



THE WORLDWIDE LEADER IN PHARMACEUTICAL SERVICES



Dr. Oppel Greeff
President, Clinical Technology Services
Quintiles Transnational

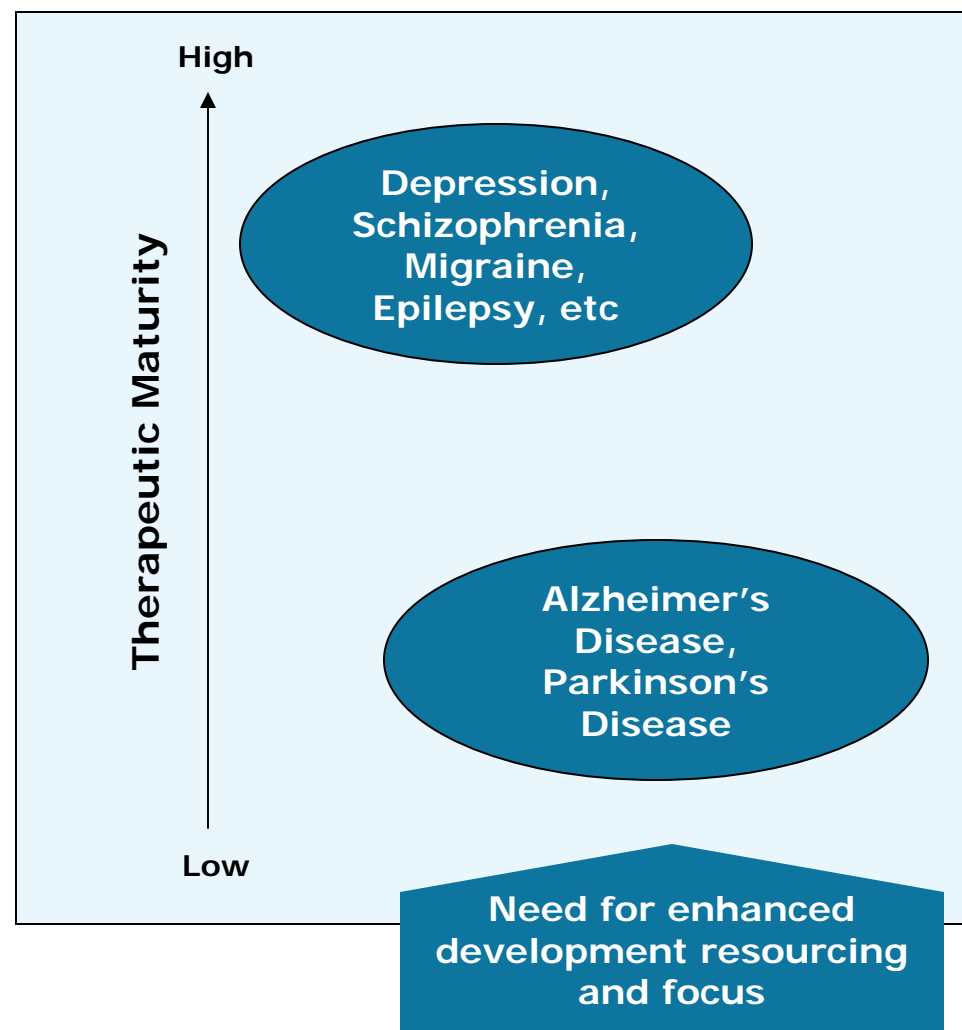
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The Role of CROs in CNS Pre-Clinical Development

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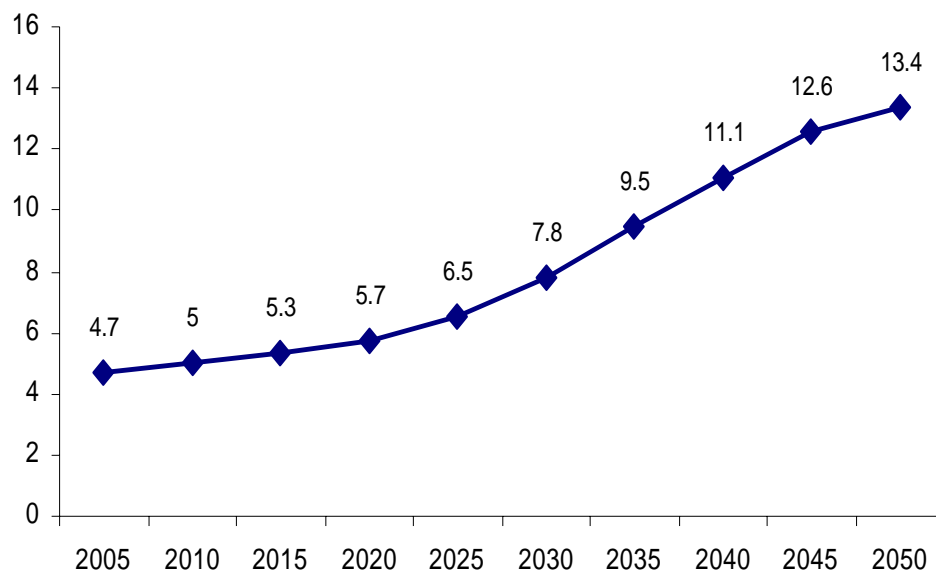
The growing CNS Disease Burden

- CNS account for 35%* of world's disease burden in Disability Adjusted Life Years (DALYs)
- In the US, CNS disorders account for ~20%* national healthcare spend
- And the BAD NEWS is, the CNS disease burden is growing faster than even the cardiovascular diseases



The impending Alzheimer's crisis

of people with AD in US (in Million)



Medicare beneficiaries with AD account for 34% Medicare spending, though they constitute only 12.8% of the 65+ population*

Aging 'Baby Boomers' will increase the Alzheimer's prevalence to alarming levels

Need to accelerate innovation

- Limited prescription drug options for Alzheimer's treatment (<10 major brands across two drug classes – Cholinesterase inhibitors and NMDA receptor antagonists)
- Even though AD is a relatively small market (~4 Bn in 2005 in the US), the following factors makes it an attractive target for innovation
 - Pace of market growth (34.5% CAGR 2001 – '05)
 - Few branded drugs
 - Low generic competition
 - Expected increase in prevalence
- Need to bring down the cost of Alzheimer's treatment
 - Funding research to delay the onset
- Need for accelerating the clinical development pipeline

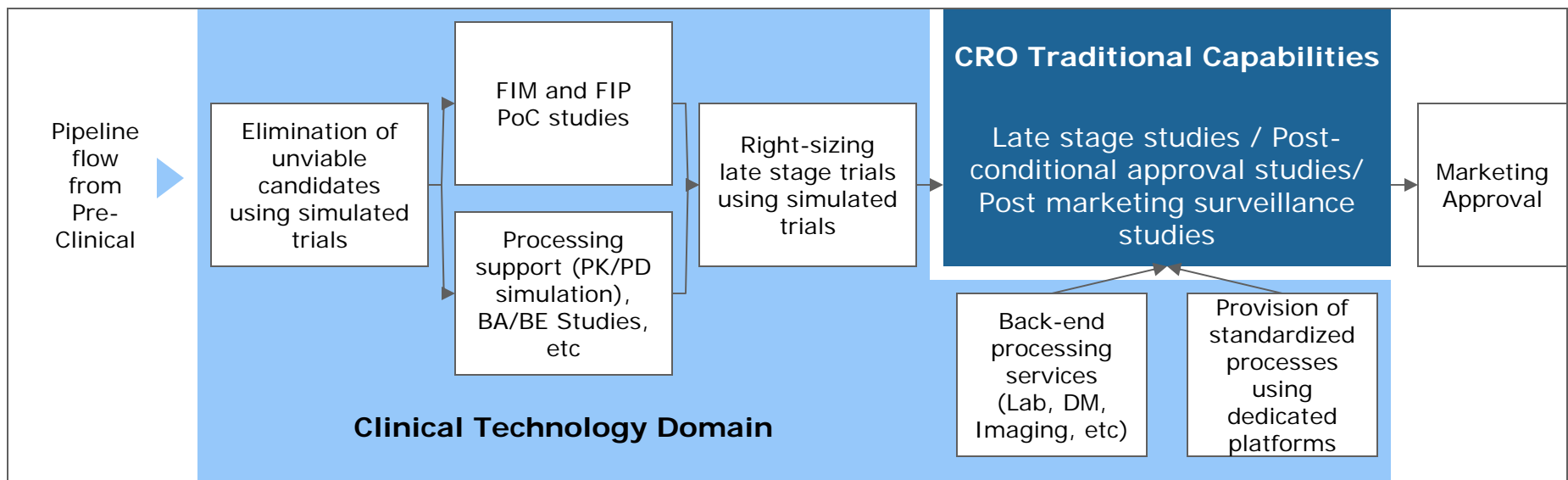
CROs can catalyze the process through innovative business models and financial partnering. Here are a few options...

CRO business model is changing



Consulting Layer

Outsourcing Layer



Risk sharing/ Financial Partnering



What does new CROs offer..

Value proposition

Knowledge/
Expertise

Therapeutic Expertise, Technology/ New Science >>
Trial Design and Optimization

Transformational
Outsourcing

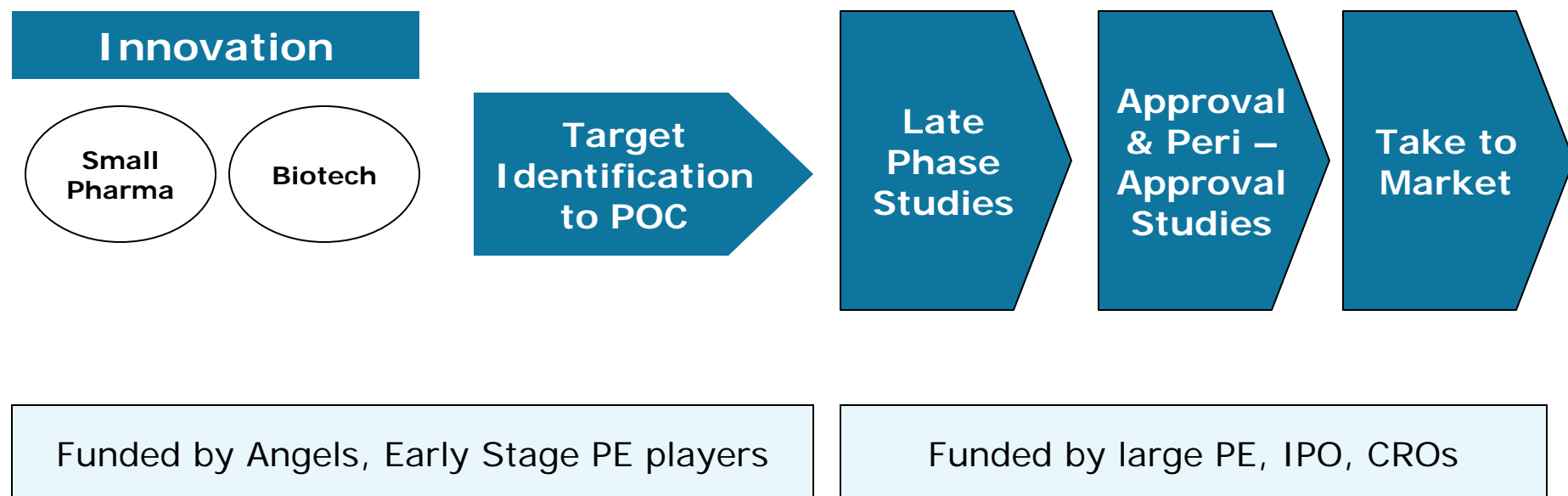
Access to patients, Project Management, Offshore data
processing, Enabling infrastructure/ technology (Labs),
Experienced resources, Process improvements

Risk/ Reward
sharing

Outcome based pricing, Investments in NCEs,
Collaborative development and marketing

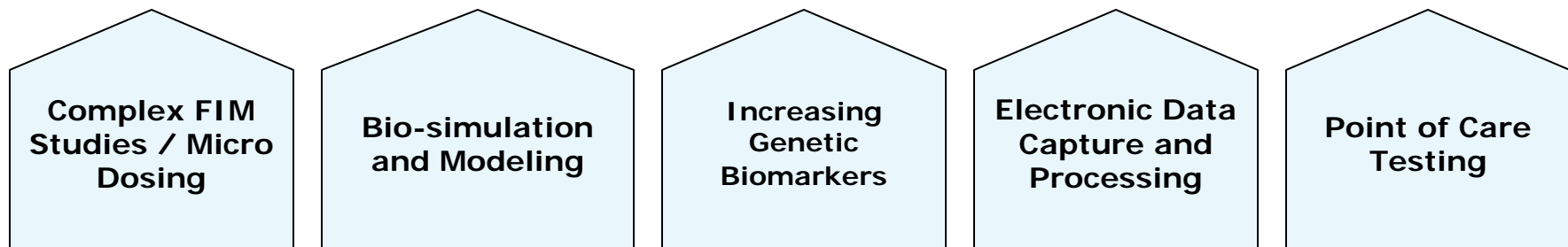
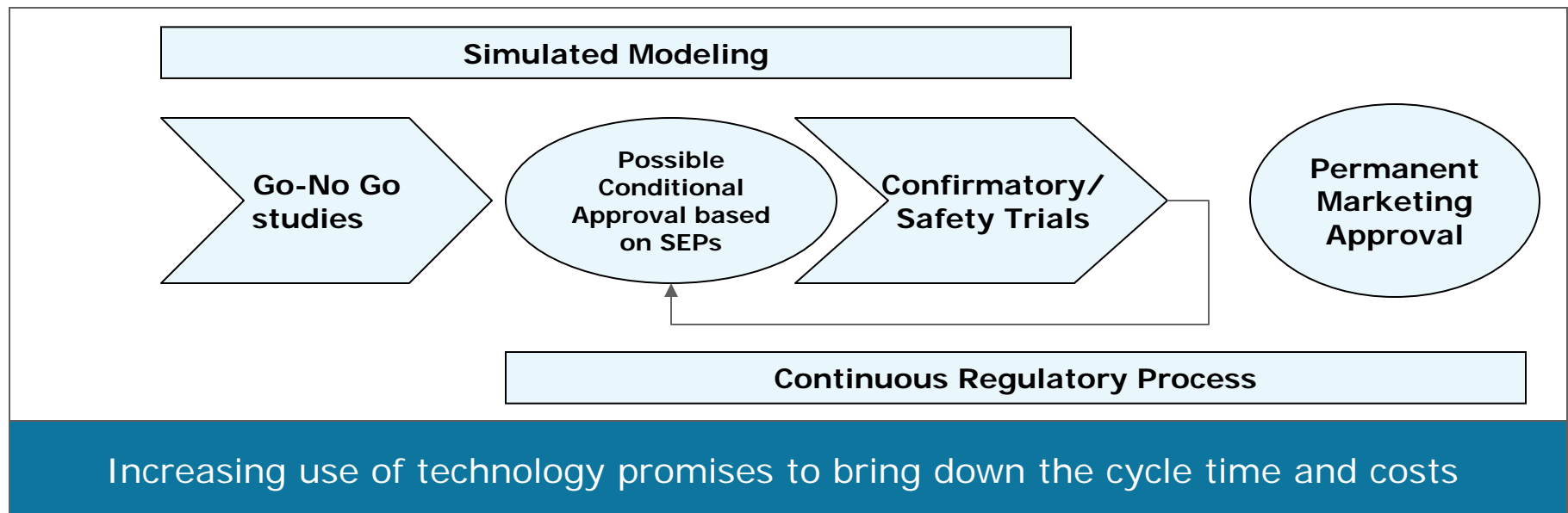
From being a service provider to a strategic partner...

CROs investing in innovation



Full service CROs can bring in the development expertise and the 'take to market' capabilities...

...along with emerging technology

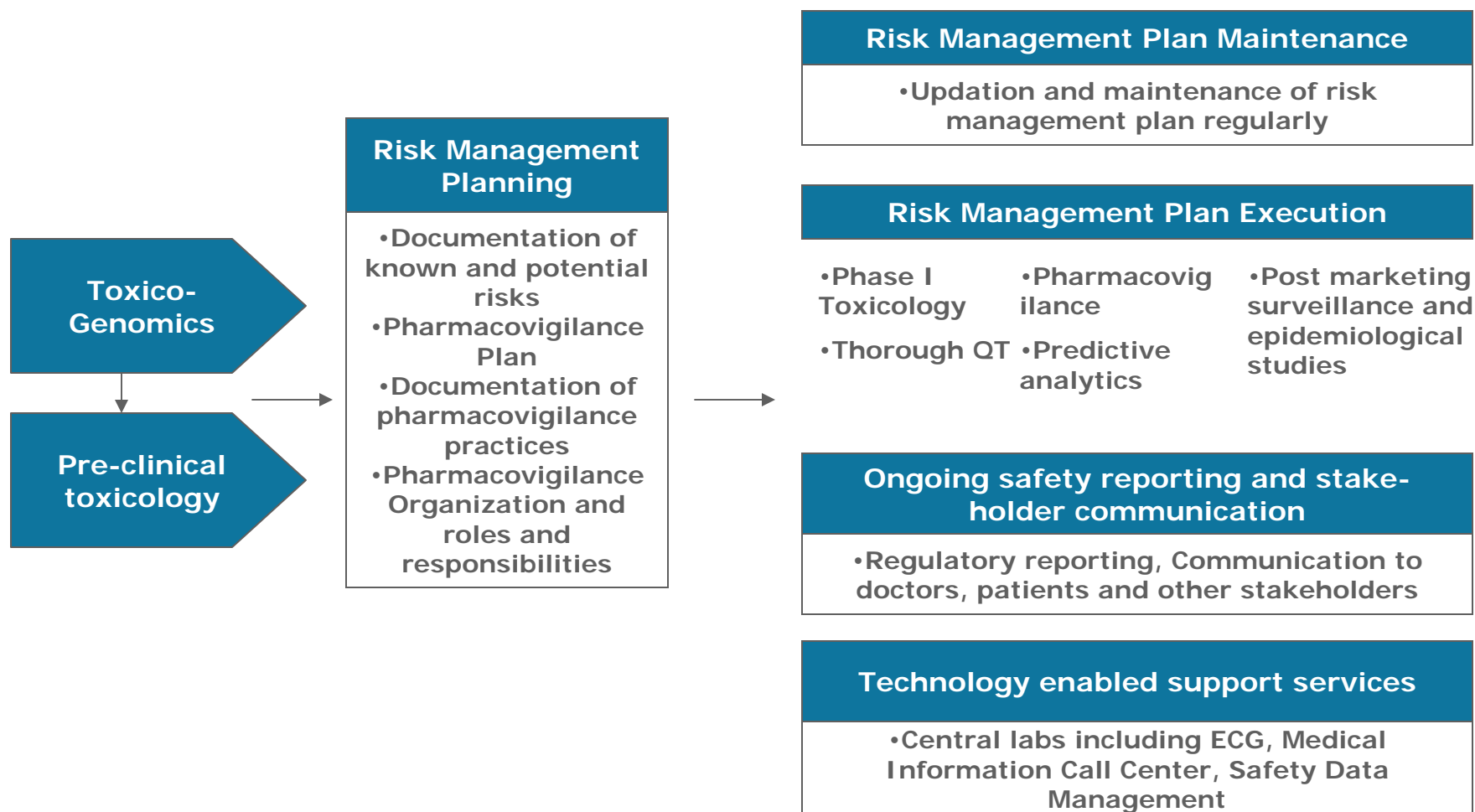


CROs are at the forefront of this revolution...

What does that mean

- Early elimination of potential failures
 - Translational modeling using pre-clinical data
 - New generation bio-markers as surrogate end points
- Rigorous Phase I/IIA studies
- Optimization of late trial designs
 - Adaptive trial designs
 - Smaller patient populations
- EDC and Clinical Trial Management systems to bring down the transactional costs of trials
- Global processing models to leverage the strengths of alternative geographies

Partnering CROs to manage safety



In Summary, CROs can help

- CROs offer an excellent strategic partnership opportunity for CNS innovators
- Emerging CRO business model allows multi-dimensional engagement
 - Outsourced clinical development
 - Clinical Technology Services
 - Risk-reward sharing models with financial participation
- Off-shore processing and transformational outsourcing
- An opportunity to come together and solve one of the bigger healthcare problems facing 21st century.



Thank You