Internationale concurrentie

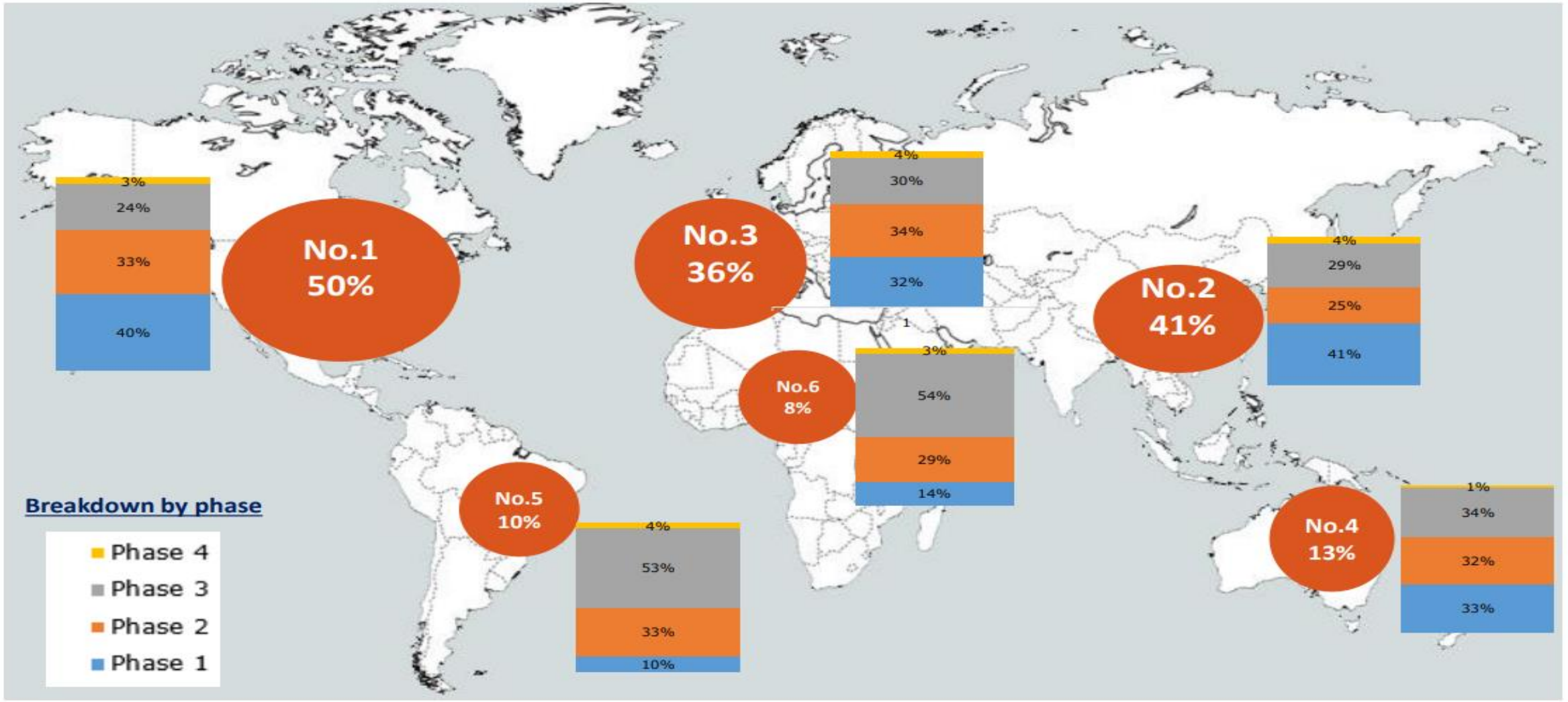
DCRF- EU CTR event

Arjan Ooms

Clinical Research Director in the Netherlands

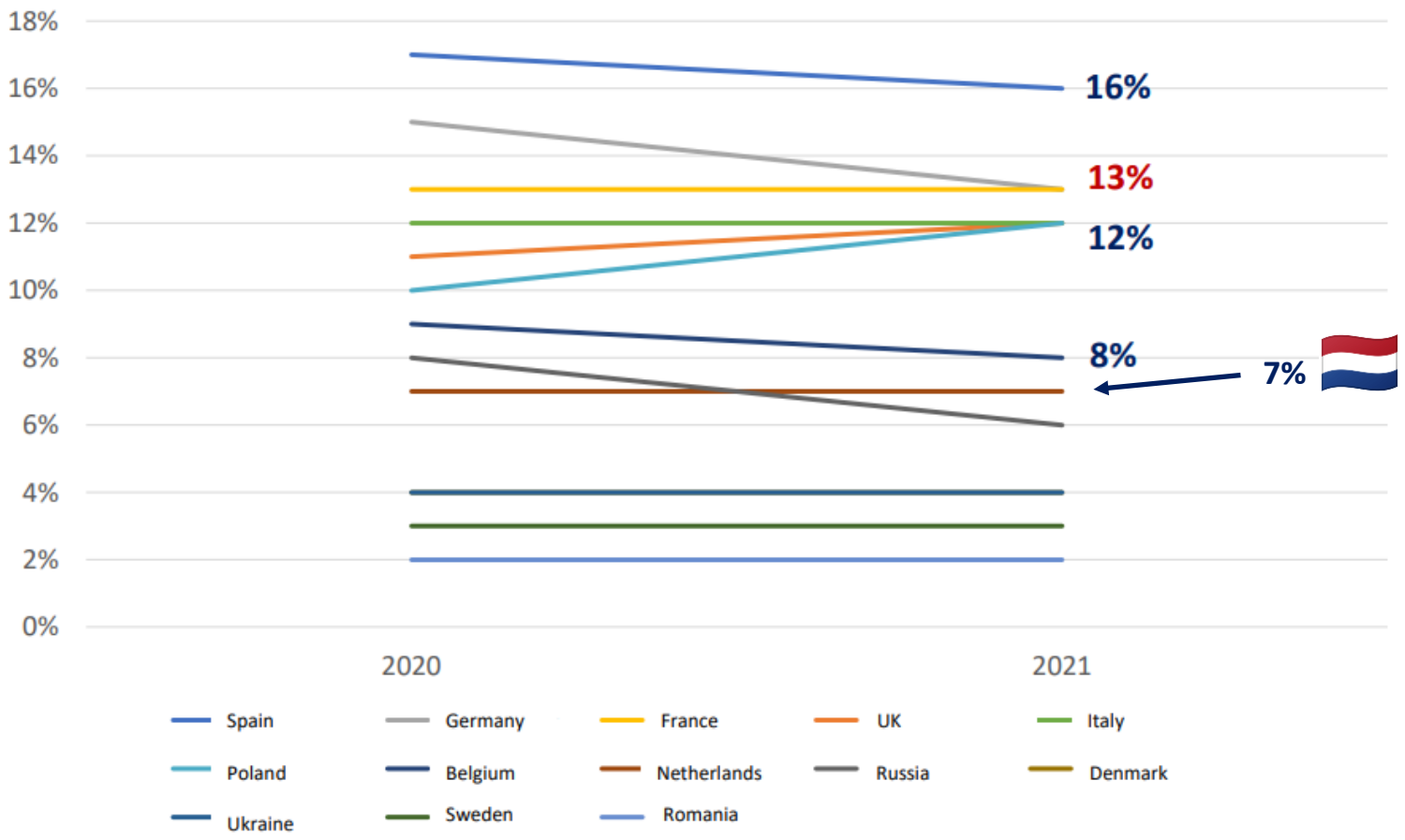
January 17, 2023

Europe #3 major region globally in conducting clinical trials



Bron: 3684 industry-led clinical trials for pharmaceutical products launched in 2021 (Leem industry survey 2022)

Netherlands ranks #8 with Denmark behind Belgium for trials conducted in Europe



Bron: 3684 industry-led clinical trials for pharmaceutical products launched in 2021 (Leem industry survey 2022)

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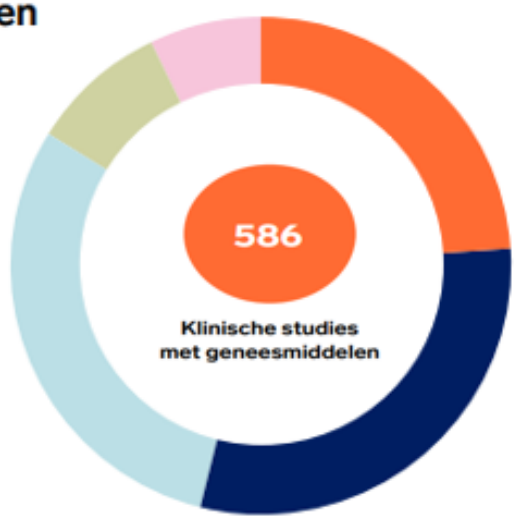
Netherlands attractive country for clinical research

Nederland actief betrokken bij alle fases van genees-middelenonderzoek

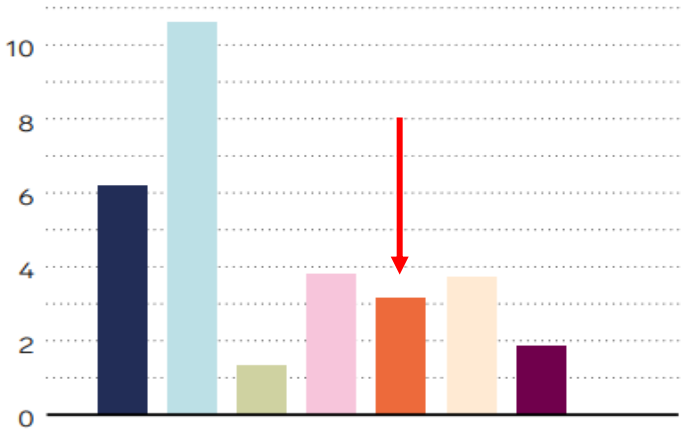
Geneesmiddelenonderzoek; aantal studies per fase

- 24% Fase I
- 9% Fase IV
- 30% Fase II
- 8% Overig
- 30% Fase III



Relatief weinig klinische studies in Nederland

Geneesmiddelenonderzoek; aantal studies per 100.000 inwoners

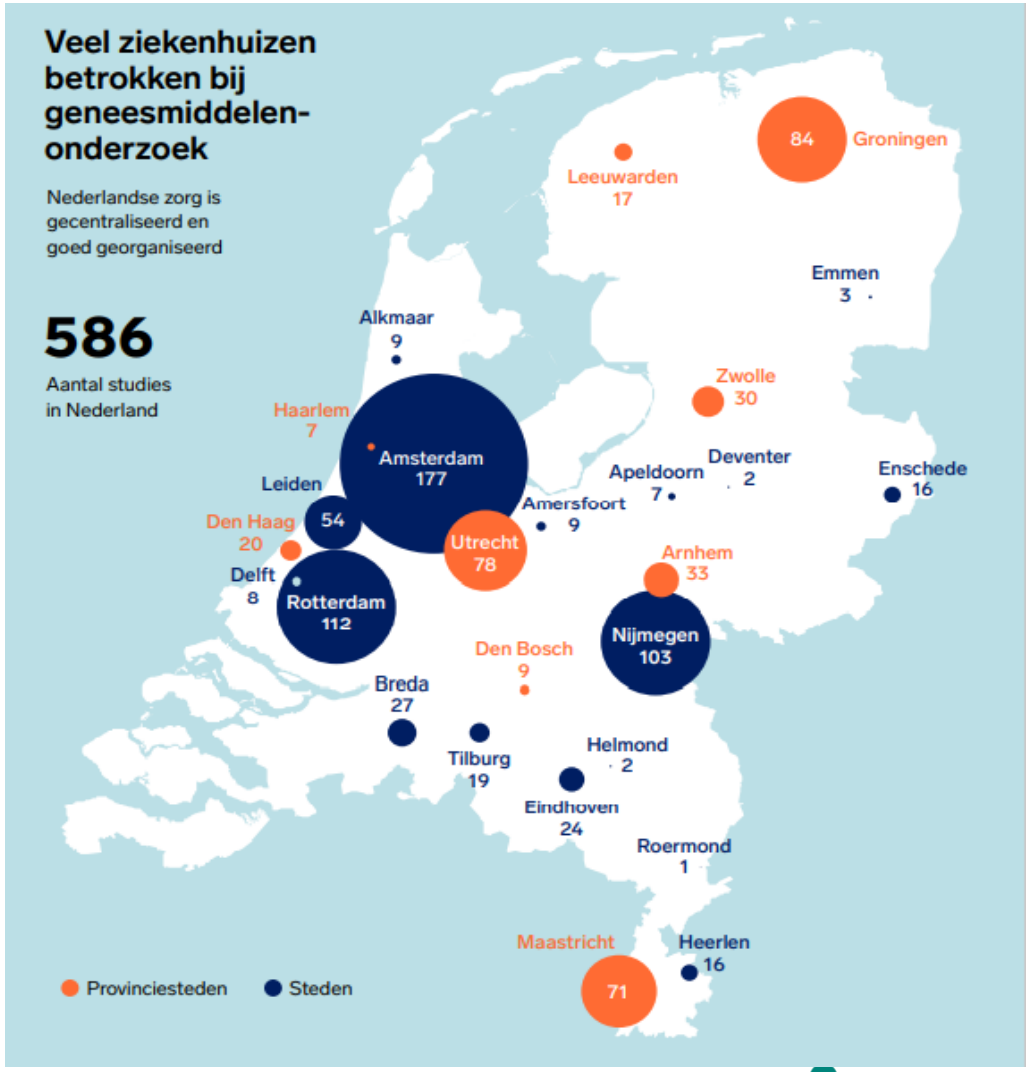


- België
- Denemarken
- Duitsland
- Frankrijk
- Nederland
- Oostenrijk
- Verenigd Koninkrijk

Veel ziekenhuizen betrokken bij geneesmiddelen-onderzoek

Nederlandse zorg is gecentraliseerd en goed georganiseerd

586
Aantal studies in Nederland



Bronnen: CCMO Jaarverslag 2020, Clinicaltrials.gov 2021, Boston aan de Noordzee 2021

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Country selection

INCIDENCE

COUNTRY STRENGTHS & WEAKNESSES

START-UP TIMELINES

COUNTRY KOL INVOLVEMENT

HISTORIC PERFORMANCE

COUNTRY SOC COMPARED TO PROTOCOL

RESOURCE CONSIDERATIONS

SITE/PATIENT AVAILABILITY

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Efficient START-UP via EU CTR

This new regulation, became effective on January 31, 2022, ensures a greater level of **harmonization of the rules for conducting clinical trials in the EU.**

The goal of **Clinical Trial Regulation EU No. 536/2014** is to **create an environment that is favorable to conducting clinical trials in the EU**, with the highest standards of safety for participants and increased transparency of trial information.

The regulation will **increase the efficiency of all trials in Europe (evaluation in 60-79 days)** with the greatest benefit for those conducted in multiple Member States.

It aims to foster innovation and research, while helping avoid unnecessary duplication of clinical trials or repetition of unsuccessful trials.

Europe wide Regulations
Harmonisation – Efficiency - Transparency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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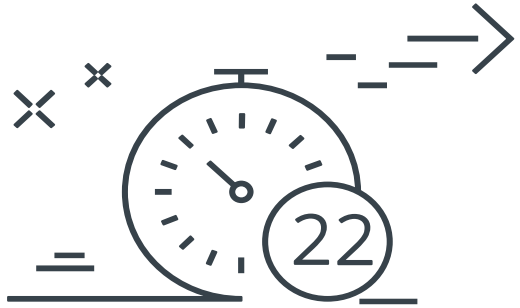
EU CTR 2018-2024 journey



Workstream Kick off & Setting the stage

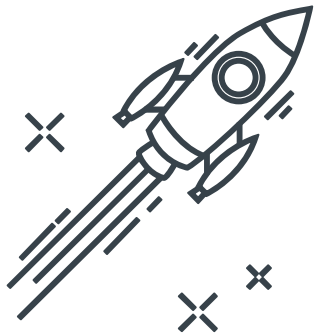
2018-19

Preparing for EU CTR

2020

Count down begins

2021



EU CTR Go Live Implementation

2022

Transition Period

2023

All new studies need to be submitted under EU CTR

End of Transition Period

2024

All studies submitted or transitioned to EU CTR

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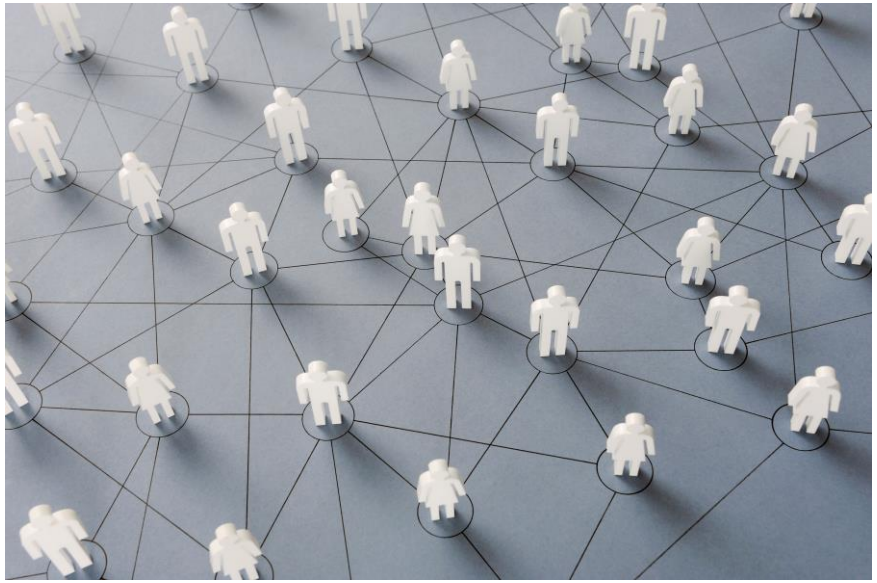
7

Conclusion + take away message

- EU CTR is a major imperative change, and we need to comply with the new EU CTR
- We are well prepared for EU CTR, but it is still early days, many unknowns. 2023 is year to bring down the cycle times
- As of now all new protocols will be submitted under EU CTR
- ***Take away message for continued success***
  - ***Good planning (e.g., VGO)***
  - ***Culture of collaboration***
    - ***also, to discuss challenges around staff and inflationary pressure affecting clinical trial***

Culture of collaboration and ability to connect the dots
…delivering as One Dutch Team



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