Regulatory Affairs (clinical trials)

Costantino Congiatu
Regulatory Affairs Manager

5th June 2017

PPD®

Contents

1) Professional Profile

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

- School of Pharmacy
- Prof Chris McGuigan Lab
- Medicinal Chemistry
- Anticancer Nucleotide Prodrugs (aka phosphoramidates or ProTides)

- Cardiff ProTide (University spin-off)

morvus

- NBGW, Carmarthen
- R&D
- ProTide Project Management
- Patent Litigation
- Due Diligence

PPD

- Global CRO, Cambridge
- Reg Affairs
- Clinical Trials

2) Working at PPD (Contract Research Organization)

19,000+ Professionals worldwide

89 Offices, clinics and labs in **47** countries

PPD's Global Footprint

HAVE WORKED WITH **all of the top 50** PHARMACEUTICAL COMPANIES
AND MORE THAN **750** BIOTECHNOLOGY COMPANIES

PPD worldwide

19,000+
EMPLOYEES

2,400+ clinical trials
IN THE PAST 5 YEARS

CONDUCTED CLINICAL TRIALS IN
101 countries
TO ADVANCE THERAPIES THAT
LEAD TO IMPROVED LIVES FOR PATIENTS

The Clinical Research Drug Development Cycle

DRUG DEVELOPMENT PROCESS

Out of every 10,000–15,000 new compounds identified during discovery, **five are considered safe for testing** in human volunteers. **Only one of these compounds** is typically approved **as a marketed drug.**

3-6 YEARS

- Drug Discovery
- Pre-clinical

Pre-discovery

6-7 YEARS

Clinical Trials

Phase I	Phase II	Phase III
20-100 Volunteers	100-500 Volunteers	1,000-5,000 Volunteers

IND Submitted

0.5-2 YEARS

- FDA Review
- Manufacturing
- Phase IV Post-Approval

NDA Submitted

AVERAGE COST: $1 billion+ **DURATION:** 10-15 years*

PPD

*Source: ACRO

ppdi.com

PPD's Comprehensive Services

Laboratories

- Current Good Manufacturing Practice (cGMP) Labs
- Bioanalytical Labs
- Central Labs
- Vaccines and Biologics Lab

Early Development

- Chemistry, Manufacturing and Control (CMC) Consulting
- Dental Pain Research Clinic
- Manufacturing and Controls
- Nonclinical Development and Chemistry
- Pharmacology and Toxicology
- Phase I Clinic (for healthy volunteers)
- Phase I Patient Network
- Translational Medicine

Clinical Development

- Biostatistics
- Clinical Supplies
- Clinical Trial Monitoring
- Data Management
- Feasibility Studies
- Global Pharmacovigilance
- Medical Communications
- Medical Writing
- Patient Recruitment
- Pharmacokinetics and Pharmacodynamics (PK/
- Project Management
- Quality and Compli
- Regulatory Affairs
- Study Startup

Post-Approval

- Early Planning for Post-Approval Research
- Epidemiology
- Expanded Access and Compassionate Use Programs
- Global Pharmacovigilance
- Health Economics and Outcomes Research
- Medical Communications
- Observational Studies
- Phase IV Clinical Research
- Patient Registries
- Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans
- Established product lifecycle maintenance

Consulting

- Adaptive Trial Design
- Biosimilars
- Cardiovascular Outcomes
- Medical Devices
- Pediatrics
- Product Development
- Rare Diseases

3) Regulatory Affairs (RA) at PPD

- Secures necessary regulatory approvals for clinical development and marketing of new products
- Maintains licences in line with expected compliance standards
- Provides advice and guidance across a wide range of product types, therapeutic areas and geographies

RA leads and delivers on wide range of projects

LEAD PROJECTS

- Regulatory Development Science: RALs
- CMC
  Labelling
- Medical Devices, Diagnostics & Government Solutions
- Regulatory Functional Solutions

SUPPORT PROJECT DELIVERY

- FLEX Centre
- Regulatory Intelligence Solutions
- Electronic Publishing and Submission Management
- RCR

COUNTRY EXPERTS

- US Regulatory Solutions
- Japan Regulatory Solutions
- China Regulatory Solutions
- Country Regulatory Network

Regulatory Business Development

Regulatory Standards: processes, training, compliance

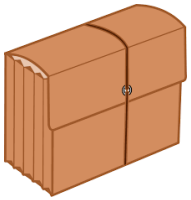
4) Regulatory Affairs Lead (Clinical Trials)

- Clinical trial objective:
  - prove drug is safe & effective in humans

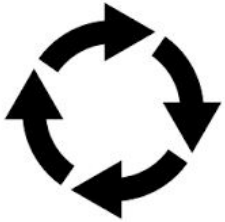
- National regulatory agencies objective:
  - protect human subjects
  - assure the integrity of the data
  - assure that the data is verifiable

Clinical trial Sponsor must receive permission from each applicable national, and/or local regulatory authority.

Clinical Trial Regulatory Affairs Lead (RAL)



Submission Dossier
(Cover Letter, Application Form, Protocol, IB, IMPD, ICF, Labels, etc)

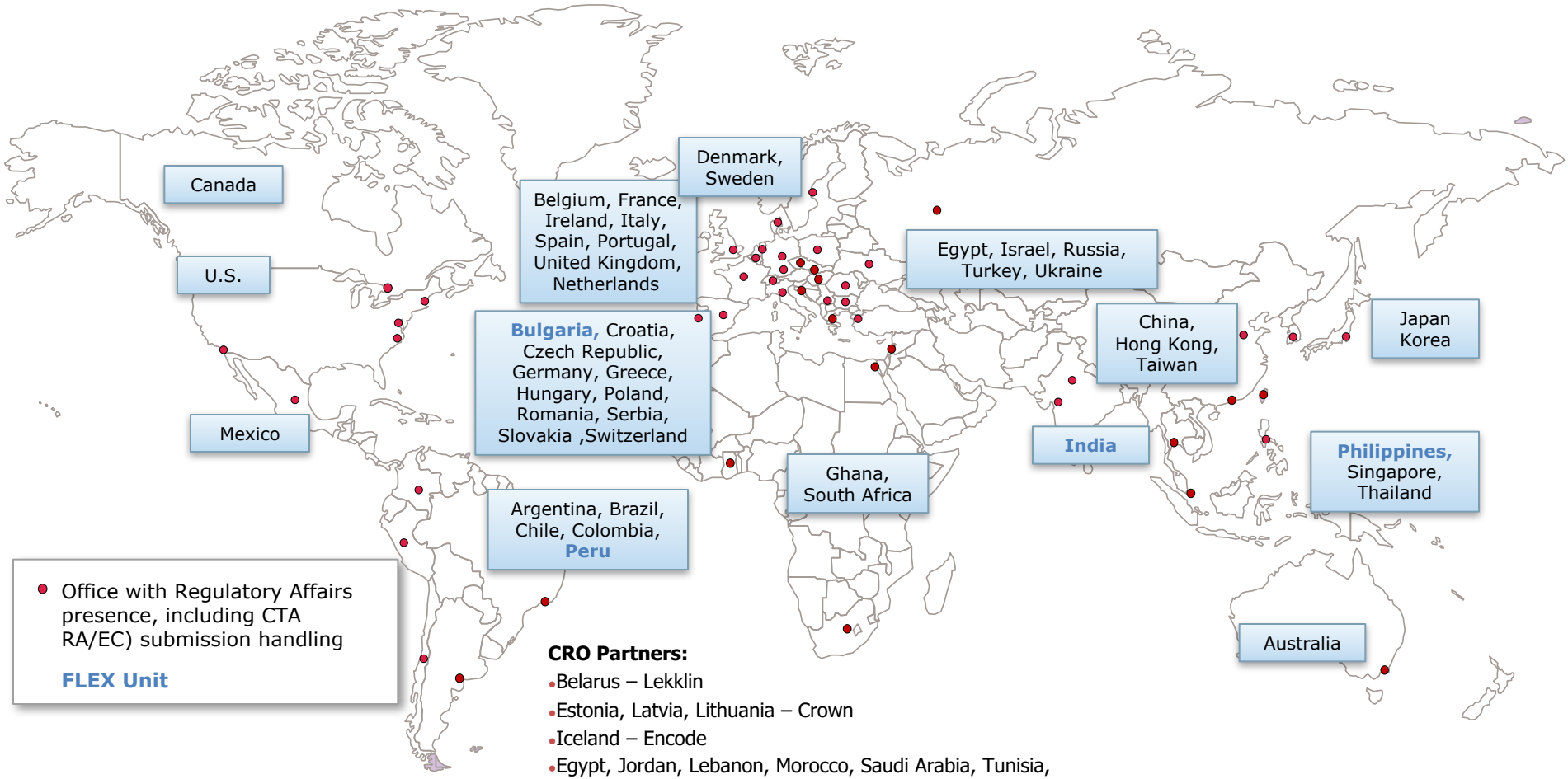


Full Clinical Trial Maintenance
Initial Application
Amendments
Annual Progress Report
End of Trial
Clinical Summary Report

Submission Coordination and Support
Project team, local teams and clients
Meetings
Tools to manage projects
Multiple projects at same time
Proposal preparation, bidding and bid defence activities

Travel
F2F Client meetings

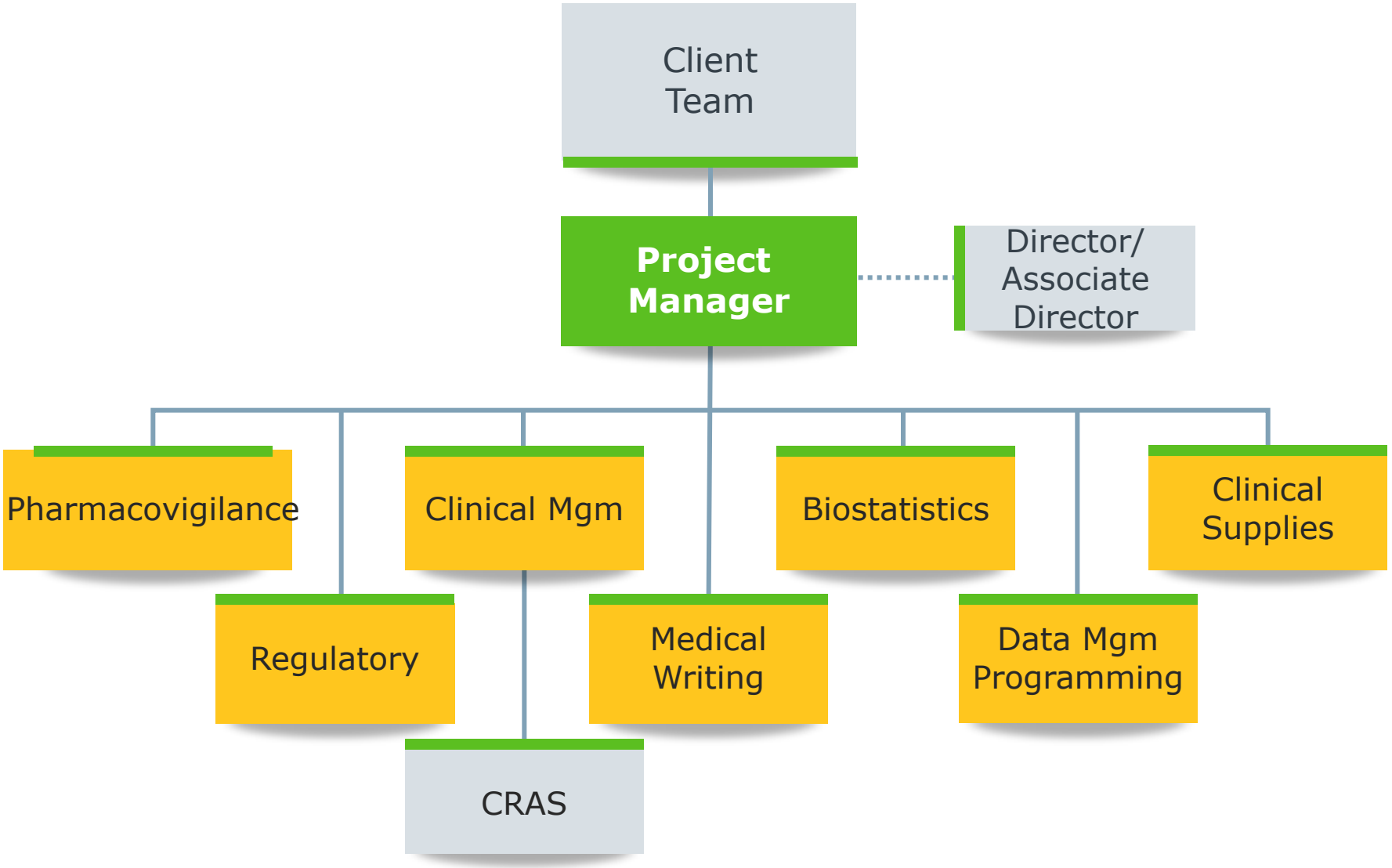
PPD Regulatory Footprint



CRO Partners:

- Belarus – Lekklin
- Estonia, Latvia, Lithuania – Crown
- Iceland – Encode
- Egypt, Jordan, Lebanon, Morocco, Saudi Arabia, Tunisia, United Arab Emirates – MCT and CLINART
- Kazakhstan - SynRG
- Macedonia - Comaq

Clinical trials: Project Team Structure



Regulatory Affairs: what do we need

- Life-science graduates
- Previous experience in RA preferred, not essential for all roles
- Excellent communication skills
  - English language
  - Written and oral
  - Client-friendly
  - Global mind-set
- Business acumen
  - Understand broad business context of projects
  - Ability to sell RA services and expertise
  - Understand competition
- Creativity and innovation
  - Able to find solutions to problems
  - Ability to foresee risks and implement mitigations
  - Flexible
  - Able to work with high degree of autonomy
- Able to think and act quickly
- Go the extra mile

PPD Culture

- Strong teamwork culture - creates togetherness, momentum and minimises internal competition
- Robust and tested processes - deliver consistent and compliant outputs. We don't fix them if they are not broken.
- Continual and positive encouragement from management and peers to identify and implement new ways to deliver more and better returns to our clients.
- Close and enthusiastic support from key functions like Legal, Finance, HR positively enhances business.

5) Tips

- Homework
  - search the employer (e.g. values, history, key facts)
  - understand the job you are applying for
  - adapt your CV
  - boost your profile (e.g. Topra courses)

- Networking (e.g. LinkedIn, recruiters, referrals)

- Interview
  - read & understand the job specifications
  - prepare for telephone and F2F meetings
    (why do you want to work for us? why regulatory affairs? why you? what's in for us?)
  - practical examples/situations
  - attitude, communication and mannerism

Relax…..every interviewer hopes you will be the new star!!!