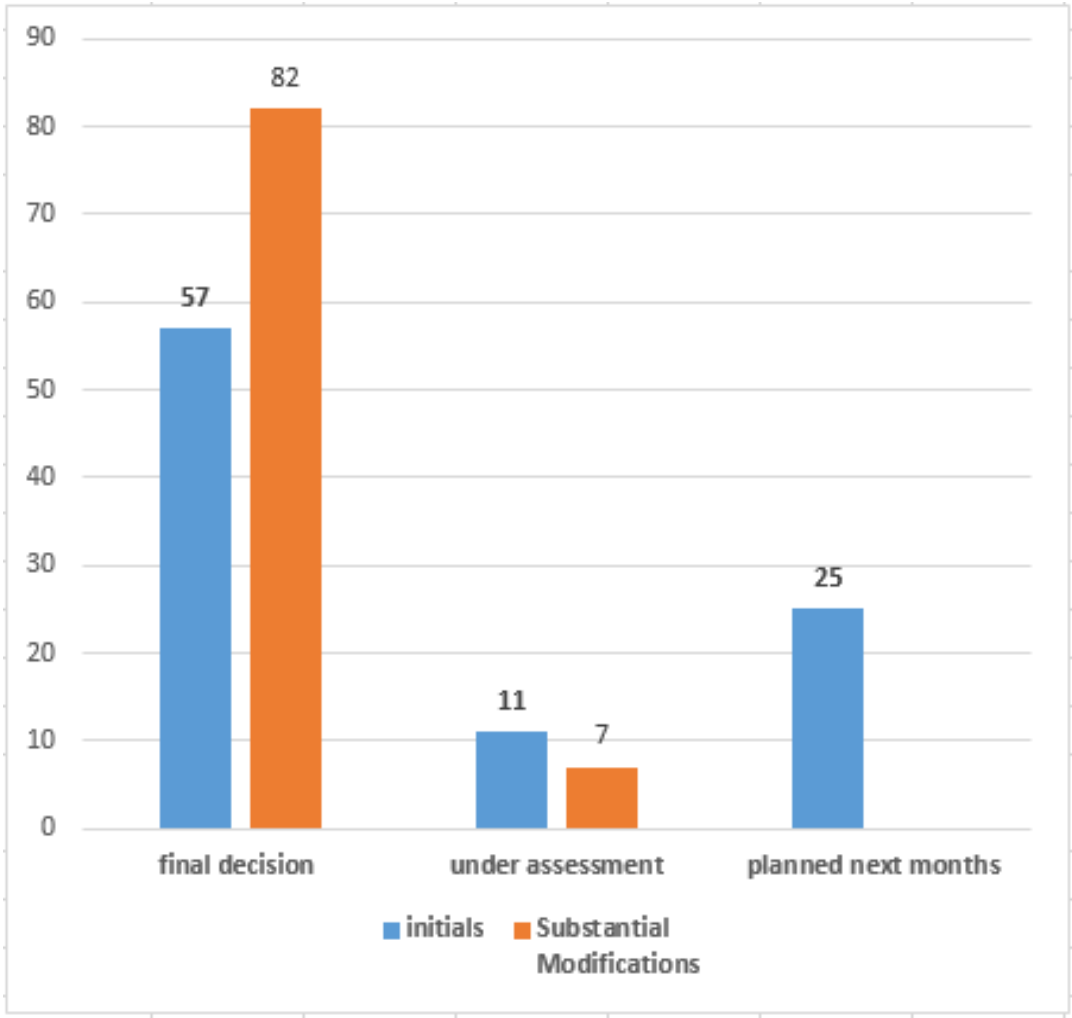
1. Pilot project procedure updates

VHP plus timelines :

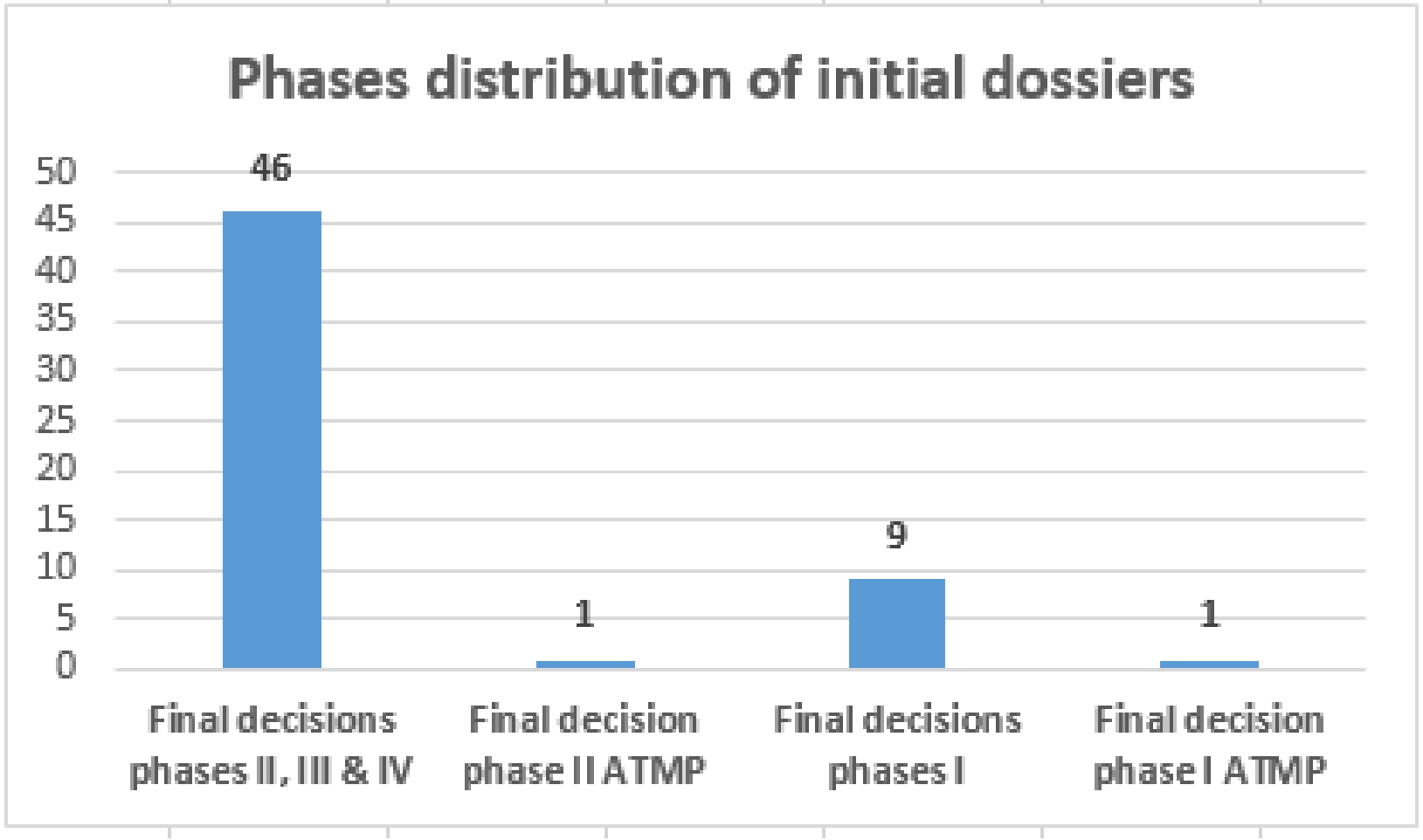
Step	DAY	Part II process with NCP
Submission to the VHP-A by sponsor and Confirmation of receipt sent to Sponsor	-5	submission of part II via CESP to NCP
Date informing NCA on VHP/VHP-Dossier location in VHP area	-5	begin validation of part II by NCP
Final acknowledgement of receipt to Sponsor	0	Part II dossier should be complete at day 0 of VHP (except written statements) ICFs and patients questionnaires included **in language of evaluating EC.**
DAR/GNAs to be stored in VHP-area/VHP-Database by Ref.-NCA	20	
Statement on ASR/GNAs by P-NCAs and additional GNA to be entered in VHP-DB	25	
Date of consolidated List of GNAs by Ref-NCA in VHP-Database due by	28	
Date acceptance P-NCA of consolidated list of GNA	29	
TC on GNA before	30	
Info of Sponsor on GNAs by	32	Questions on part II sent to the sponsor
Response on GNA by sponor due by	42	
Assessment of response by Ref.-NCA in VHP-area / VHP-Database by	49	Answers from the sponsor on part II to be provided for **day 49 (17 days timeline to answer).**
Response of P-NCAs on assessment by Ref.-NCA in VHP-Database by	56	
Final ASR by Ref-NCA to be stored in VHP-area by	57	
TC on unsolved GNA before	58	
End of VHP / final info to Sponsor	60	Info to the sponsor on part II by NCP
National applications by Sponsor	80	Mandatory submission of written statements with official submission of part II
National approvals by NCA	90	EC approval letter to the sponsor at the latest for day 90.

2. Pilot figures

Global overview pilot dossiers (2017 + 2018 + 2019 so far)

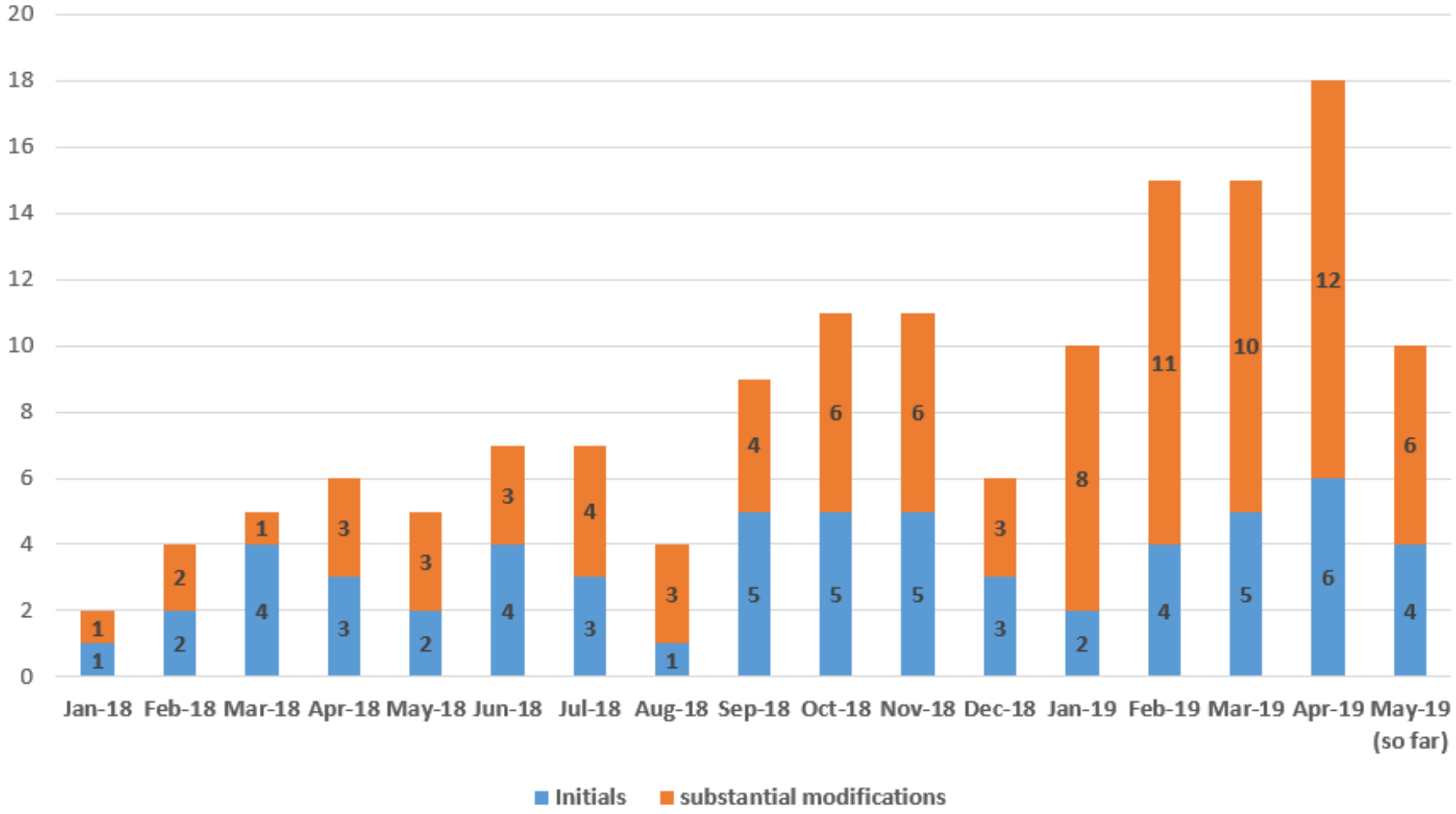


2. Pilot figures



2. Pilot figures

Evolution of the pilot submissions : number of initials raises from beginning 2019



Mean timeline between submission and final conclusion (as presented at the BRAS meeting in September 2018)

Timeline from reception to final conclusion (March 2018)

	Nbr received	Max timeline following pilot procedure: from reception until final conclusion	Nbr within timelines	Nbr out	Average timeline (real)
Initial					
phase I	**2**	47	1	1	**51**
phase II-IV	**9**	65	7	2	**58**
SM					
phase II-IV	**6**	61	6	0	**34**

Timeline from reception to final conclusion (data 3/9/2018)

	#	Max timeline (procedure) : from submission until final conclusion	# withintimelines	# out	Average timeline (real)
Initial					
phase I	**5**	47	4	1	**39**
Phase I ATMP	**1**	77	1	0	66
phase II-IV	**19**	65	17	2	**56**
SM					
phase II-IV	**21**	61	21	0	**29**

2. Pilot figures

Mean timeline between submission and final decision : update info session end January 2019

Timeline **from reception to final conclusion** (**data 03/09/2018**)

	#	Max timeline (procedure) : from submission until final conclusion	# within pilot procedure timelines	# out pilot procedure timelines	Average timeline (real)
Initial					
phase I	**6**	47	5	1	**39**
Phase I ATMP	**1**	77	1	0	66
phase II-IV	**21**	65	19	2	**56**
SM					
phase II-IV	**24**	61	24	0	**29**

Timeline **from reception to final conclusion** (**data 31/12/2018**)

	#	Max timeline (procedure) : from submission till final conclusion	# within pilot procedure timelines	# out pilot procedure timelines	Average timeline (real)
Initial					
phase I	**8**	47	7	1	**38**
Phase I ATMP	**1**	77	1	0	66
phase II-IV	**29**	65	26	3	**54**
SM					
Phases II, III & IV	**35**	61	35	0	**29**
Phases I	**2**	47	2	0	23
Phases I ATMP	**2**	77	2	0	24

2. Pilot figures

Mean timeline between submission and final decision :

Update 22/05/2019

Timeline from reception to final conclusion (data 31/12/2018)

	Nbr	Max timeline (procedure) : from reception until final conclusion	within pilot procedure timelines	# out pilot procedure timelines	Average timeline (real)
Initial					
Phase I	**8**	47	7	1	**38**
Phase I ATMP	**1**	77	1	0	66
Phase II-IV	**29**	65	26	3	**54**
SM					
Phases II, III & IV	**35**	61	35	0	**29**
Phases I	2	47	2	0	**23**
Phases I ATMP	**2**	77	2	0	**24**

Timeline from reception to final conclusion (data 22/05/2019)

	Nbr	Max timeline following pilot procedure : from reception until final conclusion	Nbr within pilot procedure timelines	Nbr out pilot procedure timelines	Average timeline (real)
Initial					
Phase I	**9**	47	8	1	**37**
Phase I ATMP	**1**	77	1	0	66
Phase II-IV	**45**	65	40	5	**55**
Phase II ATMP	**1**	95	1	0	87
SM					
Phases II, III & IV	**75**	61	74	1	**29**
Phases I	**5**	47	5	0	**15**
Phases I ATMP	**3**	77	3	0	**38**

2. Pilot figures

Mean total timeline
(between submission and final decision or all conditions met)
Update info session end January 2019

Total timeline (data 03/09/2018)

	Number of received dossiers	Average timeline to issue the final decision	Average timeline to have all conditions met
Initial			
phase I	**5**	39	**60**
Phase I ATMP	**1**	66	66
phase II-IV	**19**	56	**66**
SM			
phase II-IV	**21**	29	**30**

Total timeline (data 31/12/2018)

	Number of received dossiers	Average timeline to issue the final decision	Average timeline to have all conditions met
Initial			
phase I	**8**	38	**54**
Phase I ATMP	**1**	66	66
phase II-IV	**29**	54	**62**
SM			
phase II-IV	35	29	**36**
phase I	2	23	23
Phase I ATMP	2	23	23

2. Pilot figures

Mean total timeline (between submission and final decision or all conditions met) : update 22/05/2019

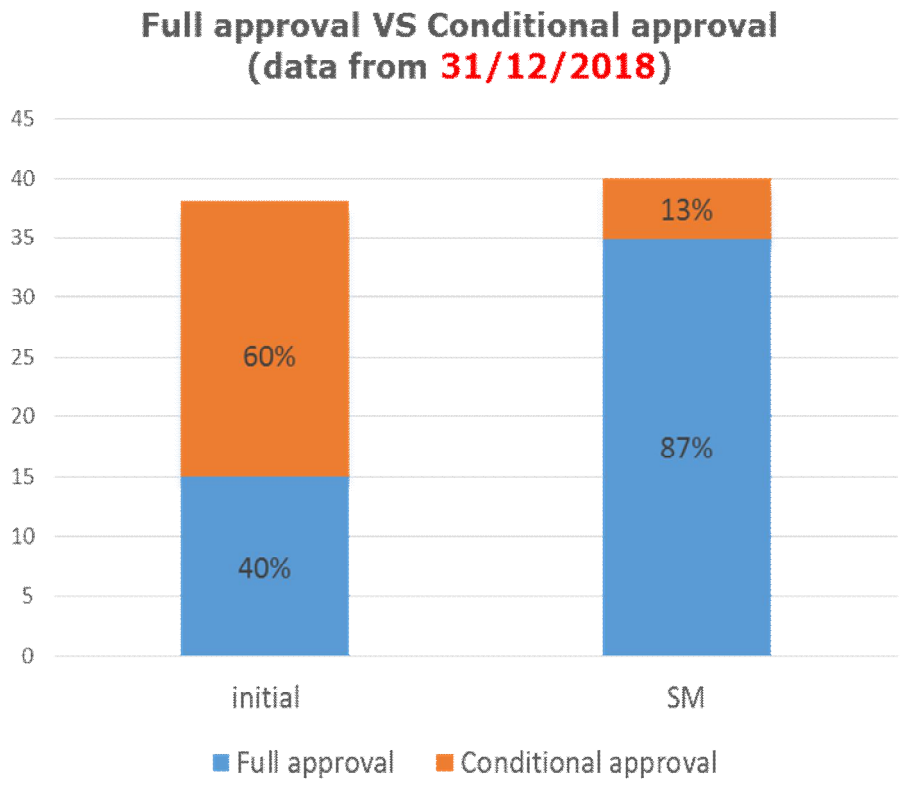
Total timeline (data 31/12/2018)

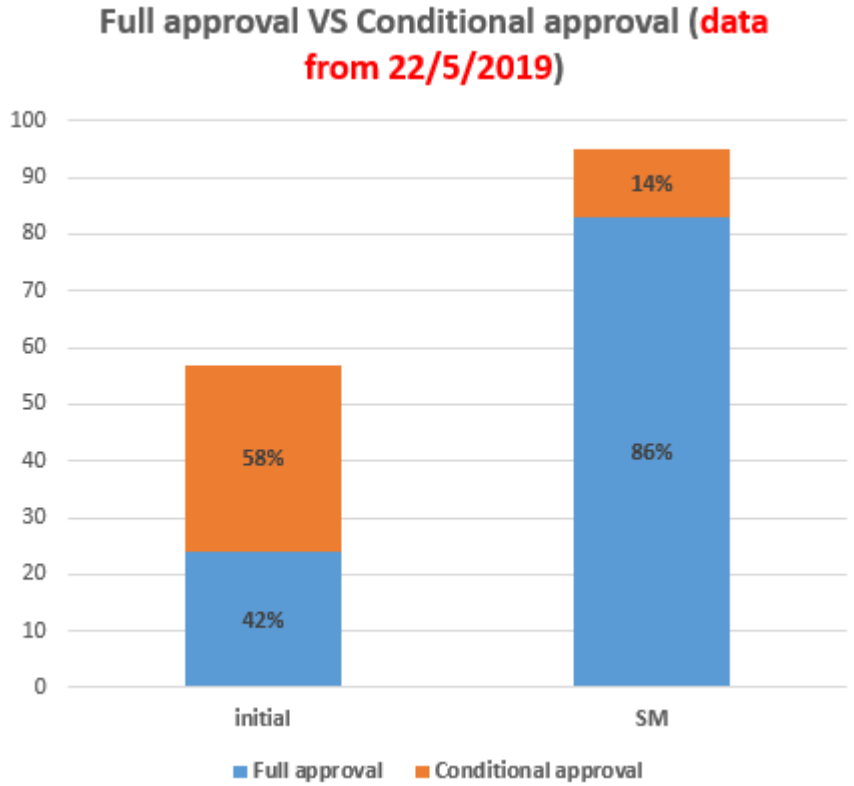
	Nbr of received dossiers	Average timeline to issue the final decision	Average timeline to have all conditions met
Initial			
Phase I	**8**	38	54
Phase I ATMP	**1**	66	66
Phase II-IV	**29**	54	62
Phase II ATMP	/	/	/
SM			
Phase II-IV	35	29	36
Phase I	2	23	23
Phase I ATMP	2	23	23

Total timeline (data 22/05/2019)

	Nbr of received dossiers#	Average timeline to issue the final decision	Average timeline to have all conditions met
Initial			
Phase I	**9**	37	52
Phase I ATMP	**1**	66	66
Phase II-IV	**45**	55	63
Phase II ATMP	**1**	87	87
SM			
Phase II-IV	75	29	33
Phase I	5	15	15
Phase I ATMP	3	38	38

2. Pilot figures





2. Pilot figures

Validation

- Validation performed for 67 dossiers (57 already finalized and 11 ongoing)

- 12 dossiers were complete from the beginning which represents 18% of the dossiers

- Mean time for validation (from submission to T0)
  => 11 days for initials phases II-III-IV (= 17% of max. timeline)
  => 7 days for initials phases I (= 13% of max. timeline)

- Between 1 and 4 validation questions per initial dossier (see next slide)

- Substantial modifications : validation questions very rare (3% of the SM) – Mean time for validation of SMs : 0,5 day for phases I and 1,75 days for other phases.

3. Our feedback on submitted dossiers

Validation

Most frequent validation questions :

- Written statement (not provided or incomplete)
- ICF not provided in all the languages of the participants
- Informed consent procedure missing
- GCP training can be included in the CV of the principal investigator or provided separately but date of certificate (**maximum validity = 3 years**) and preferably the name of the certifying organisation should be given
- Experience of the principal investigator in CTs (+ therapeutic domains) not available in CV
- DOI of the investigator not present or incorrectly completed
- GDPR statement
- Application form incorrectly completed
- Denomination of the documents not according to the pilot procedure (PilotXXX_EudraCTXXXX-XXXXXX-XX_...)

3. Our feedback on submitted dossiers

Evaluation (reminder)

Part I

- ✓ Clinical trial termination criteria should be included in the protocol. A section/paragraph should state that the sponsor has the right to terminate the study at any time and define reasons for the termination of the study prematurely (e.g. incidence or severity of adverse events indicates a potential health hazard for patients, patient enrollment is unsatisfactory, poor protocol adherence etc.).
- ✓ The DSMB charter (at least draft version) must be provided if a DSMB is foreseen for the trial.
- ✓ Adequate arrangements should be available in the protocol to secure data compliant with GDPR.
- ✓ Please pay attention to CTFG's "Recommendations related to contraception and pregnancy testing in clinical trials" when preparing the protocol.
- ✓ IB : the RSI section should be written according to the recommendations of the CTFG – Q&A document on RSI.

Part II

- ✓ ICF : please pay attention to the translations, consistency with protocol and other trial documents and compliance with GDPR

4. Answers to feedback received from sponsors

- The timelines to obtain the **written statement** can be very long depending on the involved sites. Lack of harmonisation of the procedure to obtain written statement among the sites.

Yes, this is a known issue and we are working on.

Actions already taken :

- a letter has been prepared and will be shortly sent to the CEO of the hospitals to insist on the importance of timelines in clinical trials to keep Belgium competitive in Europe.

- The College works on communication to all involved to remind the written statement does not represent a formal obligation of participation to the clinical trial but a statement that this is possible to perform the trial in the hospital.

4. Answers to feedback received from sponsors

- The **higher number** of received questions from the evaluating EC than in the regular procedure.

- Some questions could be avoided (see previous slides)

- Part I and part II of the dossier are assessed following the AR templates that were developed at EU level. These templates have been developed taking the requirements of the CTR into account. AR part I is the template also used in VHP where a lot of questions are also sent to sponsors.

- In the regular procedure, the CTA dossier is presented to the EC of the hospital by the principal investigator. Some of the questions/issues are already discussed orally and are thus not sent afterwards to the sponsor.

4. Answers to feedback received from sponsors

- If the trial is part of the **VHP** with another country than Belgium as reporting member state, it is not possible to participate to the pilot.

- It is possible to participate to the Pilot VHP plus process whether Belgium is RMS or not.

- The submission of the first Pilot VHP plus dossier is foreseen in June with Belgium as CMS.

4. Answers to feedbacks received from sponsors

- **For phases I trials**, the timing of the whole approval process is crucial.

Figures for the 9 phase I trials:

Timeline for final conclusion

Diff. Date reception /Tfinal
60
38
33
36
30
35
37
36
30
37

Timeline to obtain full approval

Total timeline
121
49
41
53
36
35
37
63
30
52

- Corner in red means winter clock stop included
- For several reasons, the 1st phase I had extra-ordinary timelines (if figures are only calculated on the 8 other phases I, mean timeline for final conclusion is **34** days and mean timeline for full approval is **43** days).

4. Answers to feedbacks received from sponsors

- **Does the evaluating EC has the expertise with phases I trials ?**

- The recognition procedure of ECs following law of 7 May 2017 is ongoing. Some of the ECs also asked for a specific recognition for phase I trials.

- In the pilot, volunteers ECs were asked if they had experience in phase I trials and if they would be interested in the future in a specific recognition for phases I trials. Only ECs that declared to have an expertise in phase I trials are selected by the college for the assessment of phase I pilot dossiers.

5. Safety reporting clarifications

- DSURs and SUSARs follow the current (Directive process) but have to be sent to the evaluating EC instead of the leading EC

- Mandatory to send these documents to FAMHP and to EC following law of 7 May 2004. This is the decision of the sponsor if he wants to provide safety documents to additional stakeholders.

- USM have to be sent to the NCP (CTRpilot@fagg-afmps.be) as they have a direct impact on the trial and on the documents (protocol and/or ICF)

- Guidance for sponsors and list of notifications will be updated to make all this clear.

6. Additional information and clarifications

- Chapter VI of CTR (article 36) : we do not require the notifications of start of trial, start and end of recruitment as the portal is not yet available.

- Template for CV of the investigator :

A template has been developed at EU level.

It is now available in the zipped empty submission dossier on the FAMHP website.

- Reminder : GCP training (not older than 3 years) must be well documented in the CV (at least the date and preferably also the organization) OR the certificate must be provided.

The most important trials experience should be documented in the CV.

- In the future, the name of the evaluating EC will not be communicated before submission to the applicant and an application form without EC mentioned in it will be accepted.

6. Additional information and clarifications

- Substantial modification :

The SM application form has to be provided but also the latest version of **annex I application form** (PDF and XML), if modified (with modifications highlighted) or not.

- Addition of a site :

If this site is the site of the evaluating EC, a new evaluating EC will have to be selected. It would be appreciated if this kind of modification could be announced in advance by the sponsor.

Pilot guidance for sponsors :

The guidance will be updated taking into account questions received by applicants/sponsors.

7. Conclusion on pilot and questions

Why choose the pilot or the pilot VHP plus process rather than the current process ?

- Excellent preparation for CTR for all, especially sponsors
- Single submission for multi sites trial
- No need to align with the meeting dates of a particular EC
- No site specific forms to be used
- Single authorisation (from agency/Ethics) – competitive timelines.
- Single authorisation of amendments – very competitive timelines
- Easy addition of an extra site (after 3m)
- In general very positive appreciations from sponsors who already participated
- Translations for protocol synopsis: English accepted
- Zero fee

7. Conclusion on pilot and questions

- **Thanks a lot for your interest and participation**
- Do you have questions ?
- Don’t hesitate to send us your questions to CTRpilot@fagg-afmps.be

CTR Pilots: Belgium versus other EU member states

DG pre, R&D

24/05/2019

Greet Musch

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federal agency for medicines and health products

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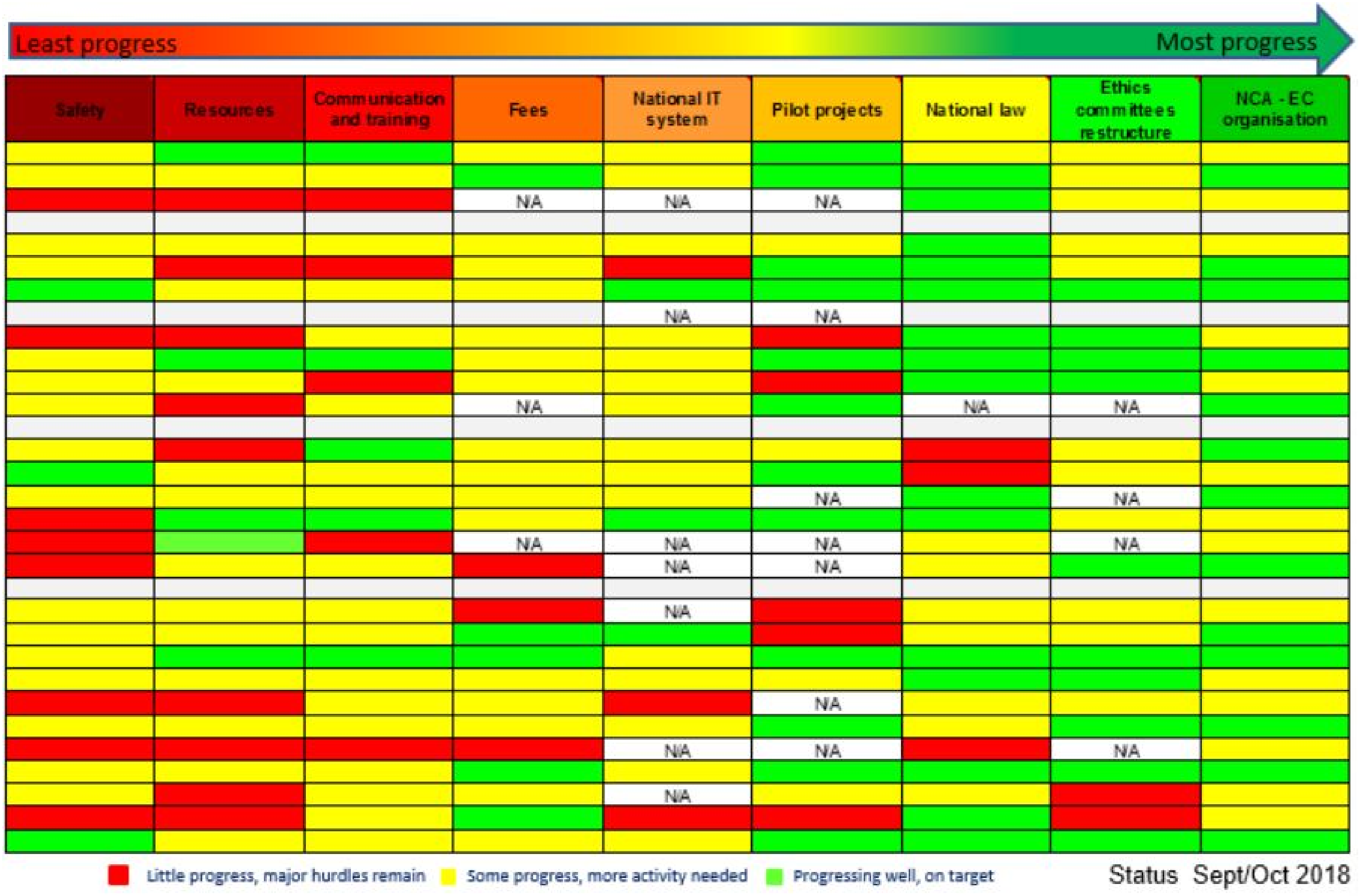
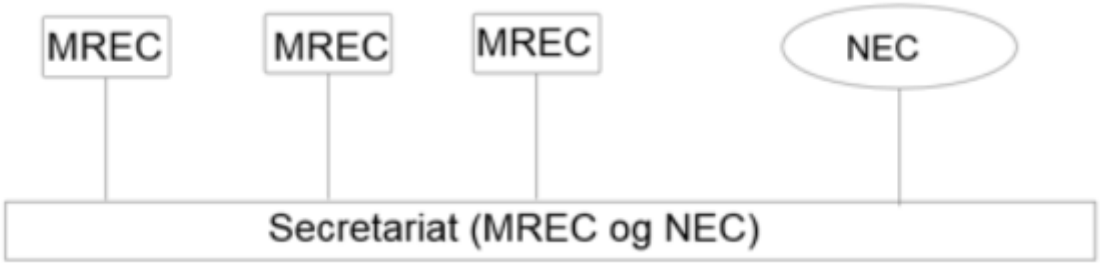
National implementation- heat map



Denmark: Danish solutions for the CT Regulation

- **New:**
  Centralizing of the research ethic handling of medicinal trials
- **3 new Medicinal Research Ethic Committees (MREC),**
  assess protocol, IB and Part II
- **Placed under the Ministry of Health**
- **Served by same secretariat**
  (current secretariat for National Committee on Research Ethic, NEC))



National pilot in Denmark: VHP-plus

- The pilot for the Regulation in Denmark is the VHP-plus
- As the new MREC is not established yet our VHP-plus only concerns CTs with ATMP and/or children

The Netherlands - CT regulation : one ethics committee (MREC), one assessment

- Decentral and concentrated:
  review by limited number of accredited MRECs (12)
- Controlled: oversight by the CCMO
- Integrated: all documents in one review
- Peer review: review by experts in accredited MRECs
- Limited central review: by CCMO (ATMP, vaccin, oligonucleotides, RNA interference, non-therapeutic research with minors and incapicitated subjects)

A national clinical trial office (CCMO)

- One national contact point
- Responsible for coordination and suppor

NL - Medical Research Ethics Committee

- Full overview
- Requirements for the MREC-composition at least a physician, a paediatrician (for trials with minors), a ethical expert, a lawyer, a research methodologist, a lay person, a clinical pharmacologist and a hospital pharmacist
- External expert advice, if required
- A minimum number of research dossiers is reviewed, 20 per year

Central support for MRECs

- Technical IMPD assessment
- Assessment of safety

Pilot experience

All 12 MRECs and CCMO participate in VHP plus since January 2017.

Portugal

- **National legislative proposal (Law) implementing CTR**
  - currently undergoing national legislative procedure
  - sets the national system provisions and responsibilities

- **PT CT assessment / authorization internal organization**
  - **INFARMED, I.P. – PT NCA, National Contact Point**
  - **Ethics Committee for Clinical Research (CEIC)**
  - 1 **national EC** competent for **CT-IMPs review**
  - created in 2005, placed under the Ministry of Health

- **Responsibilities and cooperation**
  - Part I by NCA/INFARMED and EC/CEIC
  - Part II by EC/CEIC only
  - Part I consolidation and decision by NCA
  - Safety - SUSARS and ASR assessment
    - by NCA/INFARMED, EC/CEIC involvement when necessary

Portugal

- Complemented by a **Memorandum of Understanding**
  - supporting national cooperation procedures & timelines
  - to be tested under a **pilot**
    - expected to start: beginning -**2019**
    - Drawing from experience of **VHP plus** (PT joining from start)
    - Unique submission by national Portal
    - Joint assessment by use of CTFG part I AR-template / on share system
    - Communication by email

- **Challenges**
  - Staffing
  - Timelines
  - High dependency on IT systems support
  - NCA and EC interaction for part I AR joint preparation

Sweden

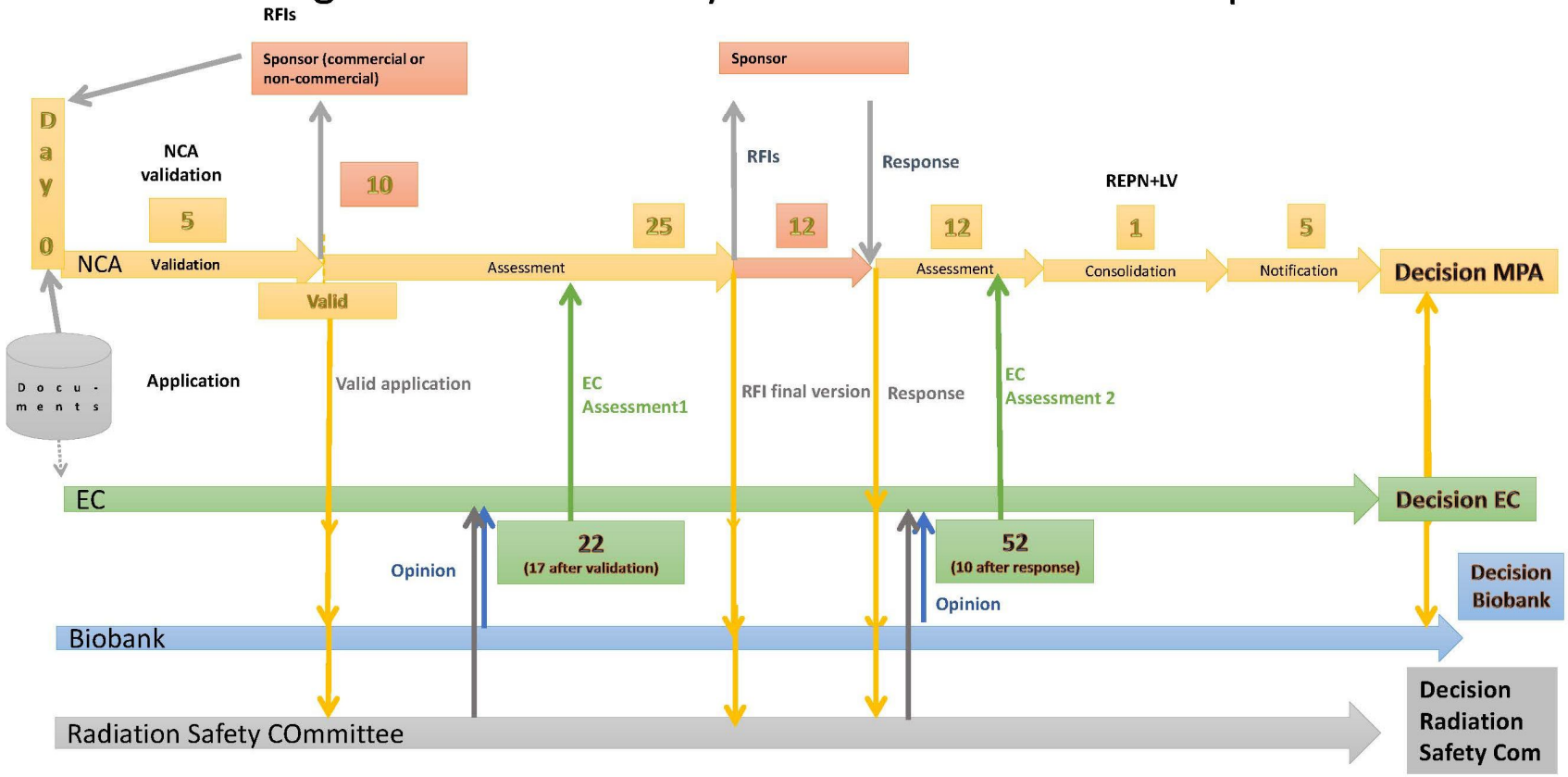
CTR National pilot – interaction between several Swedish authorities under existing national laws:

- NCA (Swedish Medical Products Agency)
- EC (newly formed Ethical Review Authority – earlier organised as six independent authorities)
- Biobank Sweden
- Regional Radiation Safety Committees

Plan to continue allowing sponsor to submit future parallel applications on trial aspects not covered by the CTR, e.g. environmental aspects of GMOs and medical devices

Sweden

Graph summarizing interactions between NCA (MPA), EC (Ethical Review Agency), Biobank and Regional Radiation Safety Committee in the Swedish pilot for the CTR



Germany

National Contact Point: BfArM

Ethic Committees and CT Regulation:

- 36 registered ECs (of current 53)
- CT assigned by annual distribution list, and a few rules

Responsibilities:

- Part I by NCA (BfArM and/or PEI) and EC; consolidation by NCA
- Part II by EC only
- Decision by NCA – respect EC conclusion
- Safety reports both involved

Pilot for initial CTA and substantial amendments

- 33 EC participate
- CTR timeline, within current law, missed deadline back to current
- Assessment Report written jointly - using CTFG's AR template, consolidation (and decision) by NCA
- Report and communication within Sharepoint
- Process optimization

Germany - Experiences

110 Pilots since December 2015:

- 77 approved, 4 rejected, 6 ongoing
- 11 not submitted in time to start pilot, 3 deadline missed by sponsor, 9 withdrawn after GNAs,

- **82% commercial and 18% non-commercial sponsors**
- **Responsible EC depend on site of principal investigator, not all ECs active involved yet**
- **Advantage to have internal guidance and templates in place**
- **Timelines met by regulators; in mean 2 days earlier than max. time of CTR**

Challenges:

- Need to know when the other body is ready to proceed next step
- Consolidation and exchange in short time, e.g. after response assessment
- Future challenges: Multinational CT and safety reports

Germany - Experiences

Duration of the stages of the procedure

Last update: 29.03.2019

Actual duration of proceedings in days

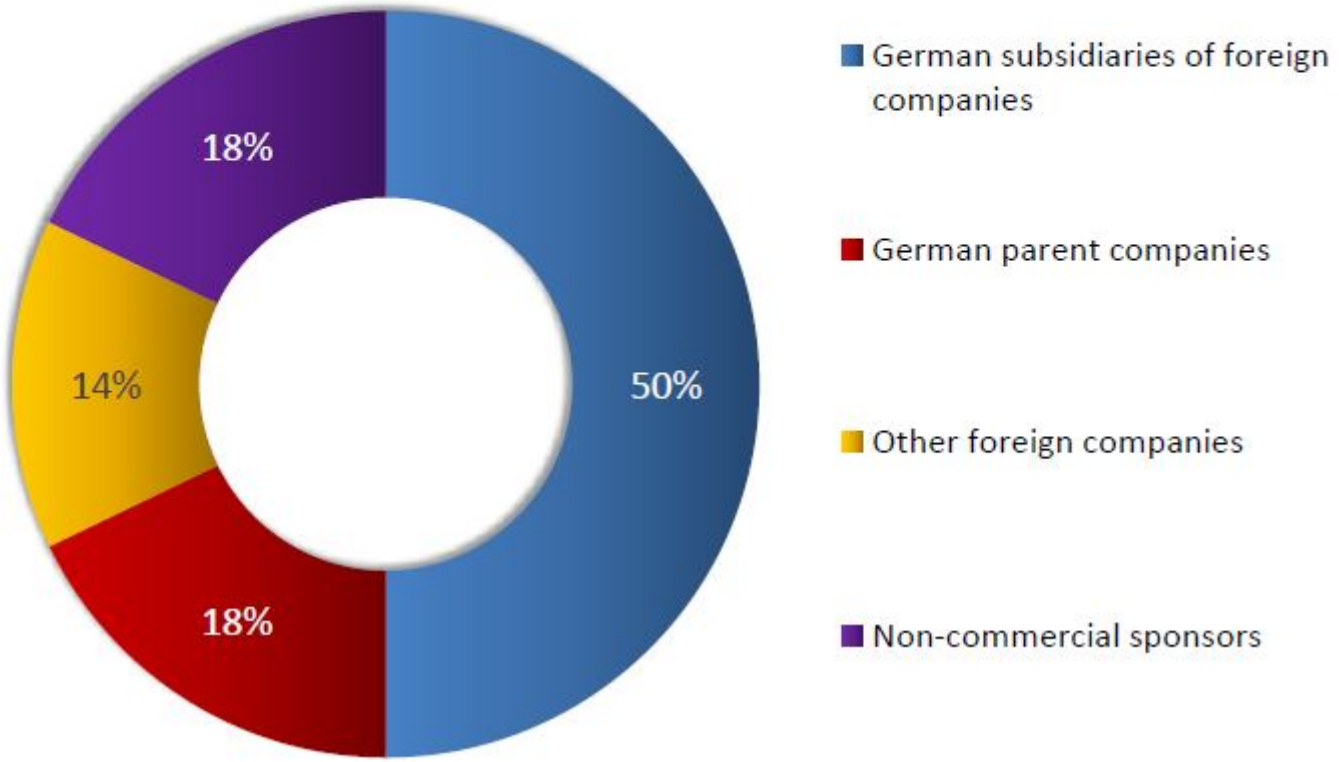
process step	Mean	SD	Median	Min	Max	limit
validation (n=138)	7,1	1,9	7,0	2	12	≤ 10
Elimination of validation deficiencies* (n=19)	6,4	3,1	8,0	0	10	≤ 10
Verification of the elimination of validation deficiencies* (n=20)	3,7	1,4	4,0	1	5	≤5
Content check (n=124)/assessment phase	23,1	3,4	24,0	6	29	≤ 26
Removal of the GNAs/RFI* (n=100)	**10,5**	**2,2**	**11,0**	**2**	**15**	**≤ 12**
Final examination and decision (n=96)	9,4	2,2	10,0	4	13	≤ 12
Overall procedure (n=138)						

* under the responsibility of the sponsor

Germany - Experiences

Germany - Experiences

Distribution by sponsor type
(„Letter of Intent“, n=46)



Italy

Coordinated assessment AIFA and EC: The Pilot Project

Italy

Coordinated assessment AIFA and EC: Main charecteristics of t0eh pilot project

- The Sponsor and the Coordinating Ethics Committee (CEC) voluntarily agree to participate in the coordinated assessment process.

- AIFA acts as a mediator between Sponsors and CEC. The CEC adheres to the procedure and agrees to comply with the VHP timelines.

- If the deadlines are not met during the procedure, the CEC can not conclude the assessment process which will be finalized only during the national phase.

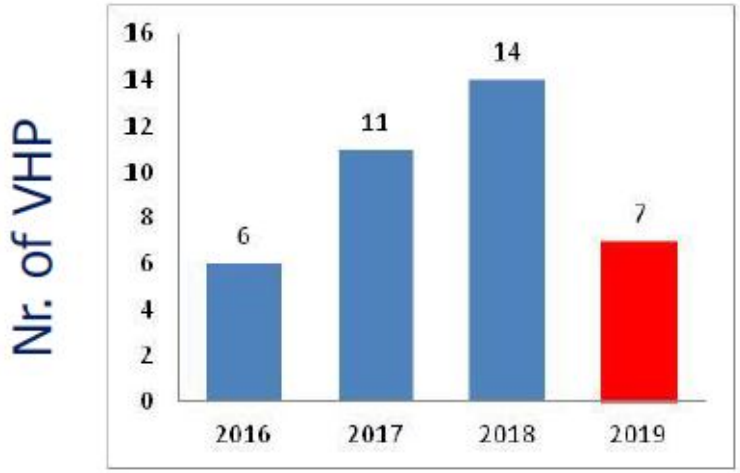
- The conclusion of each phase of the VHP will be shared with the Sponsor through specific communication.

Italy

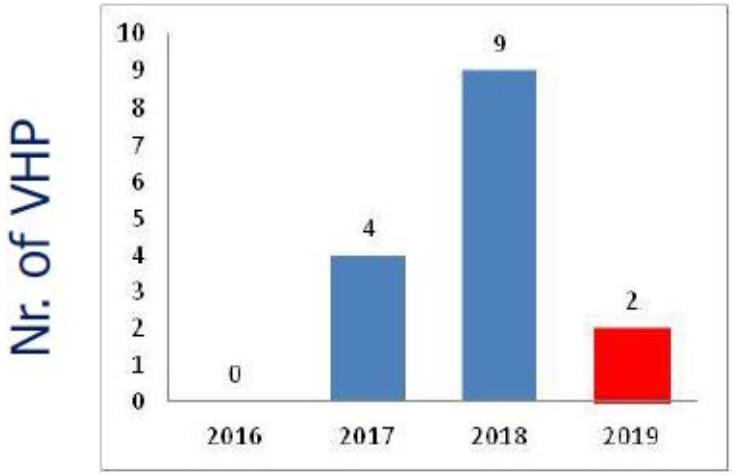
Application of VHP with request of participation to the pilot projects

The project started in may 2016 and so far the joint assessmnet AIFA/CE has been requested for 38 procedures distributed in the years as follows:

Studies



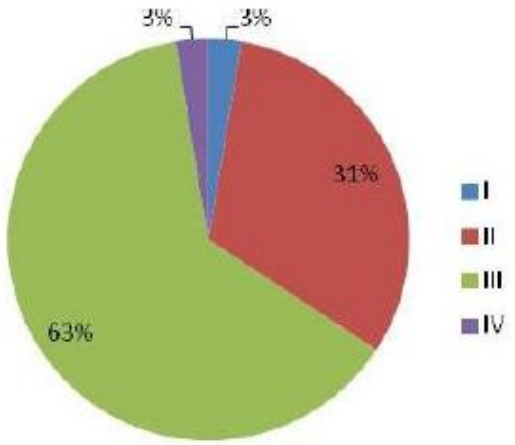
Substantial Amendment



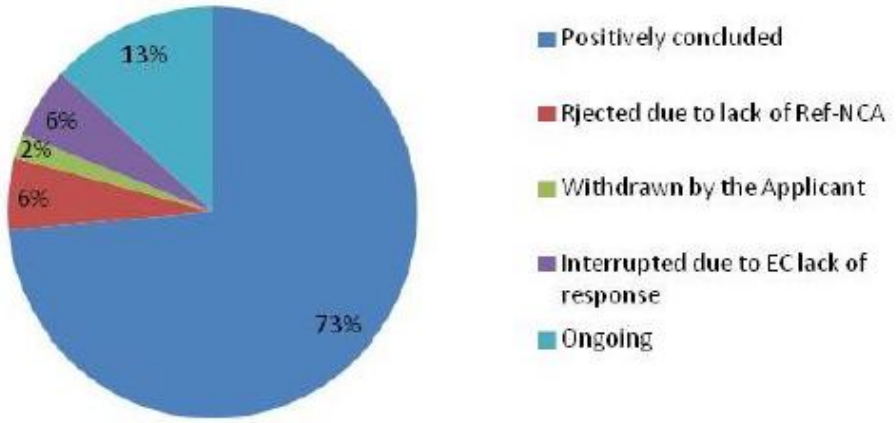
Italy

Preliminary Results of the pilot project

Distribution of Application on teh basis of the trial phase



Outcome of the procedure assessed through the pilot project

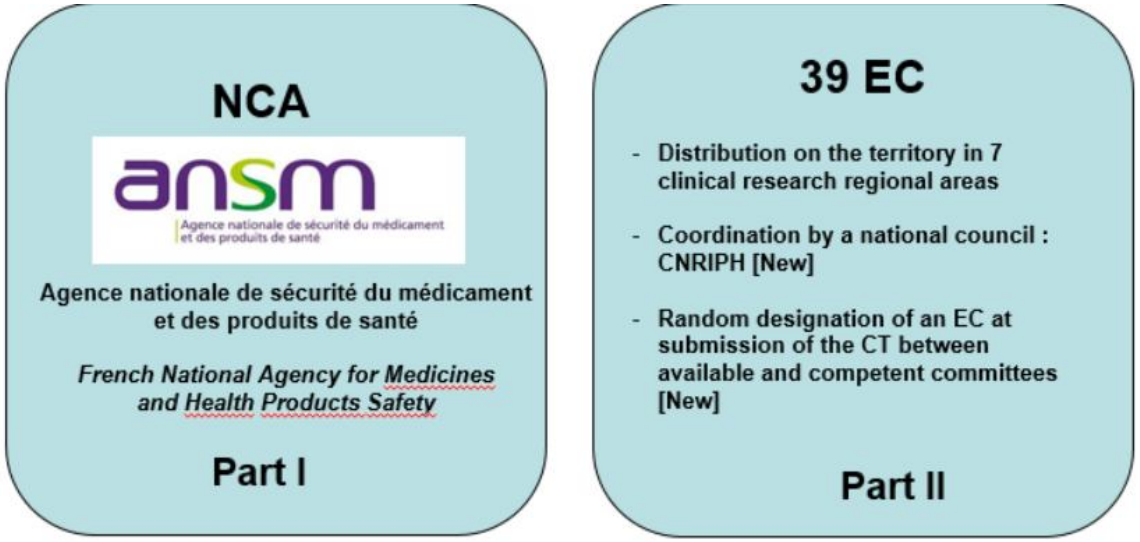


Italy

Brief summary of the experience

1. Issues coming from the EC mainly on clinical part
2. Positive feedback from the interaction with Ecs
3. The assessment approach
4. The concept of Grounds for Non Acceptance (GNA)
5. How to correctly formulate a GNA
6. The definition of conditions
7. The assessment of a substantial amendment in VHP
8. Positive feedback from the industries

France



Please note that methodology is actually evaluated by ECs but this evaluation will be performed by NCA in CTR

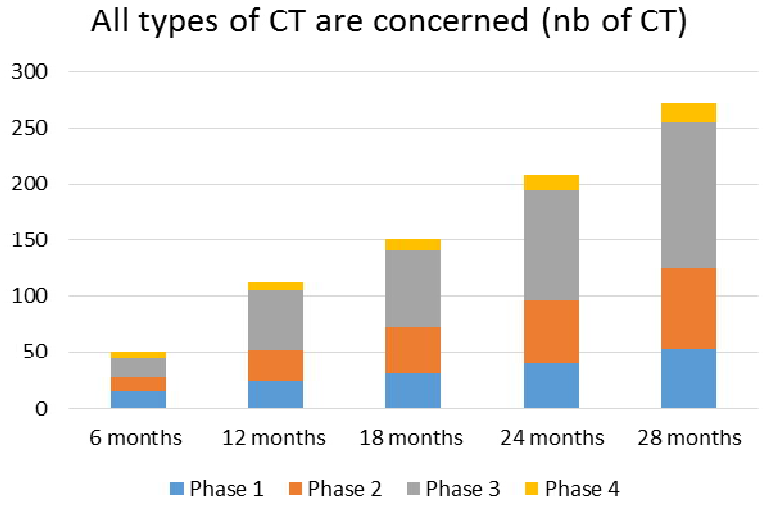
Remaining issues in France before CTR:

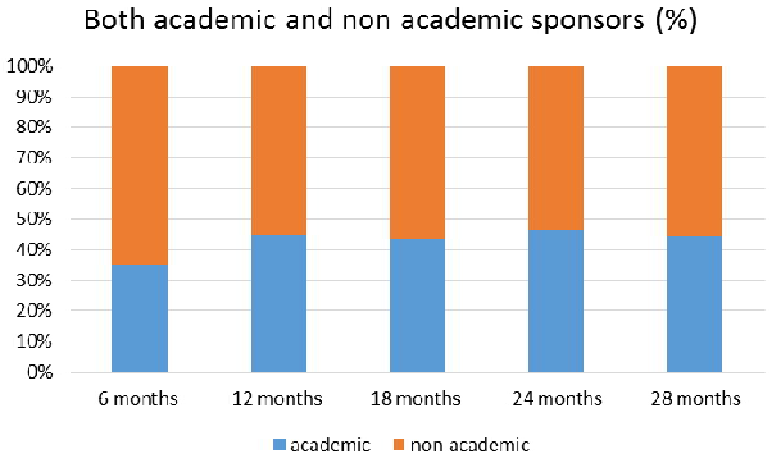
- IT systems interconnection: between NCA and ECs and with future CTIS
- NCA and ECs scientific coordination when needed: initial application, SM, safety issues
- logistical problems that need to be resolved (e. g. ECs' secretariat to be strengthened)

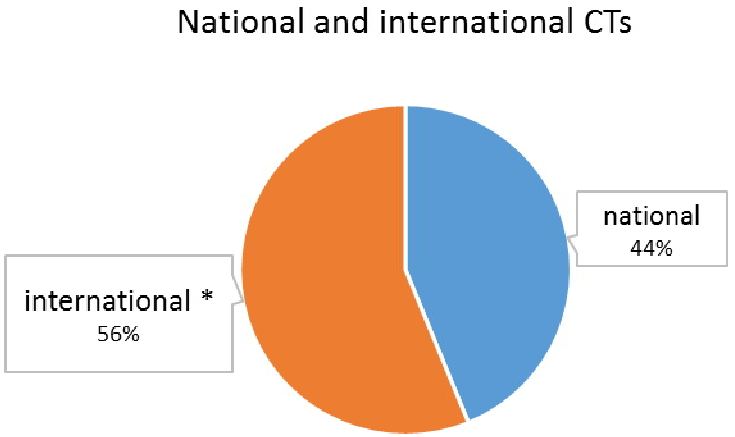
France
28 months experience

1st Phase: ANSM + 21 volunteer ECs
123 CTs in 14 months

2nd Phase: ANSM + **all** ECS
151 CTs in 14 months (ongoing)







Coordination between NCA and Ecs is feasible in daily practice
PP still concerns only 16% of CT in FR (volontary procedure by the applicant)
A constant increase is noted (growing adherence for all involved parties)

Overall conclusions at EU level

- Most Member States (MS) are gaining experience with pilots : Learning by doing .

- Experience with pilots for multi-national trials is only starting now in most MS : participation in VHP-Plus is strongly encouraged (with Be als RMS) !

- The great majority of clinical trial applications are approved .

- Criticalities related to the timelines are mostly at « the validation step « and at « the consolidation of answers to RFI's « .

- Criticalities related to the assessment are mostly related to « DSMB , Contraception , RSI , Unblinding , trial designs « .

- CTFG is working with all MS (NCA's and ethics committees) on the harmonisation procedure for reducing the GNA's / conditions raised during the pilots :

  - Enhancing the experience in assessing pilots in the multi-national setting
  - Training of assessors from NCA's and ethics committees
  - Enabling a consolidated scientific opinion on « complex trial designs «

- CTIS is progressing in the good direction and should facilitate the current administrative burden / workprocessflows.

- Certain degree of urgency to train all to be ready !!

Facilitating CTR pilots via National Innovation office

Zero STA fee concept for national STA requests related to

- **CTA's submitted in Belgium following the CTR process (pilots) :**
- - key features:
    - ➢ valid CTA submission should be submitted < 2 years of formal STA
    - ➢ applicable to **all** types of Applicants
    - ➢ Not cumulative with reduced STA fee concept for SMEs & academics
    - ➢ Scope : for initial & follow-up STA requests

  - key facilitator for innovators to:
    - ➢ seek proactively formal STA on clinical development projects / trials
    - ➢ facilitating formal CTA approval, high-quality clinical research & increased outcomes

  – **GO LIVE: 30 th of May 2019** : communication via website famhp foreseen .

EUPD + Demo

DG pre, R&D

24/05/2019

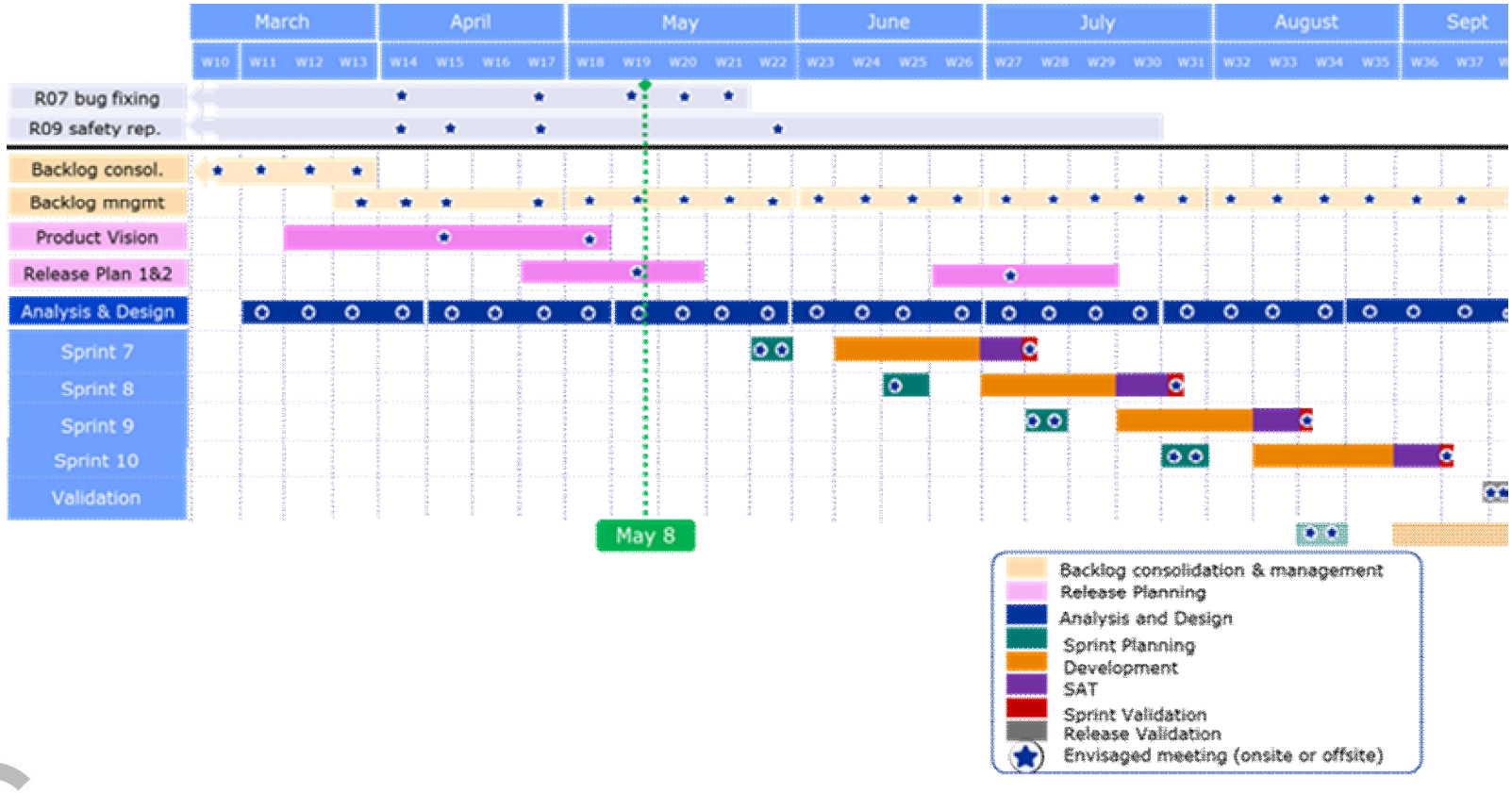
Pieter Vankeerberghen

famhp
federal agency for medicines and health products

.be

C. EUPD + Demo

- Approved product vision. This is a global view on the contents of the 3 major releases: (i) for audit, (ii) for go live and (iii) after go live.
- From the product vision – there is now a release planning for the first release, this is in more detail below
- Timelines are till Sept 2019. Next steps: define scope second release followed by defining date for audit. ☺



Backlog are all the items to be fixed, according to priorities. Sprint means mini release. SAT is site accept. tests

Thanks a lot for your interest and participation

Contact

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