

# PAREXEL® CONSULTING

17 Nov 2016 PDA <Johnny Murphy, MBA





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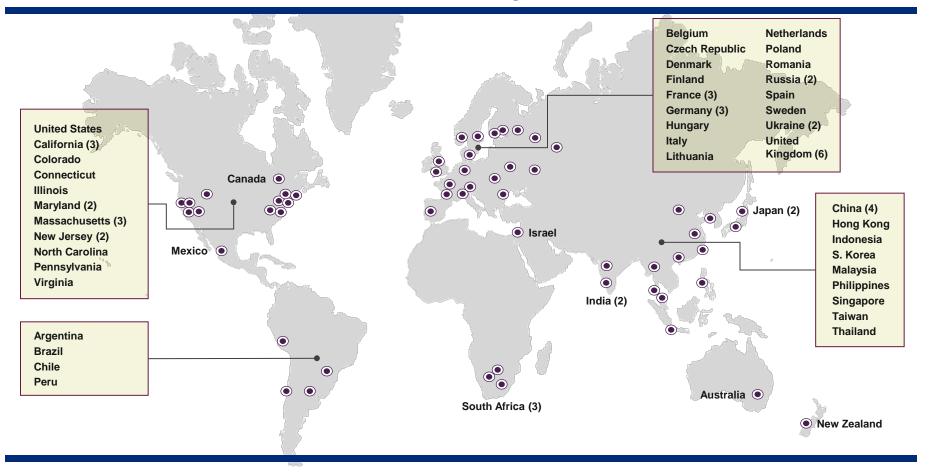
# FULL RANGE OF EXPERTISE

PAREXEL CLINICAL RESEARCH SERVICES	PAREXEL INFORMATICS	PAREXEL CONSULTING	PAREXEL ACCESS
<ul> <li>Early Phase Services</li> <li>Phase II-III Services</li> <li>Clinical Trial Supplies &amp; Logistics</li> <li>Quantitative Clinical Development</li> </ul>	<ul> <li>Clinical Data Management (DataLabs<sup>®</sup> EDC)</li> <li>Randomization and Trial Supply Management (ClinPhone<sup>®</sup> RTSM)</li> <li>Electronic Patient-Reported Outcomes (ePRO)</li> <li>Perceptive MyTrials<sup>®</sup> Platform and Infrastructure</li> <li>Study Management and Monitoring (IMPACT<sup>®</sup> CTMS)</li> <li>Medical Imaging</li> <li>Regulatory Information Management (LIQUENT InSight<sup>®</sup>, LIQUENT SmartDesk<sup>™</sup>)</li> </ul>	<ul> <li>Regulatory Strategy and Operations</li> <li>Regulatory Outsourcing Services</li> <li>Integrated Product Development</li> <li>Strategic Compliance &amp; Risk Management</li> <li>Regulatory Information Management &amp; IDMP</li> </ul>	<ul> <li>Late Phase Interventional</li> <li>Observational Research</li> <li>Drug Safety</li> <li>Market Access Consulting</li> <li>Medical Communications</li> </ul>



# PAREXEL GLOBAL PRESENCE

### Located in 77 offices throughout 51 countries





# EMERGING COMPANIES FACE ENORMOUS PRESSURES

PERCENT OF R&D ORIGINATED OUTSIDE THE TOP 25 PHARMACEUTICAL COMPANIES

 Working under financial constraints

- Demonstrating proof-of-concept
- Creating Target Product Profiles with endpoints that support regulatory approval

 Identifying the right partner for protocol design, site selection and data collection/integrity

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- Managing ever-changing regulatory and reimbursement landscapes
- Overcoming limited time and resources



## PAREXEL® CONSULTING



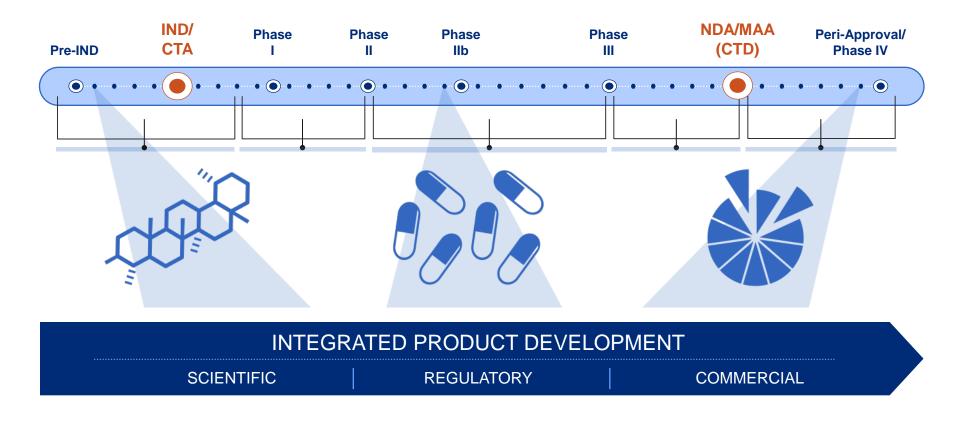
## ADDRESSING YOUR DRUG DEVELOPMENT NEEDS EVERY STEP OF THE JOURNEY

- Incorporating needs of key global stakeholders early
- Addressing product efficacy, safety, <u>and value</u>
- Innovating throughout for faster, smarter development



# MAXIMIZING THE VALUE OF YOUR PRODUCTS

Leveraging our unique fusion of scientific, regulatory and commercial expertise to get products to market smarter and faster.





# DRIVEN TO SOLVE THE COMPLEX

## Integrated product development and lifecycle management:

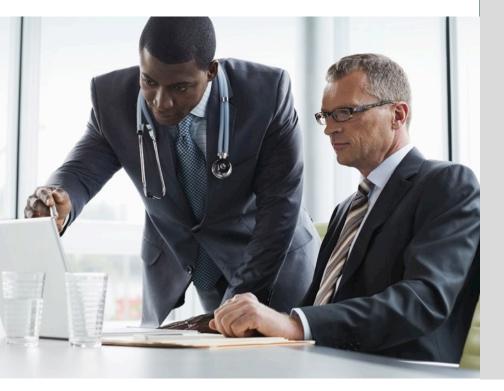
Clinical, regulatory & commercial planning to effectively guide new treatments to market—and keep them there



PAREXEL Consulting's integrated services translate client vision to bold solutions throughout the development lifecycle, understanding the need to differentiate your product today and anticipate how to sustain that competitive edge tomorrow – through to the next decade – and beyond.



# REGULATORY COMPLIANCE AND RISK MANAGEMENT



Applying agency and industry experience to proactively avoid manufacturing risks and effectively respond to urgent challenges

# Our trusted experts, including renowned former regulators

- Institute proactive compliance
- Have a strong track record of helping companies overcome regulatory crises



# THE PAREXEL DIFFERENCE

## PAREXEL Consulting delivers 1,200+ projects a year to a variety of clients in a broad range of therapeutic and product areas

### **CLIENT PROFILES**

- Emerging to Mid-Sized Biopharmas
- Specialty Biopharmas
- Large Biopharmas
- Medical Device/Diagnostics
- Drug and Biologic Generics
- Investment Banks and VCs
- Law Firms
- Biopharma Distributors

#### THERAPEUTIC AREAS

- Oncology
- Cardiovascular
- CNS
- Endocrinology / Metabolism
- Infectious Diseases
- Allergy / Immunology
- Pulmonology
- Gastroenterology
- Obstetrics / Gynecology

#### **PRODUCT AREAS**

- Drugs
- Biologics
- Medical Devices/Diagnostics
- Vaccines (Prophylactic, Therapeutic, Defense)
- Biosimilars
- Generics
- Combination Products
- Cosmeceuticals
- Nutraceuticals



## CONTACT US



Our integrated services translate client needs to bold solutions throughout the development lifecycle

WE ARE ALWAYS AVAILABLE FOR A CONVERSATION

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