CLINICAL TRIAL CONDUCT IN EMERGING MARKETS

How Do You Get To Maximum Value In A Scalable Manner?
Success Factors For Clinical Research

Quality is key in complex trials

- Quality
- Speed
- Cost

Quality is key in complex trials
306 inspections between 1988-2012 in CEE
99% no or voluntary action indicated

Source: www.fda.gov
Quality of Data: Query Rate

Query Rates Comparison - Developed vs Emerging Global Regions

A Query rates normalised to the number of CRF pages
B Query rates normalised to the number of data parameters

Based on data from ACRO (2005-2010): 26 phase II/III conducted globally: 4,721 sites and 63,871 pts

No statistically significant difference between regions or in comparison to North America in overall query rates or in database changes

Source: DIA Journal 2012 46:45 http://dij.sagepub.com/
What Drives Patient Enrollment?

1. Site selection
2. Site start up
3. Patient recruitment

- Highly trained, enthusiastic investigators motivated to follow GCP
- Easy access to patients
Project Operational Delivery

- Where to go…
- What is your priority
  - Quick start up?
  - Fast recruitment?
  - Specific target patient population?
  - Selected therapeutic area?

A flexible, study-specific strategy is key
CEE: Is There a Start-Up Advantage?

Slovakia vs Belgium 2013

Slovakia can be a key country to deliver FPI
Countries With Quick Start-Up

Baltic States: Estonia, Latvia & Lithuania

- RA 30-60 days
- Well established clinical research market
  80 new clinical trials applications/year
- Therapeutic areas: oncology, neurology/psychiatry, endocrinology
  - Cardiovascular – one of the highest mortality rates in EU; medicines consumed 40, 9%

Smaller, less known countries can be a strategic piece in the puzzle
TA categories in CEE align with established markets – but understanding local treatment standards is key
Why Russia and Ukraine For Clinical Trials?

Metastatic Diffuse Gastric Cancer

- Rare histopathological type
- Chemotherapy-naive population
- Significant number of patients

Over 50% patients enrolled in Russia and Ukraine

[Graph showing patient enrolment by country with bars indicating # Patients Screened and # Patients Randomised]
Are Longer Start-Up Timelines a Viable Option?

Countries with large patient populations: high recruitment rates can help compensate for longer start-up timelines.
What is the Value of Smaller Countries?

Patient Enrolment - Cardiovascular Study

study completed

Romania and Slovakia provided 30% of total patients
What Makes Deep Local Expertise Important?

Diabetes Mellitus Program – Site Selection

Romania can be a key contributor to your diabetes studies
Last But Not Least…

Trial Cost
Europe: Relative Clinical Study Costs

Relative per Visit Cost in Selected CEE Countries, 2010-2011

Clinical studies in CEE still cost less than UK or US

Source: PAREXEL’s Bio/Pharmaceutical R&D Sourcebook 2012/2013, Business Insights Ltd
An Affordable Approach to Extend Your Reach

Indexed (vs. US) cost per patient, 2010-2011

Central Europe
Asia
Latin America
Western Europe
North America

Source: PAREXEL’s Bio/Pharmaceutical R&D Sourcebook 2012/2013, Business Insights Ltd

CEE offers competitive value, and costs are holding flat compared to other emerging regions
In Summary

► Emerging markets offer high quality combined with value at competitive cost

► Key success factors:
  ► Define your priorities: a dialogue can help
  ► Client-specific, flexible and creative solutions required
For more information, visit [www.covance.com](http://www.covance.com)