



RAPID & SPEED: Cost & Value to Industry

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Healthcare – Issues, challenges

- + Increasing complexity of healthcare
 - + New medical devices, technologies for improving health care, but with high levels of complexity and requiring changes
- + Unjustified discrepancies in care patterns
 - + The intensity of health-care services delivered for similar conditions varies significantly across geographic regions
- + Importance of better value from health care
- + Pressing need for evidence development
 - + Comparative and longitudinal data is needed to determine the effectiveness and usefulness of new medical interventions, treatments, drugs, devices, and genetic information

Healthcare – Issues, challenges (Cont.)

- + Promise of health information technology
 - + Electronic medical record (EMR) & electronic health record (EHR) to improve the quality and efficiency of patient care, and reduce healthcare delivery costs
- + New model of patient-provider partnership
 - + More patient involvement needed
- + Uncertainty exposed by the information environment
 - + Information important to clinical decision making is often not available

High Price of Lack of Medical Evidence

+ Priorities of healthcare system:

- + Identifying risk factors to reduce chronic diseases
- + Improving quality of health care
- + Reducing unnecessary spending

+ High costs driven by a lack of information on the effectiveness of different medical interventions

+ Solutions:

- RCTs? – impractical
- Non-RCTs? – well-known limitations
- Systematic reviews? – some effects
- Using data sets from EHRs, insurance claims, and other medical data – cost-effective and feasible but with some limitations
- **Clinical Registries** – greater effects (patient-centered, evidence-based)

Other Benefits of Dynamic Clinical Registries Like SPEED

- + Provide comprehensive performance information based on common data elements
- + A platform for tracking new devices when they become used in routine clinical practice
- + Support the need and rationale for future randomized trials (hypothesis generation, important questions answered, trial design development)
- + Could be a resource for future scientific discoveries (huge sample of well-characterized patients)
- + Link with other administrative data sources (CMS, EHR, private payers)

Economic Data - as Important as Clinical Data

- + In most clinical trials, economic data are not collected
 - Efficacy
 - Safety
- + With increasing health care costs – new data requirements
 - Effectiveness
 - + An actual value of an innovation in daily practice
 - Cost-effectiveness
 - + Effectiveness of the device/treatment and the savings relative to other devices/treatments

Health economic evaluation has become critical in health care decision-making

Potential International Benefits

+ Harmonization of Various National Registries

- + Incorporate RAPID / SPEED common data elements in all national registries
- + When national registries do not exist, utilize data from other registries to gain regulatory approval or label expansion

+ Elimination of Small Clinical Trials with No Statistical Significance

- + 20 to 30 patient trials in a specific geography to gain approval when hundreds or thousands of patients have been studied elsewhere makes no sense
- + When eliminated as an approval requirement, time to market is greatly reduced

+ Global Learning of Treatment Options & Outcomes by Technology Class

Real-World Examples of How Industry May Benefit

Clinical and Economic Data Supports Procedures

Low cost compared to RCT's & Product Specific

Registry
Addresses FDA's focus areas

Addresses CMS's focus areas
Safe, effective and patient-centric outcomes

Currently Treated Patient Population Expands
Reasonable and necessary

Indications for Use for Technologies Expand

Practice Guidelines Updated to Reflect Real

World Data
Cost of Healthcare Driven Down

Thank You!