



TOPICS

Lunteren, 8 December 2011

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Clinical Research Associate

PPD Overview

11,000 Professionals worldwide

86 Offices/clinics/labs in 44 countries



- Development services since 1985
- Clients include 49 of the top 50 pharmaceutical* companies and 150+ biotechnology companies
- Recognized by *Forbes* as one of America's best big companies

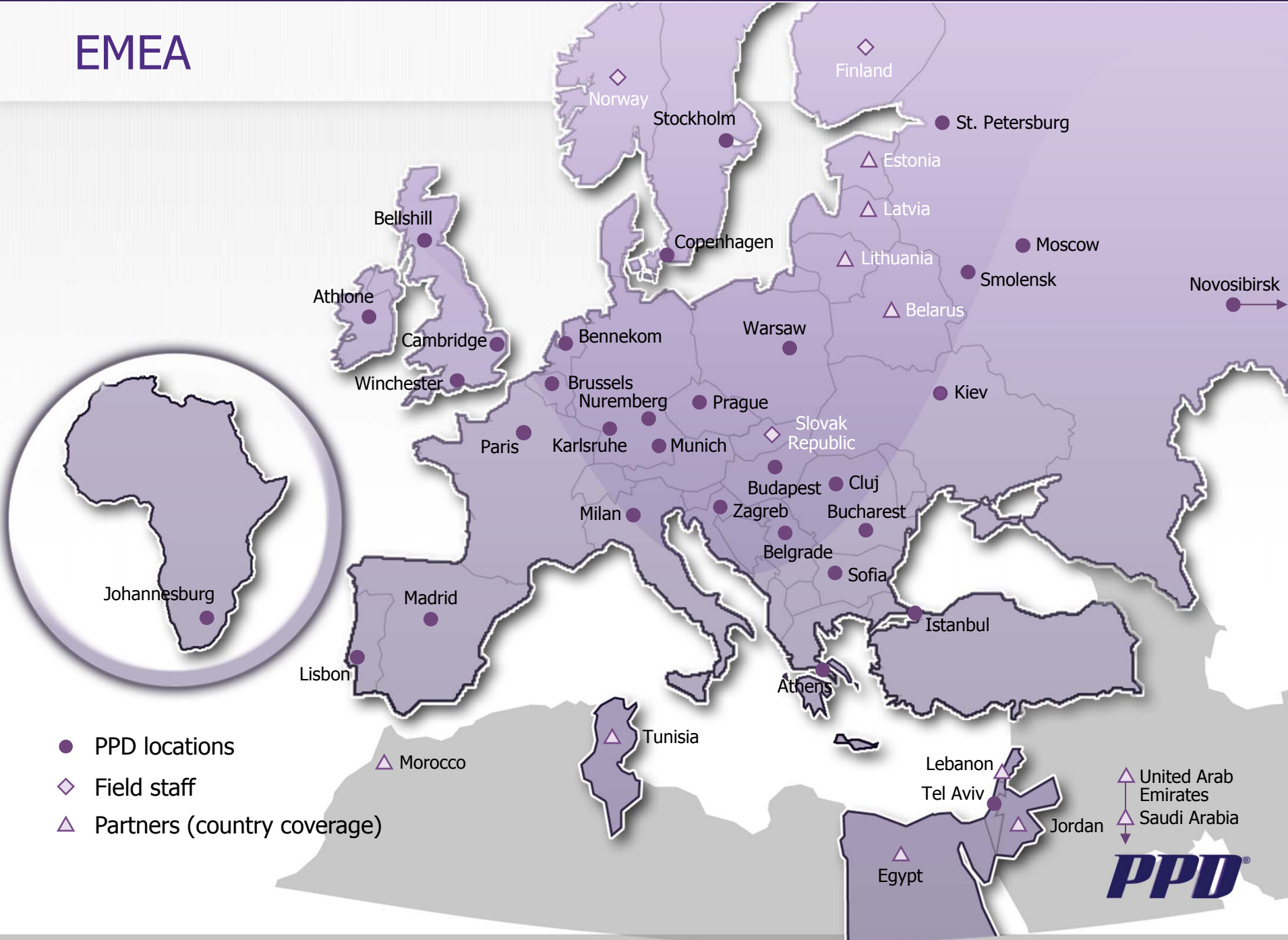


* Ranked according to 2009 R&D spend

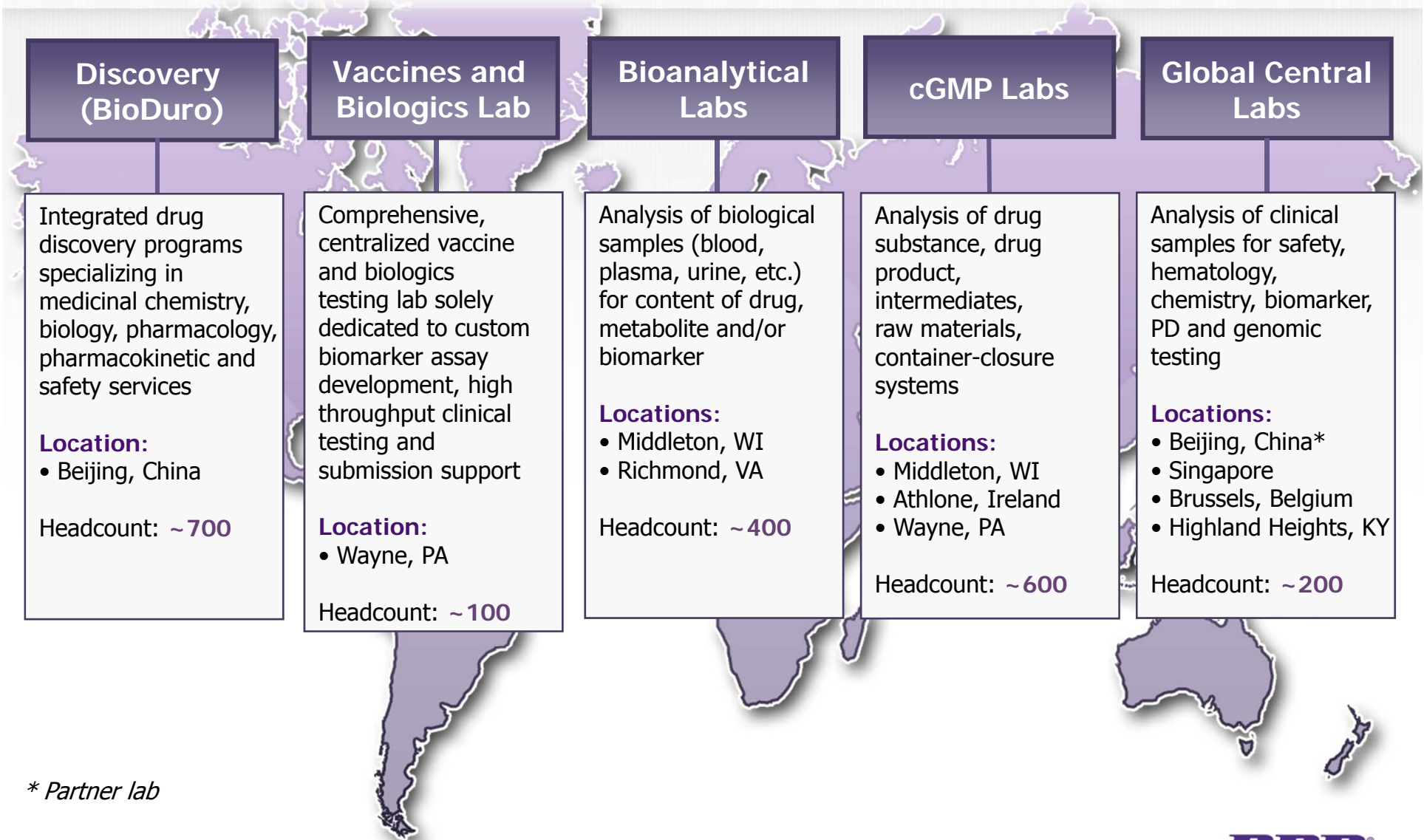
Global Infrastructure



EMEA



PPD's Laboratory Network



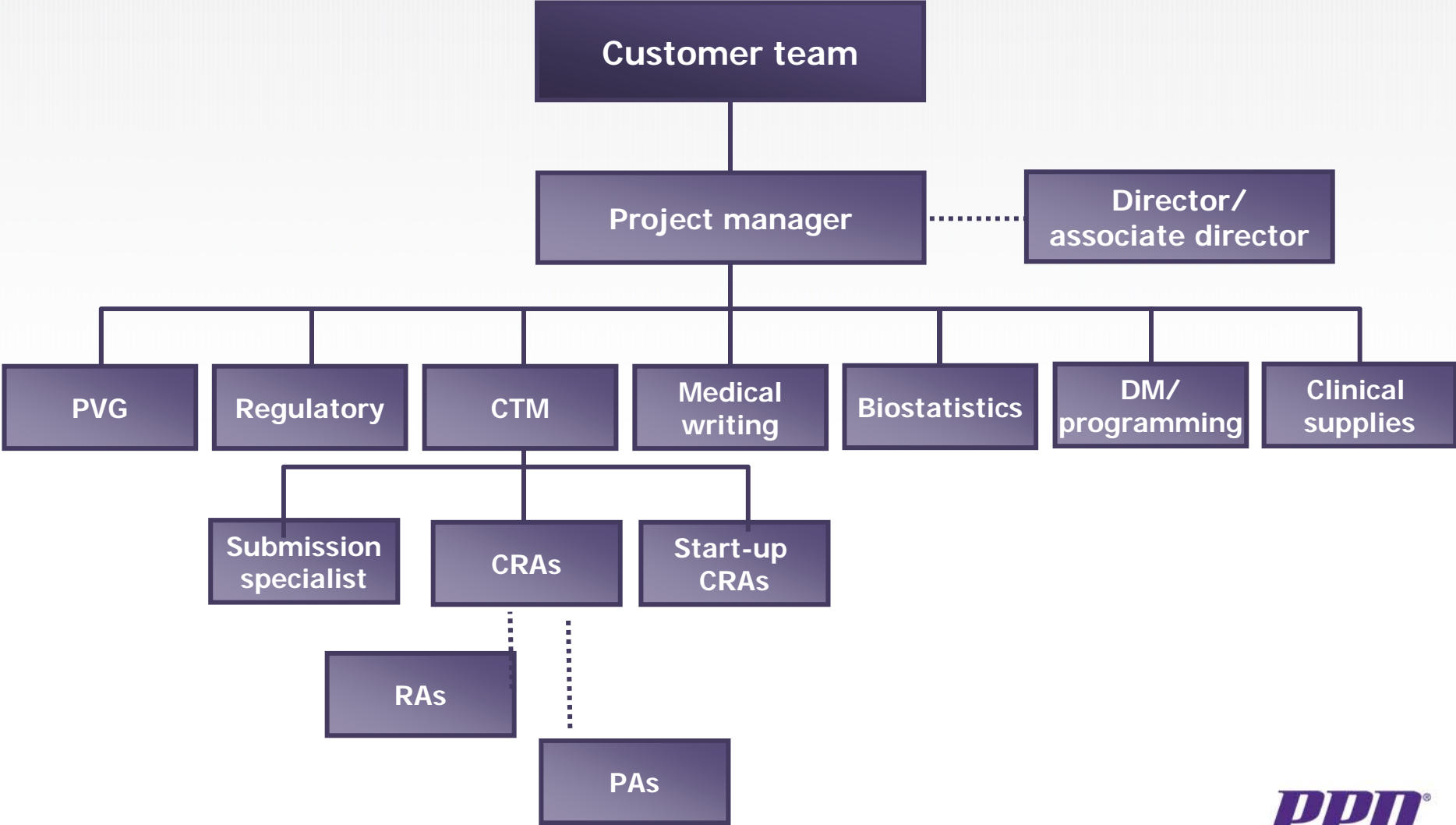
* Partner lab

PPD Clinics

**Phase I Clinic
Austin, TX
128,000 square feet
300 beds
106 studies/year**

**Dental Pain
Research Clinic
Austin, TX
8,000 square feet
10-20 beds
6+ studies/year**

Project Team Structure



Development Services from PPD

Accelerate Development

With Integrated Services & Global Reach

PPD brings you the **efficiencies** of an established worldwide infrastructure of systems, processes and services through all phases of research and development.

Capitalize On Our Strengths

Service, People & Quality

At PPD, we **adapt to your needs**, ensuring you get what you need when and where you need it.

Discovery

Preclinical

Phase I

Phase II - IIIb

Post-Approval

Global Central Labs/cGMP Labs/Bioanalytical Labs/Vaccine & Biologics Lab

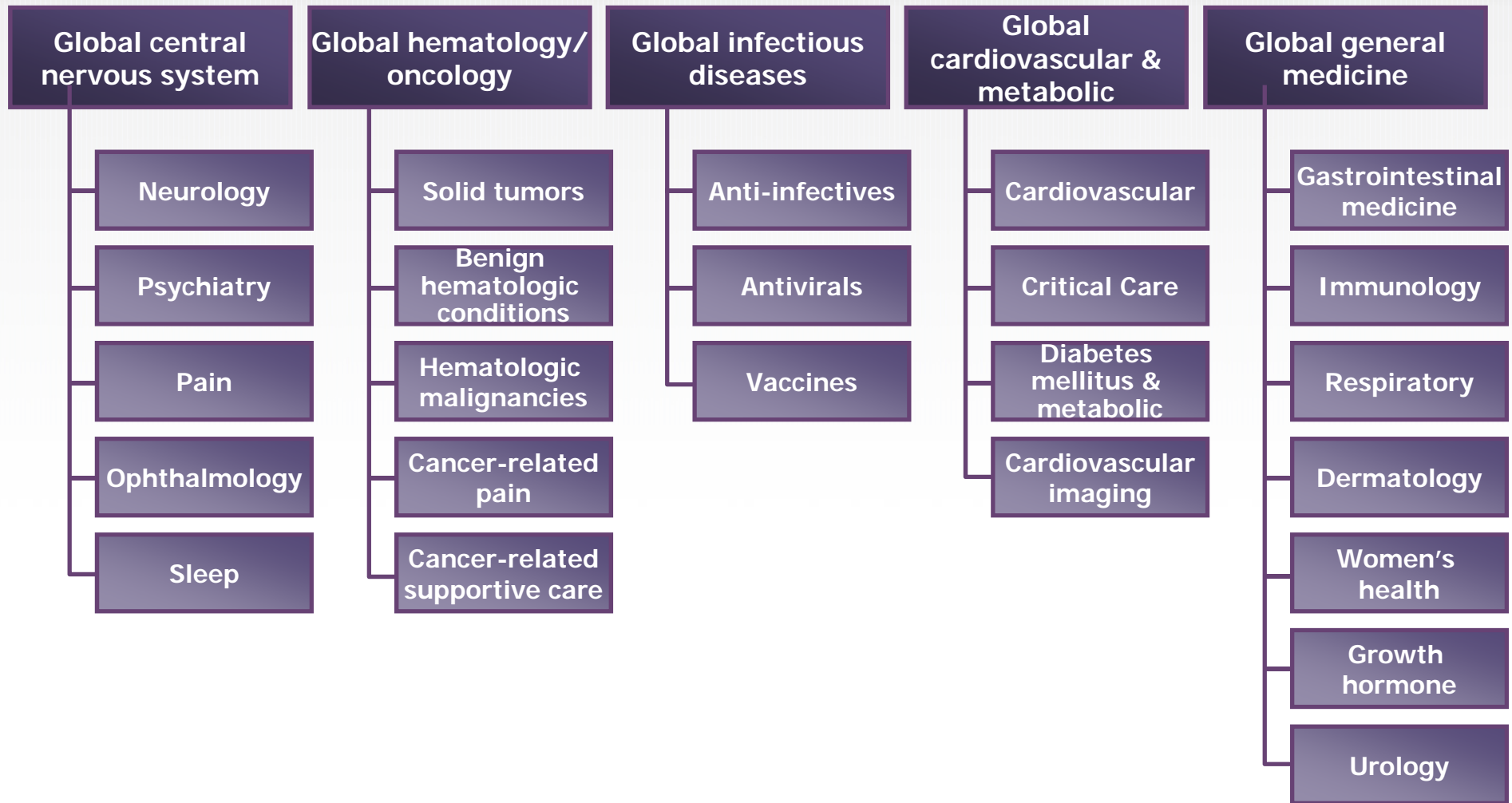
Discover New Solutions & Strategies

With Expertise & Experience

PPD combines an in-depth knowledge of science and technology with a comprehensive understanding of the product development process from both the **therapeutic and regulatory perspectives**.

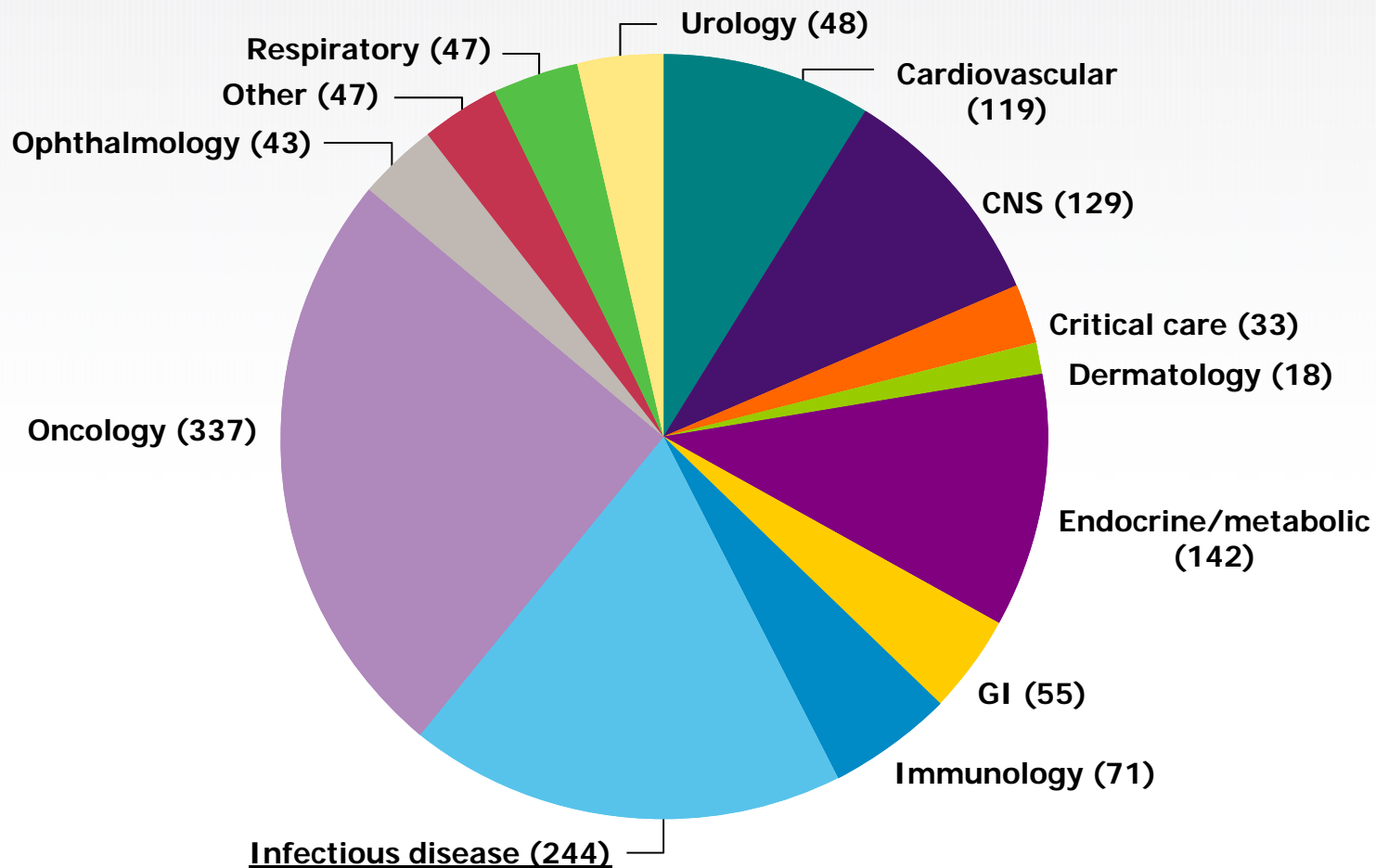
PPD[®]

Global Therapeutic Areas



PPD Experience Ongoing January 2005 – Present

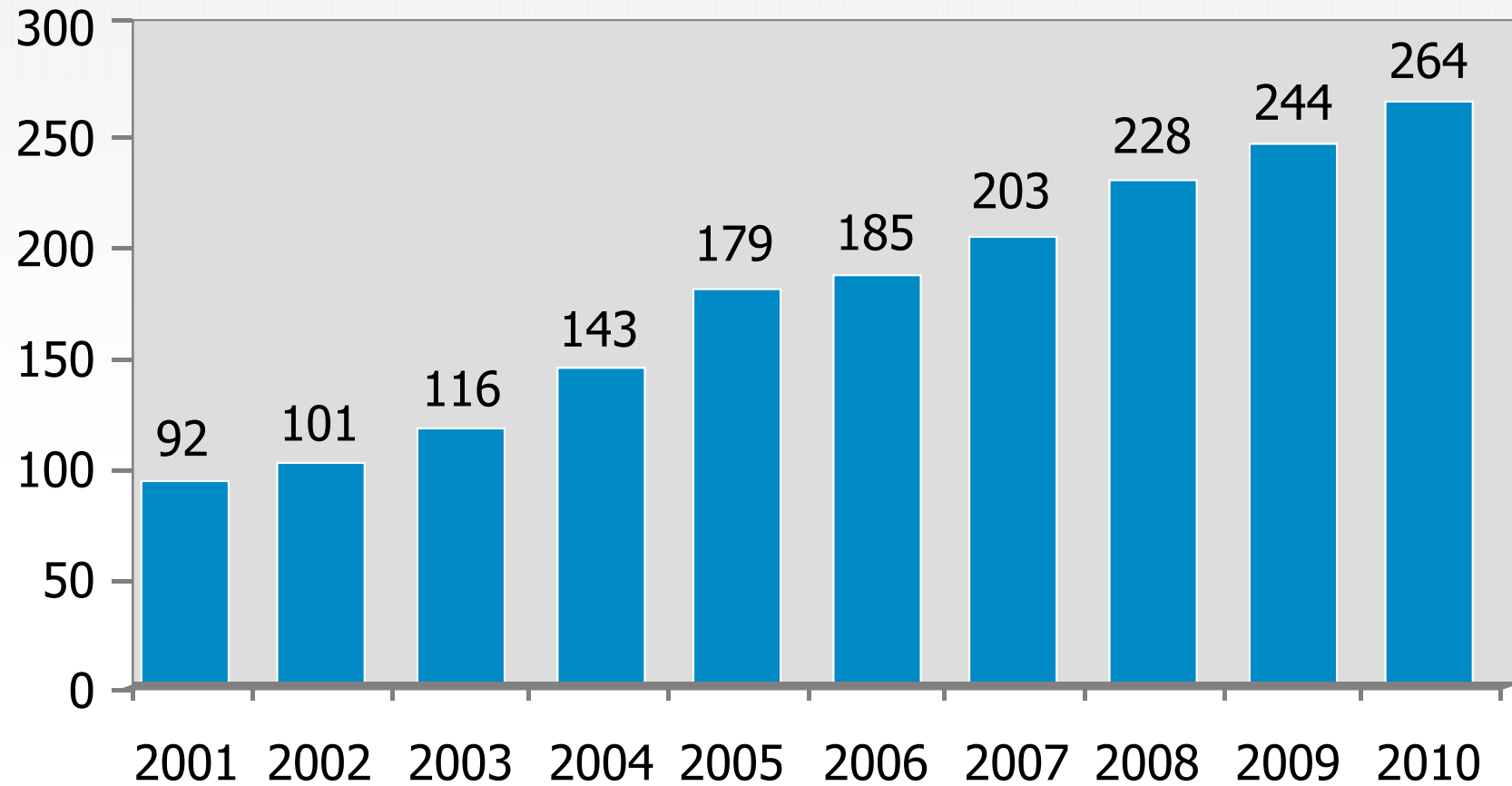
Number of Clinical Studies by Therapeutic Area*
Total: 1,333



* Includes clinical monitoring, project management, strategic resourcing



PPD Global Trials Growth



Decrease for Dutch Trials

Clinical research in the Netherlands decreased with 28%

- In 2008:
 - 391 studies
 - 140.000 subjects participating in clinical research
- In 2010:
 - 282 studies
 - 63.000 subjects participating in clinical research

(source: Annual report CCMO 2010)

Why decrease for Dutch Trials

- High start-up costs in NL
- Slow ethics committee approval process
- High price per patient compared to Eastern Europe and Asia

Global CRO Partner Network

- Eastern Europe
 - Belarus – Lekklin
- Baltic States
 - Estonia, Latvia, Lithuania – Crown
- Iceland
 - Encode
- Middle East and North Africa (MENA)
 - Egypt, Jordan, Lebanon, Morocco, Saudi Arabia, Tunisia, United Arab Emirates (UAE) – MEK, MCT and ClinServ

Global Capabilities

- Seamless management of differences created by multi-cultural environments

Regulations	Ethics
Laws	SAE reporting
Monitoring coverage	Time zones
Culture	Public holidays
Geographic locations	Language

Ensuring Harmonization

- Work within global SOPs/WPDs to produce consistent deliverables from clinical operations
 - Clean data from the agreed number of patients
 - On time, meeting the quality expectations of the customer and within budget
- Local WPDs ensure that local requirements can be met while retaining global integrity of final deliverable

Key Differentiators for the Netherlands

- **Site:**
 - Commitment to high quality service
 - Dedicated, high educated site staff
 - Well organized and modern wards, processes and systems
 - The correct amount of potential study subjects
 - Flexibility and responsiveness to meet deadlines
- **PPD:**
 - Commitment to high quality service
 - Dedicated, therapeutic-specific project teams
 - Global infrastructure, processes and systems
 - Flexibility and responsiveness

Discussion to improve Dutch position in clinical research

- How can we improve the Dutch position?
 - Faster patient recruitment
 - Lower research costs
 - Quality research staff
 - Approval process METC and CCMO
 - Etc.

Investigator Directory System (IDS)

- Contains 55,500+ investigator names by therapeutic specialty and disease indication
- Generates listings of investigators for consideration by study
- Records detailed investigator project performance data

Global Government and Health Services

- Manages large clinical programs under government contracts
- Monitors and manages a vast scope of protocols for HIV, infectious diseases, allergy, immunology, transplantation and vaccines
- Offers support from preclinical through licensure and post-approval

Strategic Development Solutions

**Comprehensive services
from preclinical strategies
to market approval**

**Integrated management
for speed, efficiency and
superior results**

**International
registration strategy
and expertise**

**Applied therapeutic
specialization for successful
product development**

Post-Approval Services

Medical information

Pharmacovigilance

Late-stage research

Registries and observational studies

Epidemiology, risk management, REMS
and outcomes research

Thank you for your attention

Any questions?