



# The CRO chase to master the evolving legislation

**Isabelle Vrancken & Mattias Dooreman**

PRA Health Sciences

23 June 2018



## Your Global, Oncology, and Cohort-Management Experienced Clinical Team

### Isabelle Vrancken, LLM

*Regulatory Affairs Associate*



- ✓ 1,5 years clinical research experience
- ✓ Local Regulatory Associate for Benelux
- ✓ Specialized: Implementation of EU CTR
- ✓ Researcher Faculty of Law (UA)

### Mattias Dooreman, MSc

*Senior Manager of Global Regulatory Affairs*



- ✓ 11 years of experience in clinical research
- ✓ Regulatory Manager for Benelux
- ✓ Specialized: Global Clinical Trial Application strategies



- Introductions to PRA Health Sciences and Global Regulatory Affairs
- Role of a CRO in the Clinical Trial landscape
  - Current challenges in Belgium
- Future Regulatory Challenges
  - 2018: GDPR
  - 2019: Brexit
  - 2020: CTR



# Introductions to PRA Health Sciences as a CRO



## PRA HealthSciences: CRO as Full Service Provider



**2 Bioanalytical  
Laboratories**  
US and EU



**Strategic Solutions**  
Staff Augmentation  
FSP  
Embedded Solutions™



**7 Clinical  
Pharmacology Units**  
3 in the US  
4 in the EU



**Post-Marketing  
Research**  
Tailored Approach  
to Real-World Research



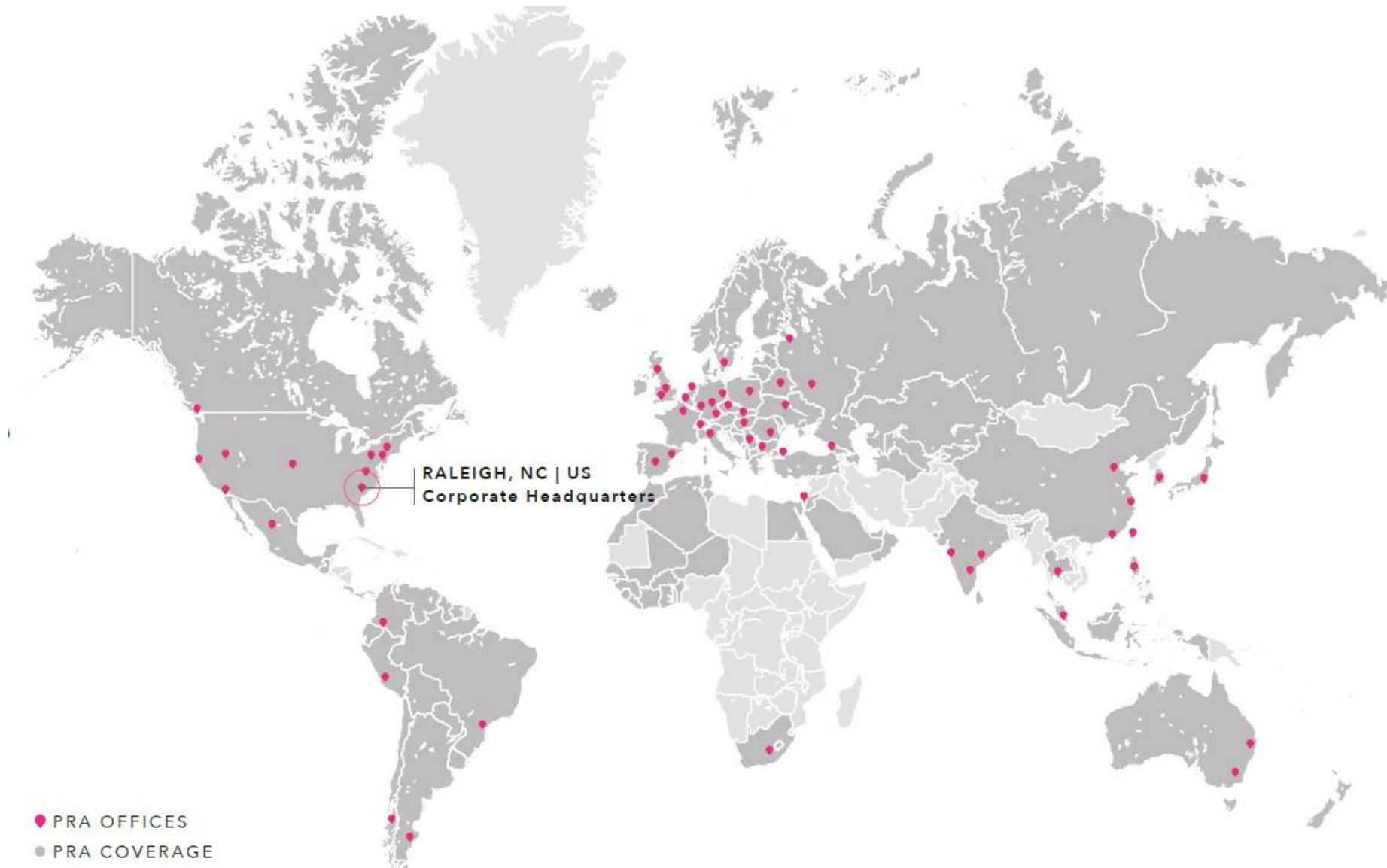
**Clinical  
Development**  
Phase II-III Studies



**7 Global Drug  
Safety Centers**

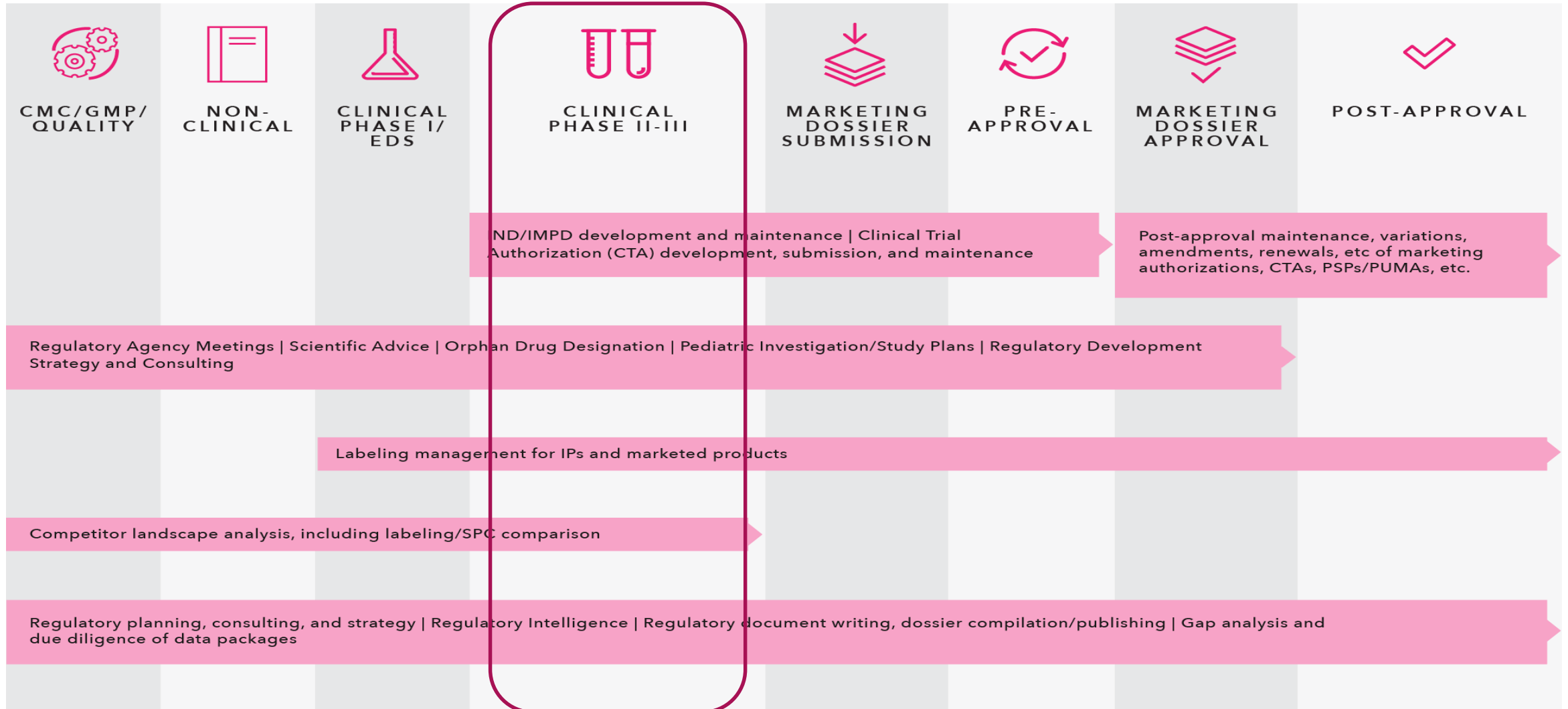


# PRA HealthSciences as Global Provider





# Global Regulatory Affairs - Scope of Services





Regulatory  
Intelligence  
Team

Country  
Consultants

Country intelligence database

Repository of applicable laws, regulations and ethical guidelines used to ensure that PRA maintain compliance in each country where we operate

Facilitate access to high-value and frequently referenced regulatory intelligence

Rapidly identify and communicate significant changes in the regulatory environment to key internal stakeholders





# Role of a CRO in the Clinical Trial landscape



- Project Management:
  - Clinical Operations on site monitoring
  - Regulatory Approvals RA and EC submissions
  - Contracts / Budgets Site Agreements and Budgets
  - Logistics Drug, Lab kits, Training materials, etc.
  - Pharmacovigilance / Data Management / Medical Monitoring / ...
- Being able to provide solid scientific and operational advice is key !
  - To the Investigators
  - To the Sponsors



## What do our clients want to know?

- When will my study get approved? → Can we do it faster?
- How much will it cost? → Can we do it cheaper?
- Will they accept our protocols? → Please look into your crystal ball?



## What can we offer our clients?

- Can we do it faster?

*« I know that the legislation in Belgium says you can expect feedback in 28 days, but.... »*

- Can we do it cheaper?

*« We can propose alternative strategies or go to other countries, but.... »*

- Please look into your crystal ball?

*« Unfortunately dealing with Ethics Committees is not exact sciences... »*



- « Grey Areas » in legislation
- Different local interpretations
- Widely different EC procedures
- No consistency among EC reviewers (even within same EC)
- Insufficient transparent communication from FAMHP



# Future Regulatory Challenges



- Sponsor prepared ↔ EC unprepared
- Uniformity EC's?
- FAMHP?
- Sponsor ↔ patient?



- Customs Union, freedom of movement
  - Importation of study drugs
  - Free movement of clinical trial supplies
- Affected people
  - Mutual recognition of professional qualifications
  - Cross border recruitment of patients
- Risk and Impact Analysis to reassure and assist clients
- Diverting clinical trial regulations?
  - To what extent will the UK remain in alignment with the CTD and CTR ? GDPR?
  - Mutual Recognition Agreement for clinical trial data





- Belated implementation: sponsor's concerns
- Loss of competitiveness?
- FAMHP?
- Impact on Ethics Committees?



# Questions?

[DooremanMattias@prahs.com](mailto:DooremanMattias@prahs.com)

[VranckenIsabelle@prahs.com](mailto:VranckenIsabelle@prahs.com)

WE ARE DEDICATED TO  
THE FUTURE OF CLINICAL DEVELOPMENT  
AND TO EVERY LIFE IT SAVES.



PRAHEALTHSCIENCES