COVID-19 vaccine trials performed in Belgium: regulatory perspective

Symposium on vaccines

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.be

Overview

- Introduction: clinical trial applications in transition
- Analysis of clinical trial application for COVID-19 vaccines in Belgium
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- Examples of trials submitted
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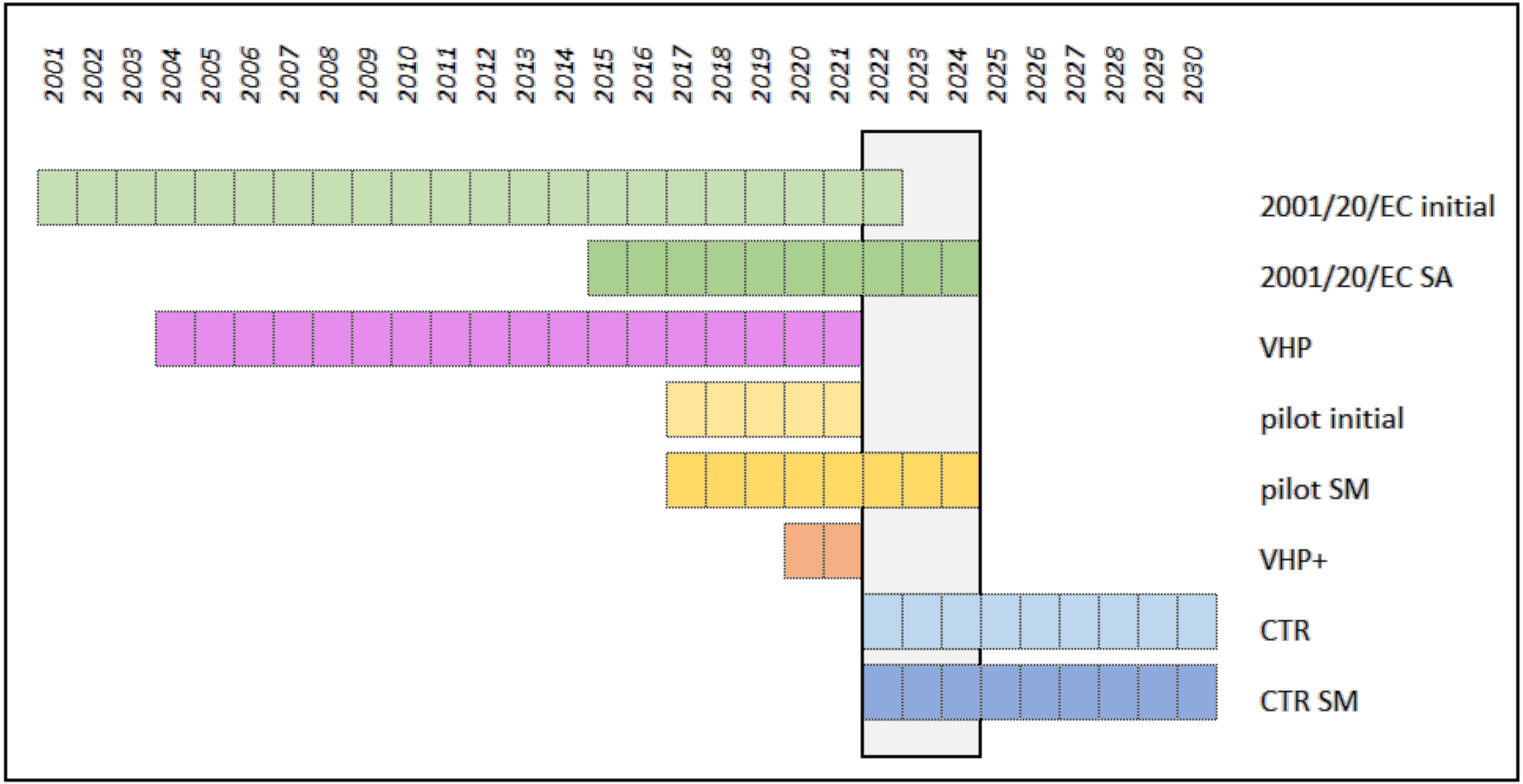
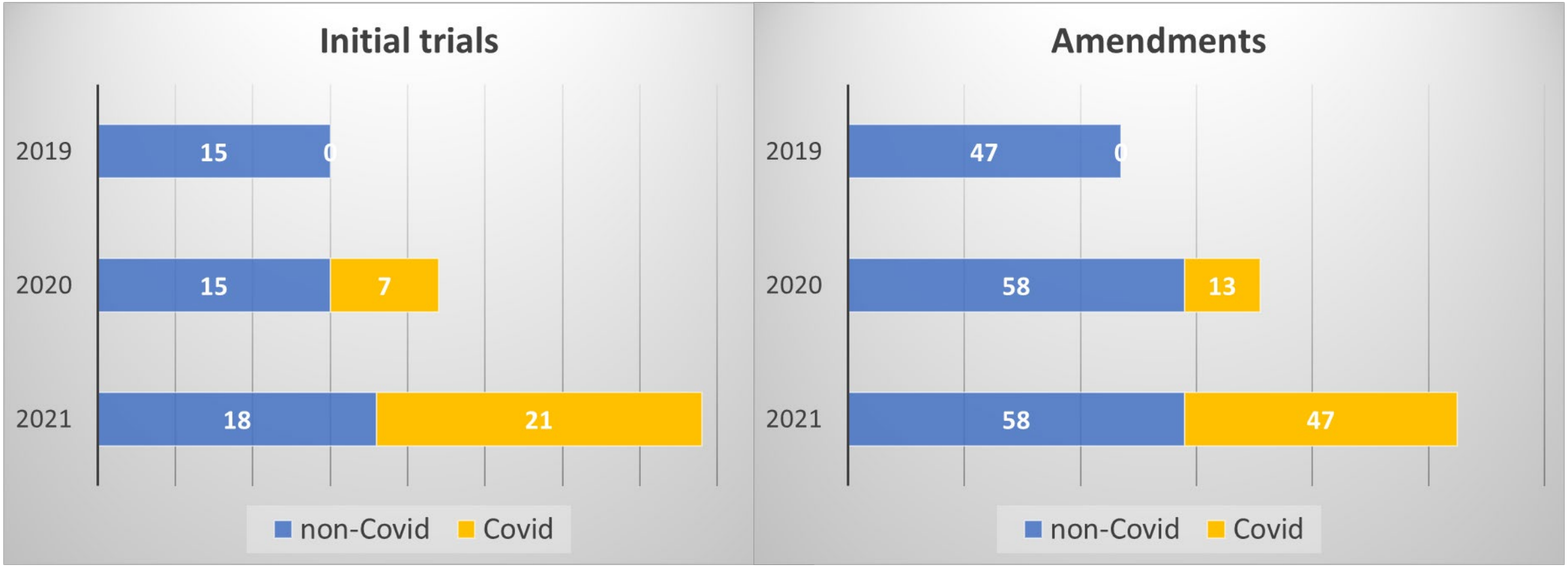
- Particularities and FAMHP's efforts to facilitate assessment
- Challenges for COVID-19 vaccine trials during the pandemic in the FAMHP
- Regulatory perspective

Introduction: clinical trial applications in transition



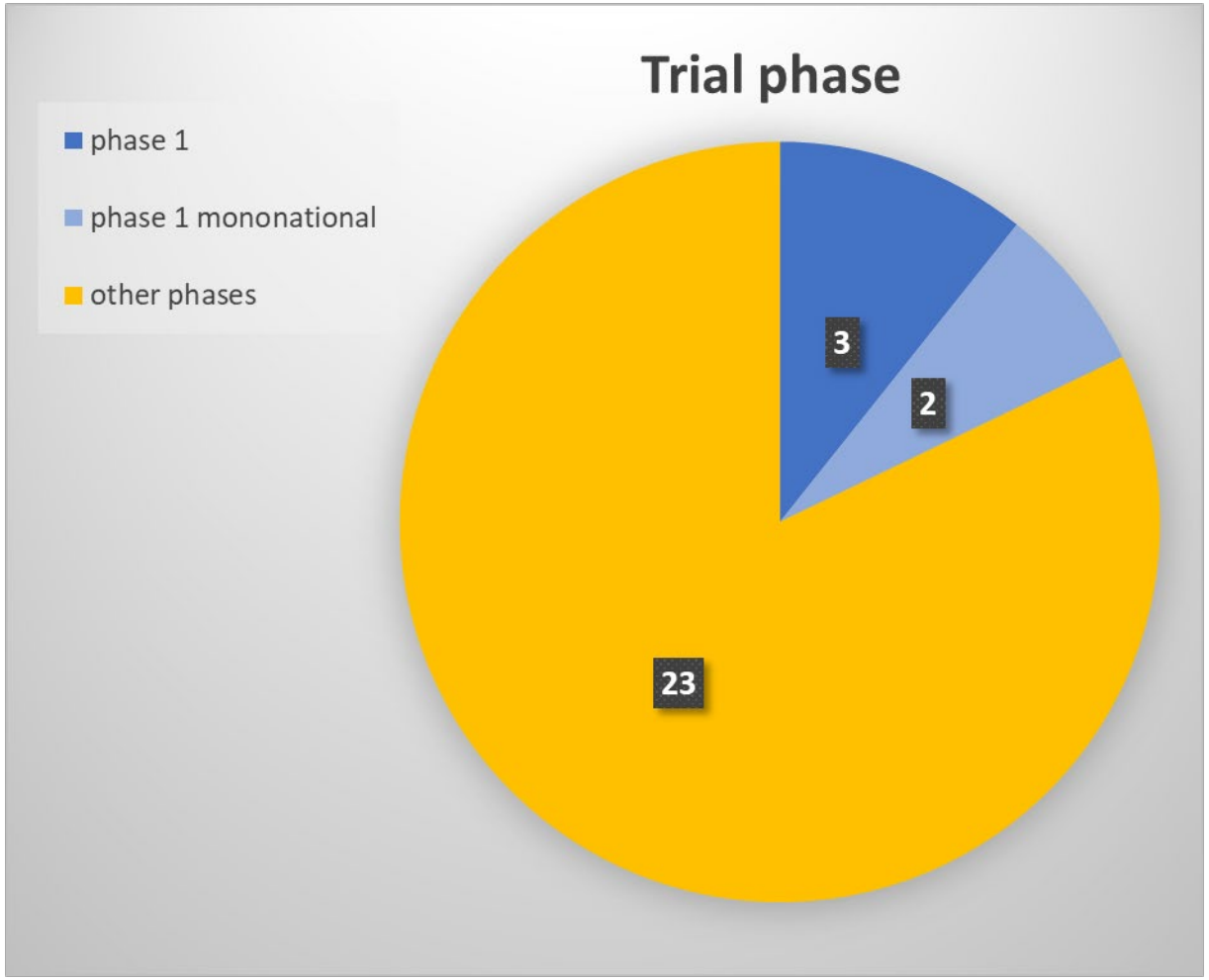
Analysis of clinical trial application for COVID-19 vaccines in Belgium (1)

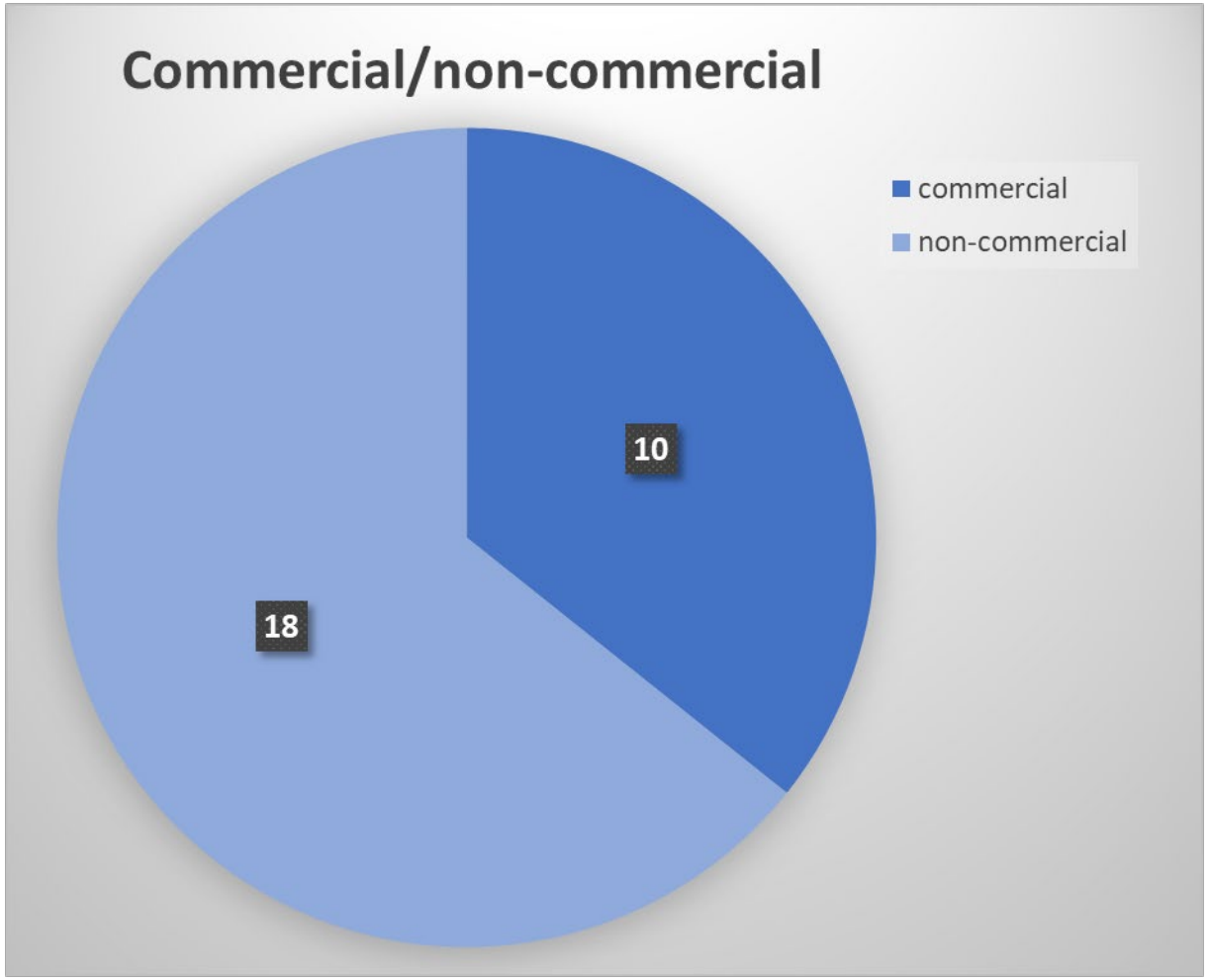
Evolution over time



Analysis of clinical trial application for COVID-19 vaccines in Belgium (2)

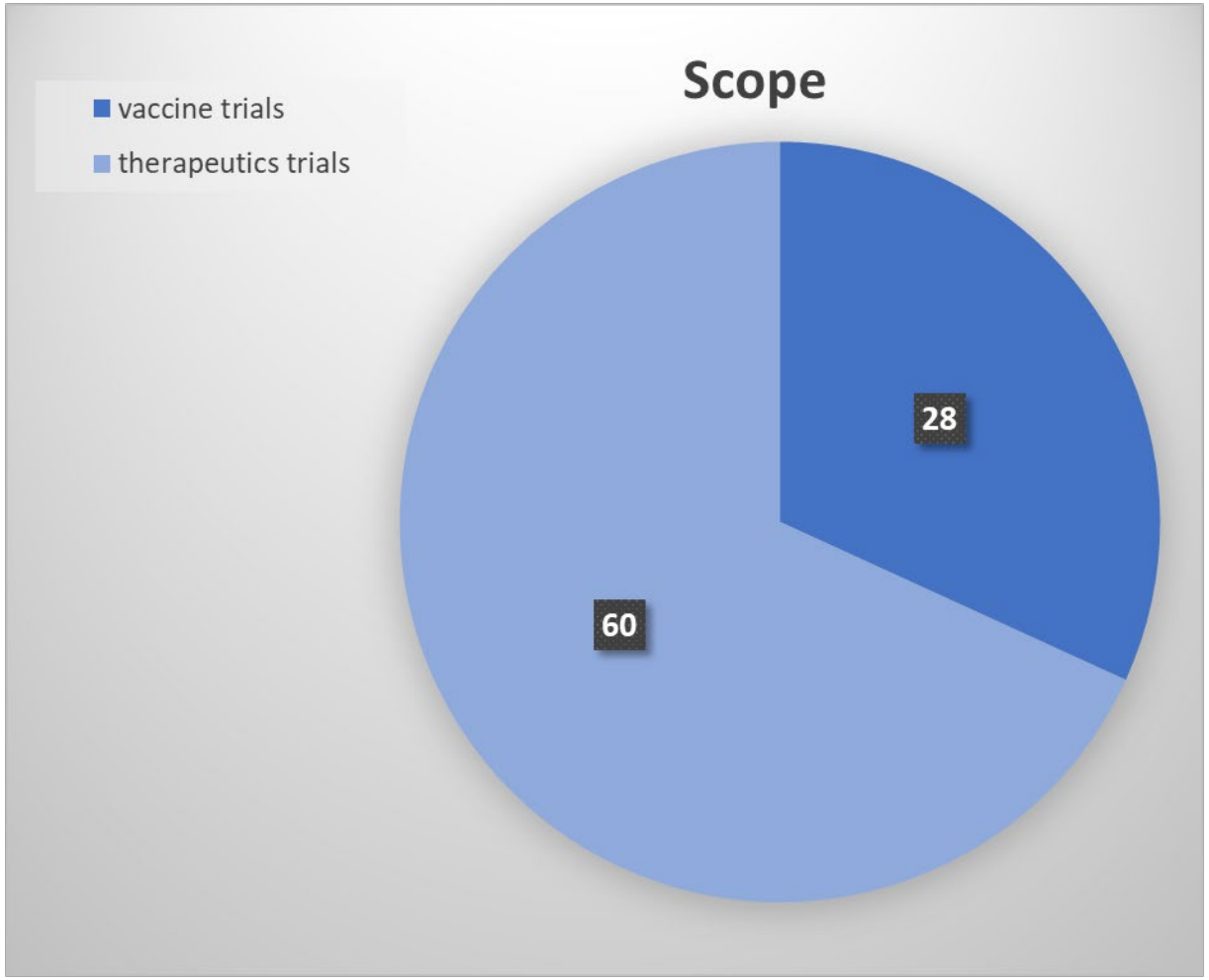
In 2020-2021

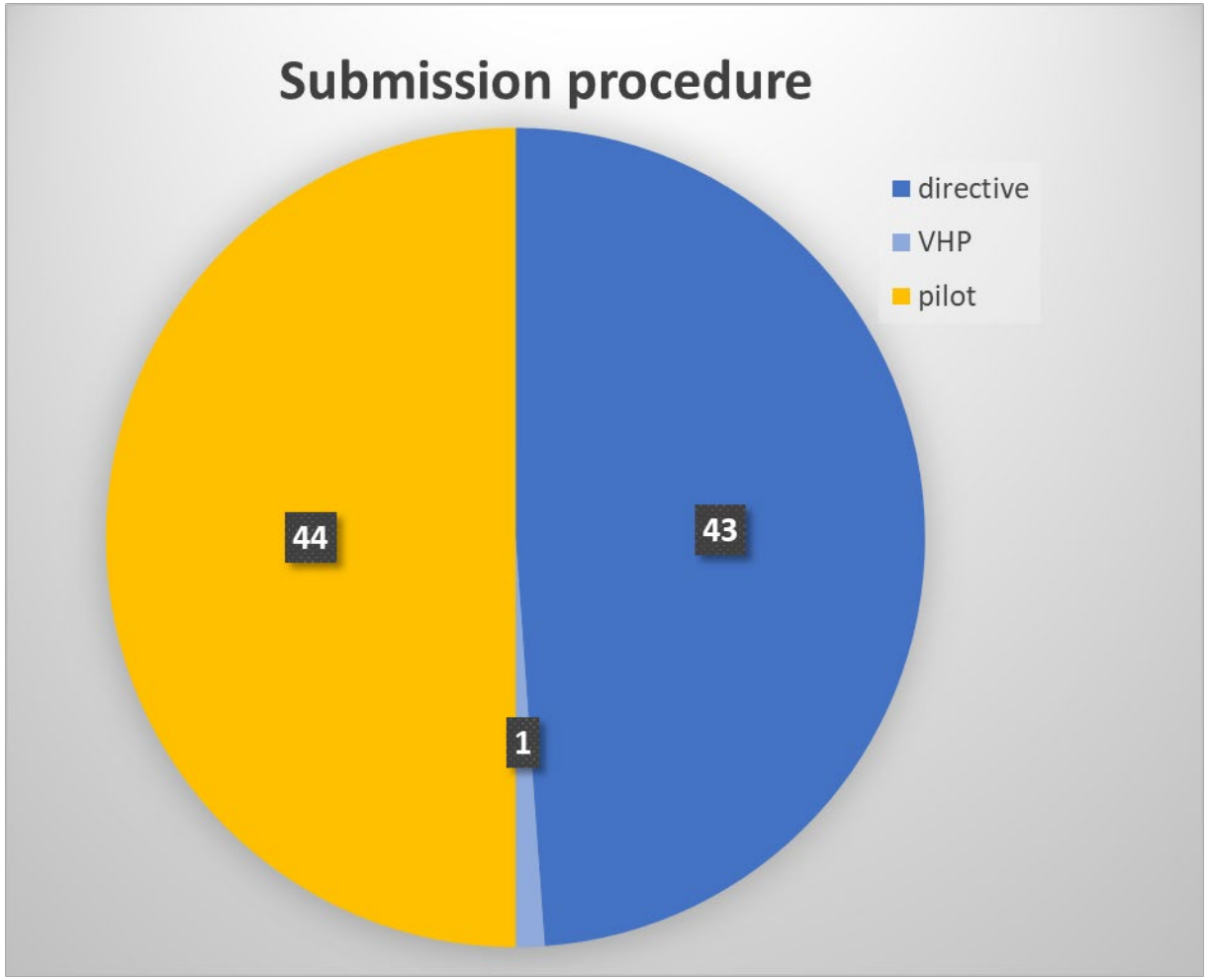




Analysis of clinical trial application for COVID-19 vaccines in Belgium (3)

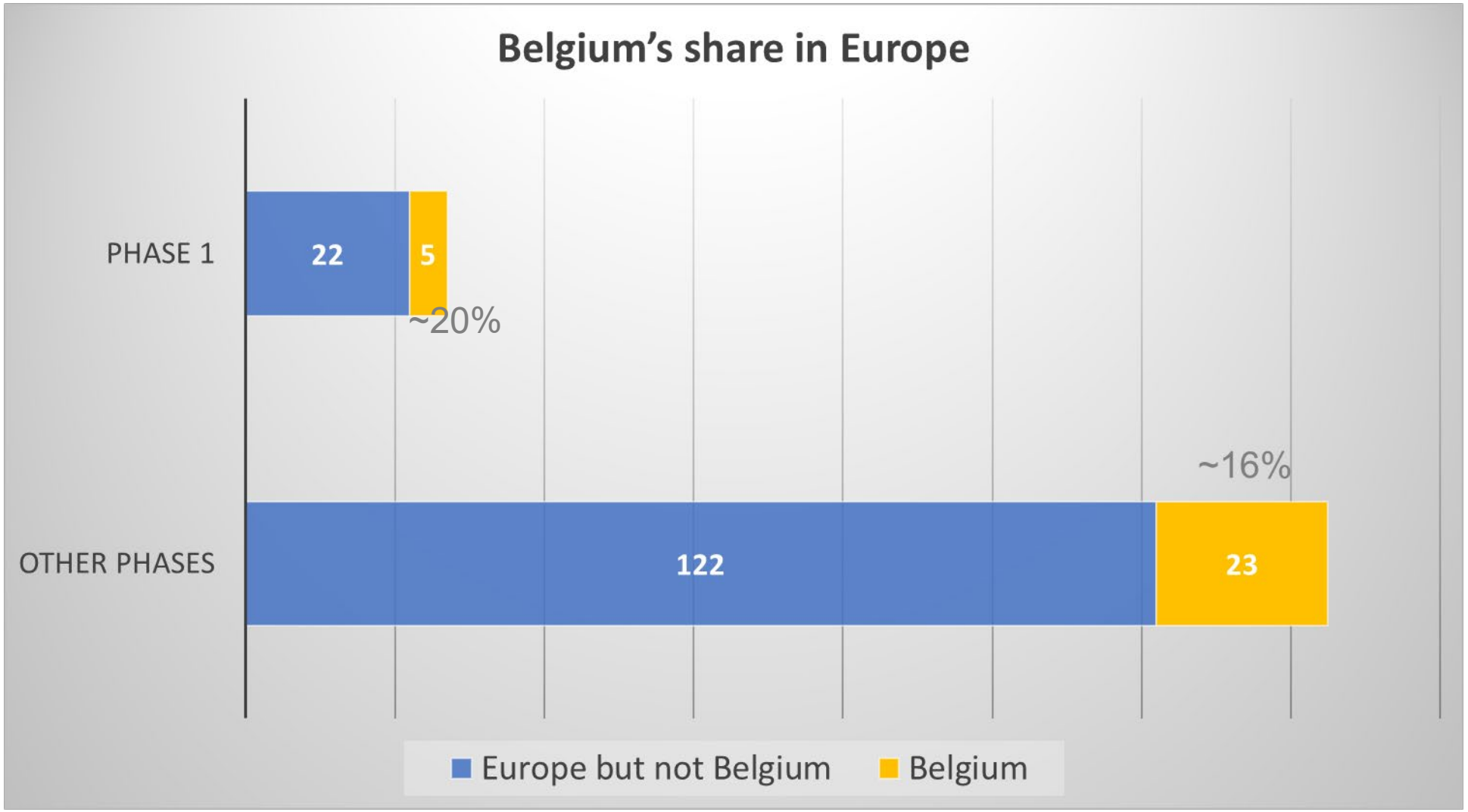
In 2020-2021





Analysis of clinical trial application for COVID-19 vaccines in Belgium (4)

In 2020-2021



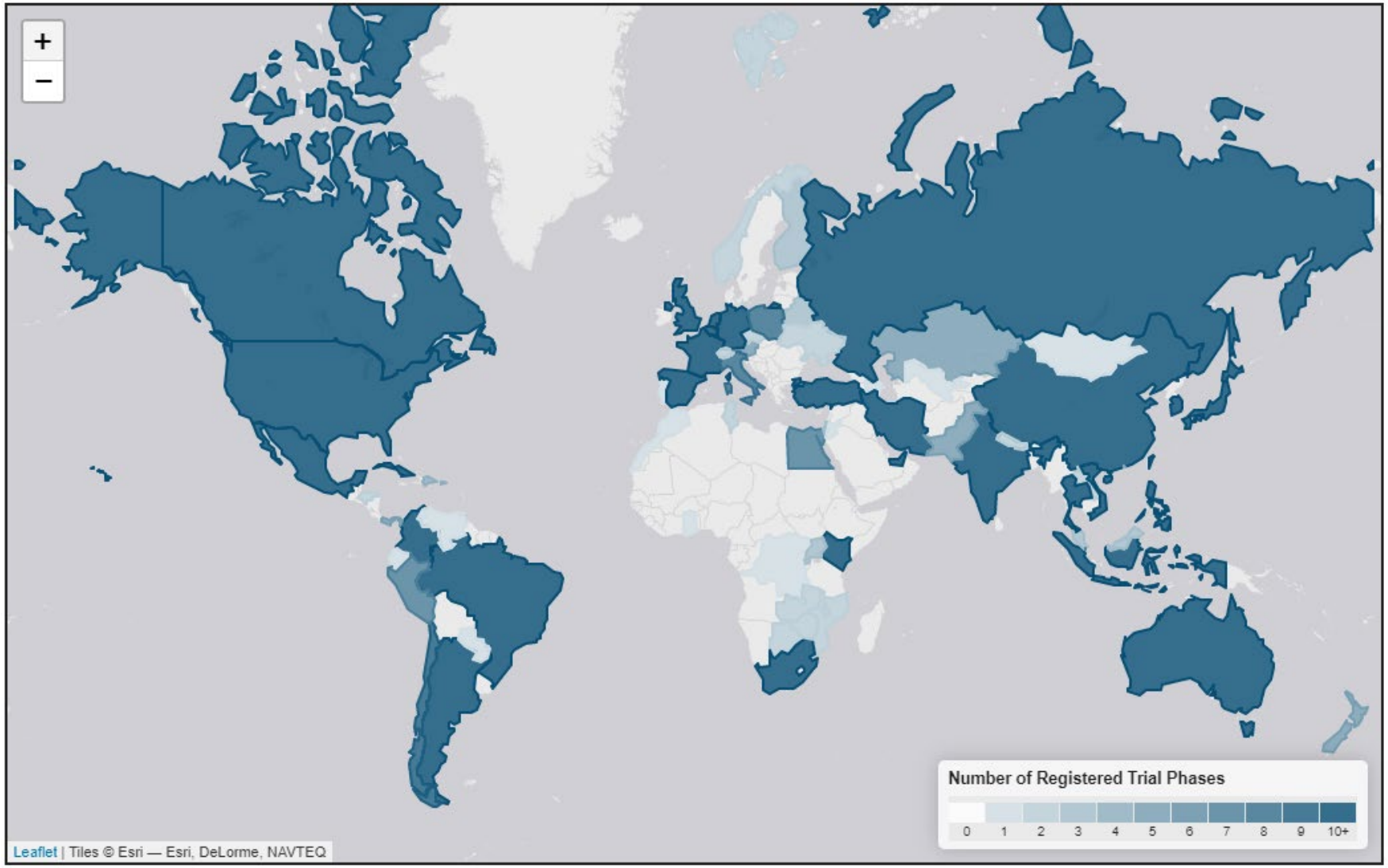
Examples of submitted trials (1)

Overview

- Trials for a novel vaccine in development
- Trials with existing vaccines for vulnerable patient populations (cancer patients, pregnant and lactating women, kidney transplant patients, haemodialysis patients)
- Trials investigating altered doses, vaccination schedules

Examples of submitted trials (2)

Trials for a novel vaccine in development



Source: https://covid19.trackvaccines.org/

Examples of submitted trials (3)

Trials for a novel vaccine in development

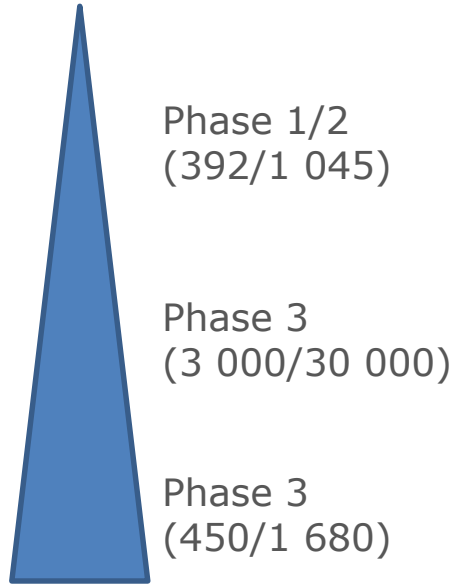
Sponsor	Vaccine type	Approved in Belgium	Trial phases in Belgium			Clinical trial stopped
			1	2	3	
Novavax	Protein subunit	x				
Moderna	RNA	x				
Oxford/AstraZeneca	Non-replicating viral vector	x				
Pfizer/BioNTech	RNA	x				
Janssen (Johnson & Johnson)	Non-replicating viral vector	x	x	x		
Clover	Protein subunit		x			
ReiThera	Non-replicating viral vector		x			
OSE immunotherapeutics	Protein subunit		x			
Institut Pasteur	Replicating viral vector		x			x
Merck Sharp & Dohme Corp	Replicating viral vector		x			x
CureVac	RNA		x	x		x

Examples of submitted trials (4)

Trials for a novel vaccine in development

Janssen Vaccines & Prevention B.V. (commercial)

- **In Belgium**
  - 2020-001483-28: A randomized, double-blind, placebo-controlled phase 1/2a study to evaluate the safety, reactogenicity, and immunogenicity of Ad26COVS1 in adults aged 18 to 55 years inclusive and adults aged 65 years and older
  - 2020-003643-29: A randomized, double-blind, placebo-controlled phase 3 study to assess the efficacy and safety of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and older
  - 2021-003953-43: COVID-19: A randomized, double-blind, phase 3 study to evaluate safety, reactogenicity, and immunogenicity of co-administration of Ad26.COV2.S and influenza vaccines in healthy adults 18 years of age and older
- **Globally**
  - Phase 1 + phase 1/2 trials: 5
  - Phase 2 trials: 5
  - Phase 3 trials: 8



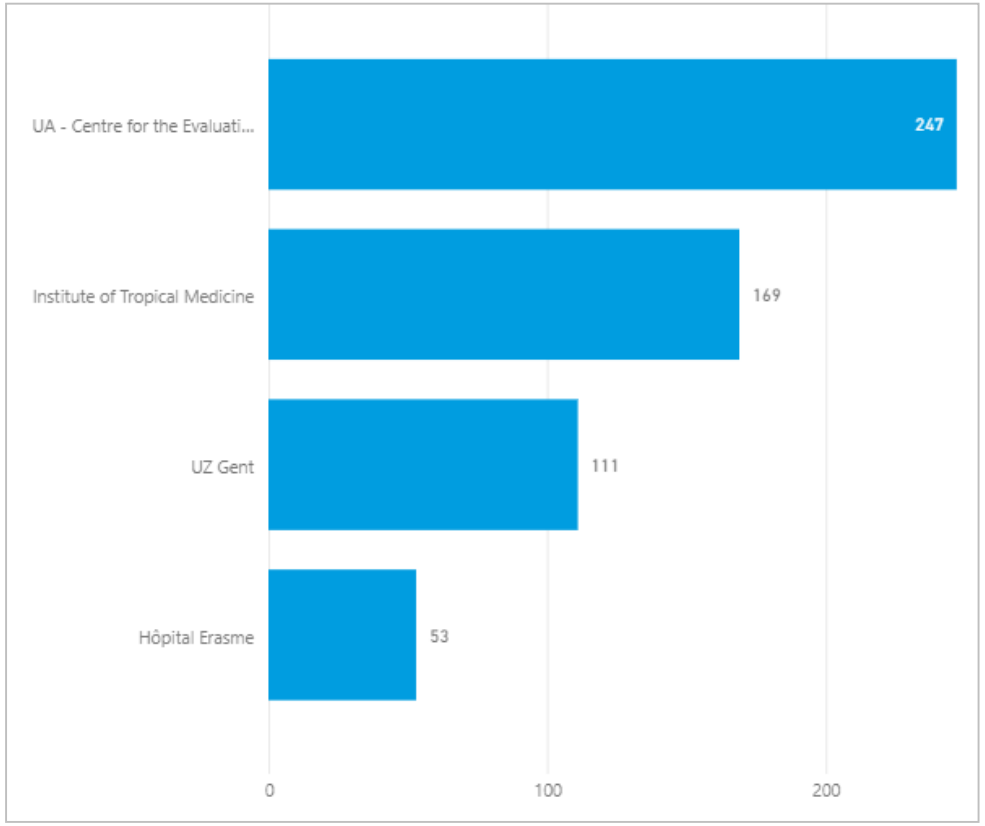
Approval in 111 countries

Examples of submitted trials (5)

Altered doses and vaccine schedules

- 2021-001993-52: COV201288: assessment of the immunogenicity and safety of marketed vaccines for COVID-19 after regular schedule and adapted vaccine schedules and routes: Comirnaty® (Pfizer), Spikevax (Moderna) and Vaxzevria® (AstraZeneca) - IMCOVAS

Recruiting Sites	Participants Recruited	Target Sample Size
4	580	560



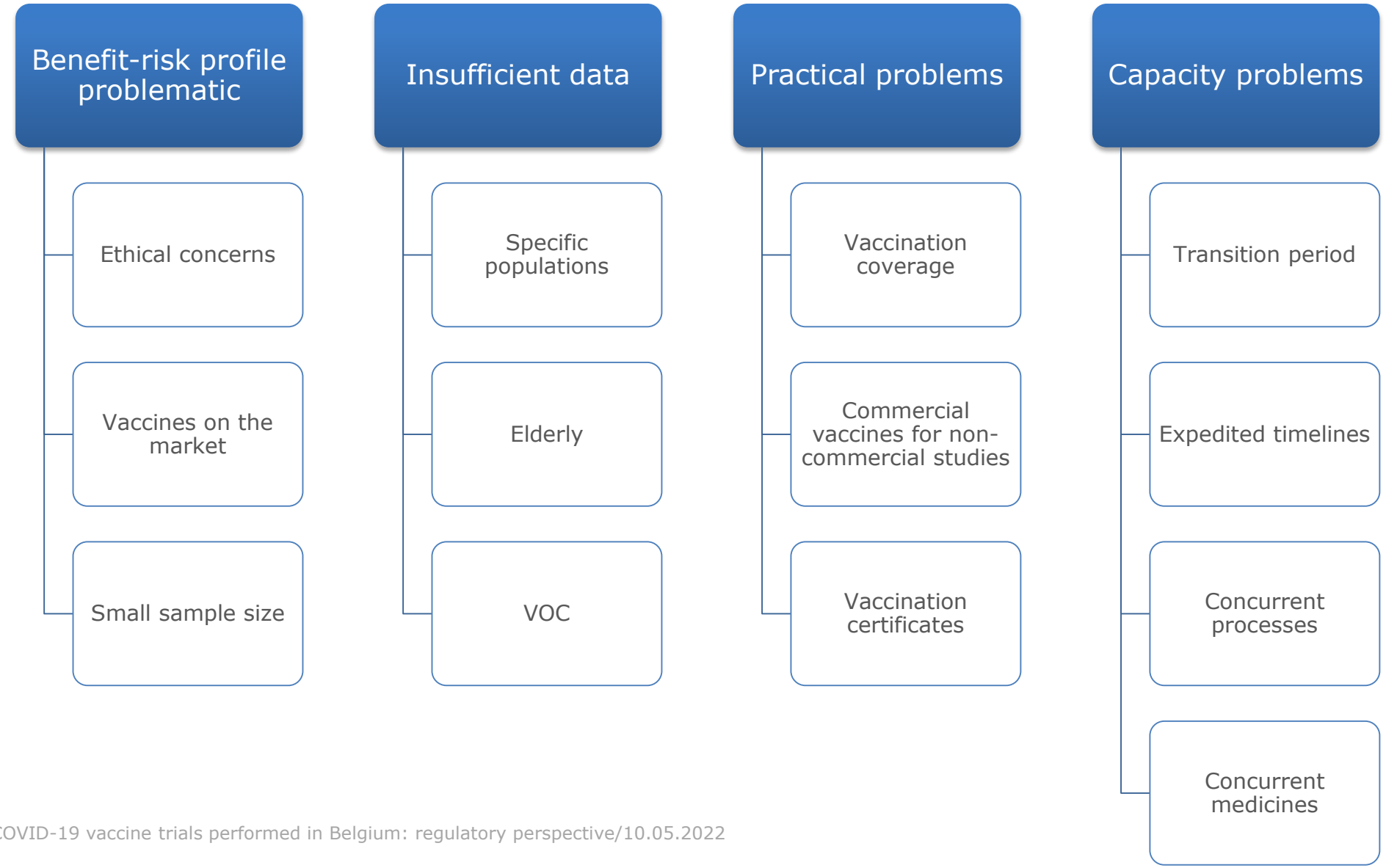
Source: https://trials.kce.be/dashboard/

- Effect on immune response if:
  - the interval between two vaccine doses is extended;
  - another brand of a COVID-19 vaccine is used for the second dose (booster);
  - half of the recommended dose is used.

Particularities and FAMHP's efforts to facilitate assessment

Expedited review	• **From 25 March 2020 until 18 November 2021:** first round evaluation within four working days (ATMP 10 days) • **From 19 November 2021 until now:** final decision within fifteen calendar days (non-CTR)
Time slots	• Time slots for CTR pilot project initial applications (twice/week) not applicable
Working groups	• Internal/external working groups to gain a better insight in upcoming clinical trials
Advice	• Scientific advice • Dossier managers maximised efforts to provide swift ad hoc regulatory advice
Belgian guidelines during the pandemic	• More possibilities to sign electronically • Missing administrative documents requested in parallel with the RFIs

Challenges FAMHP for COVID vaccine trials in pandemic setting



Regulatory perspective

Directive (2001/20/EC) and pilot substantial modifications (2001/20/EC): circular letter 653 (including GMO, ATMP)

CTR: expedited timelines in discussion for mononational trials in CTR (⇔ CT Cure project for therapeutics)

Contact

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