Clinical Development Overview

Careers in Clinical Research

Ira Daly
Head, Eastern US Business Development, QuintilesIMS
Opportunity

~$1 Billion
per clinical development program

~$8 Million
lost revenue per day a drug is not on the market

10+
years from bench to approval
QuintilesIMS Overview
(Marketing slide: let’s focus on the career opportunities….)

- **50,000** people in >100 countries
- **1,200** experts in healthcare informatics
- **530+** million global anonymous patient records
- **14** centers of excellence
- **15+** petabytes of unique healthcare data
- **~900+** clinical educators
- **Elite 100** list in 2015 for Information Technology Innovation
- **>1,100** medical doctors

Award-winning Safety Platform
>99% on-time compliance to regulatory authority

QuintilesIMS™
Collection, Monitoring, and Oversight
Example Clinical Project Team

ARO

Global Medical Advisor (MD)

Sponsor

QIMS Program Director

Global Project Lead

CV COE Head (MD)

Therapeutic Strategy Lead (PhD)

Functional Leads:
- Statistician
- Data Manager
- Recruitment & Retention
- Regulatory Start-up
- Q² Lab & Cenduit

Clinical Lead – Americas (PharmD)

Clinical Lead – EMEA (MD, PhD)

Clinical Lead – APAC

Americas Clinical Team

EMEA Clinical Team

APAC Clinical Team

25 – 40% of study labor costs are monitoring
## Case Study: Phase 3 Cardiovascular Program

<table>
<thead>
<tr>
<th></th>
<th>Pivotal Study 1</th>
<th>Pivotal Study 2</th>
<th>Outcomes Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Countries</strong></td>
<td>US &amp; Canada</td>
<td>15 (EU)</td>
<td>24</td>
</tr>
<tr>
<td><strong>Sites</strong></td>
<td>240</td>
<td>260</td>
<td>600</td>
</tr>
<tr>
<td><strong>Patients Screened</strong></td>
<td>2250</td>
<td>2250</td>
<td>25000</td>
</tr>
<tr>
<td><strong>Patients Enrolled</strong></td>
<td>1000</td>
<td>1000</td>
<td>12000</td>
</tr>
<tr>
<td><strong>Enrollment Period</strong></td>
<td>10 Months</td>
<td>10 Months</td>
<td>30 Months</td>
</tr>
<tr>
<td><strong>Total Study Duration</strong></td>
<td>28 Months</td>
<td>27 Months</td>
<td>65 Months</td>
</tr>
<tr>
<td><strong>Data Fields Entered</strong></td>
<td>720,000</td>
<td>720,000</td>
<td>14,728,640</td>
</tr>
<tr>
<td><strong>Monitoring Visits</strong></td>
<td>750</td>
<td>600</td>
<td>7,000</td>
</tr>
<tr>
<td><strong>Labor Fees</strong></td>
<td>$18,000,000</td>
<td>$19,000,000</td>
<td>$120,000,000</td>
</tr>
<tr>
<td><strong>Passthrough Costs</strong></td>
<td>$20,000,000</td>
<td>$21,000,000</td>
<td>$140,000,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$38,000,000</td>
<td>$40,000,000</td>
<td>$260,000,000</td>
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</tbody>
</table>
2020 and Beyond
Development costs of >$1 billion are not sustainable

• Technology will Transform Development
  – Data driven monitoring strategies and remote monitoring technology
  – Incorporation of wearable technology
  – Adaptive study designs
  – Regulatory approvals at early stages
  – Increase study efficiency by using real world data:
    – Smarter site identification
    – Targeted patient identification
    – Drive faster less expensive trials with less waste
  – Early signal detection to reduce phases of development (i.e. oncology)
  – Personalized medicine
  – Increased use of biomarkers and genomic data