Clinical Trial Statistics

Industry funds 80% of clinical trials
Proportion is same by # studies or by # patients

Industry focus on late-stage research
Manual effort drives costs (Monitoring, PM)

Source: Medidata CRO Contractor Product Fact Sheet 2016

Clinical Trial Costs

- 28% Project Management
- 28% Site Monitoring
- 21% Site Management
- 10% Data Management
- 8% Other
- 6% Recruitment

Source: Medidata CRO Contractor Product Fact Sheet 2016
Clinical Trial Platform

“In The Moment” Data Capture – for Sites and Patients

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**eSource / Remote Monitoring**

**Protocol Execution**
*Not just the data for statisticians*

**The Moment Matters**
*Effects everything downstream*

**Vaccines**

High Enrolling, Rapid Progression, Research Naïve, Remote Areas

- Ebola – West Africa, centrally monitored from South Africa/UK
- Tuberculosis/Malaria – South/East Africa, South America
- RSV Vaccine – South Africa, Philippines, Bangladesh, Thailand
## Priority Therapeutic Areas

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Key Indications</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNS/Pain</td>
<td>Alzheimers, MS, Pain, Depression, Migraine, Schizophrenia, Dementia</td>
<td>Complex scales, Scoring/Administration, Enrollment Criteria</td>
</tr>
<tr>
<td>Infectious Disease</td>
<td>Vaccines, Hepatitis, RSV, Malaria, TB</td>
<td># Patients/site, Same-Day Data, Offline</td>
</tr>
<tr>
<td>Immunology</td>
<td>Lupus, Colitis, Crohns</td>
<td>Complex scales, Scoring/Administration</td>
</tr>
<tr>
<td>Dermatology</td>
<td>Psoriasis, Acne</td>
<td>Images, Scales, # patients/site</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Asthma, COPD</td>
<td># Patients/site, Scales, Sensors</td>
</tr>
<tr>
<td>Endocrine</td>
<td>Obesity, Diabetes</td>
<td>High % labs</td>
</tr>
<tr>
<td>Cardiology</td>
<td>CHF, Hypertension</td>
<td>High patient volume</td>
</tr>
<tr>
<td>Gastro-Genito</td>
<td>Any</td>
<td>Scales, Complex protocols</td>
</tr>
<tr>
<td>MusculoSkeletal</td>
<td>Arthritis, Osteoporosis</td>
<td>Complex protocols,</td>
</tr>
<tr>
<td>Cancer</td>
<td>Any</td>
<td>Typically ‘standard-of-care’</td>
</tr>
</tbody>
</table>

- Full Data Capture
- QOL Scales
- Complex Monitoring
- Patient Engagement

- Study-Specific Factors
- Variable by indication

- Scales-Only eCOA
Patient Engagement

Encourage Patients to be involved
- Use devices they already have
- Make it easier to know what to do
- Encourage them

Regulations Change slower than technology
- “Screen Size” similarities, usability
- “Access” to personal data (cellphone #)
- “Availability” of smartphones
Electronic Medical Records

Inadequate for Clinical Trials
Doesn’t reflect protocol
Massive data mapping problem

Data Standards won’t fix it
Impossible to implement
Expose ‘available’ data fields

“From a configuration perspective it’s important to appreciate that the validation and mapping has to occur at each individual site, with each individual EHR vendor, and each individual EDC system.....So, upfront it’s a task that requires some effort.”

FDA / CDISC EMR Forum; 26-Jun-2012; Jonathan Helfgott (FDA); transcript minute 26:00-26:34