INTRODUCTION

Historically, long development times coupled with low success rates translated into high overall costs and risk for the industry. Digital tools are expected to accelerate clinical timelines. However, challenges accompany new technology implementation and evolving trends require agility and investment in a highly competitive environment. What is the current impact and future direction for these new approaches to therapeutic development?

KNect365 conducted a survey across clinical trials professionals from within pharma, contract research organizations (CROs), service providers, consultancies, medical device companies, sites and academia. The survey collected 214 responses across a variety of job functions, regions, and therapeutic areas of focus. Survey results reflect a majority input from European organizations and professionals from other regions also weighed in.

Partners responsible for trial management are on the front line for implementation of new technologies and evolving study designs, while also keeping to ambitious timelines. In this environment, it is not surprising that oversight of vendors is highly challenging, primarily in maintaining efficiency (adherence to timelines, cost management and effectiveness).

Patient centric approaches are expected to reap many benefits and technologies are key to realizing these benefits. Virtual trials could increase patient participation and provide enhanced efficiencies in data monitoring/analysis. Asia and N. America are ahead of Europe in employing this approach, but virtual trials are expected to increase in the next two years across all regions. Wearables and sensors improve real-time data acquisition and, for some respondents, data quality. However, data quality remains a concern for some, which is second only to data privacy/security concerns.

Currently, AI is seldom used in trials, but increase usage is anticipated during the next two years. Robotic Process Automation (RPA), Natural Language Processing (NLP) and eHealth records offer the largest benefits, presumably for data management. For early phase studies, AI utilization may serve a more analytical role for patient identification/stratification and predictive purposes.

Study design improvements for early phase protocols aim to achieve meaningful outcomes in a shorter time. Innovative designs most commonly utilize adaptive designs, while umbrella, basket and platform designs often are employed and protocol changes for QT safety studies already are used in ~25% in early phase studies. Use of ‘real world’ evidence is increasingly important as industry addresses regulatory agencies’ post-marketing requirements and provides support for new drug applications. Cost and time savings should be realized by utilizing ‘real world’ evidence. Currently, N. America and Asia utilize this data more fully than does Europe.

This survey also touches on European challenges, including the imminent EU Medical Device Regulation changes and Brexit impacts. While the regulatory changes are well anticipated, the expected impact of Brexit is negative. As the details of Brexit get ironed out, perspectives are likely to change.

As approaches to accelerate therapeutic development are sought, expectations for new technologies run high. Challenges to their acceptance, initial costs and an inevitable learning curve exist, but the benefits to improved patient centricity and cost efficiencies are driving their adoption. Asia and N. America are most attuned to technology, but European respondents see the need to embrace technologies in the near future.
RESPONDENT DEMOGRAPHICS

Regions covered in respondents’ role

- Europe: 66%
- Asia: 13%
- Middle East: 1%
- Australasia: 1%
- Africa: 1%
- South America: 1%
- North America: 17%

Therapeutic focus areas respondent companies are conducting clinical trials in

- Oncology: 52%
- Cardiovascular: 44%
- Immunology & inflammation: 41%
- CNS: 39%
- Neurology: 34%
- Infectious diseases: 32%
- Respiratory: 31%
- Endocrine: 29%
- Other: 34%
PARTNERSHIPS AND OUTSOURCING

**What impact will Brexit have on clinical trials?**

*EXCLUDING NOT APPLICABLE (24)

- Major negative: 11%
- Moderately negative: 52%
- Neither positive nor negative: 33%
- Moderately positive: 2%
- Major positive: 2%

**Vendor oversight and governance**

<table>
<thead>
<tr>
<th>Find vendor oversight ‘Not at all’ or ‘Not very’ challenging</th>
<th>Average</th>
<th>Europe</th>
<th>North America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5%</td>
<td>6%</td>
<td>6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Find vendor oversight ‘Quite’ or ‘Very’ challenging</th>
<th>Average</th>
<th>Europe</th>
<th>North America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>53%</td>
<td>62%</td>
<td>47%</td>
</tr>
</tbody>
</table>

**TOP 5**

What is the biggest challenge you face with vendor oversight and governance?

1. Adherence to timelines
2. Cost management and effectiveness
3. Communication
4. Quality of execution and data
5. Regulatory compliance

Think upfront Risk Management is ‘Very’ or ‘Extremely’ important to the success of trials

**How prepared do you think your company is for the EU Medical Device Regulation implementation?**

*EXCLUDING NOT APPLICABLE (24)

- 1 - Not at all prepared: 7%
- 2: 16%
- 3: 24%
- 4: 33%
- 5 - Fully prepared: 22%
To what extent is your company currently utilizing Real World Evidence?

How likely is it that your company will increase its use of virtual trials in the next two years?

What is the primary benefit to a patient-centric approach?
Technology is ‘Very’ or ‘Extremely’ important to their company’s patient engagement strategy

Average 63%

Europe 54%
US 74%
Asia 85%

What is the primary benefit derived from the use of wearables and sensors?

- Real-time data acquisition: 36%
- Improved data quality: 30%
- Increased patient compliance: 17%
- Reduced costs: 7%
- Larger patient pool: 5%
- Increased patient retention: 4%

What is the primary concern with using wearables and sensors?

- Data privacy and security: 35%
- Data quality: 22%
- Patient or physician resistance: 18%
- Difficulty in incorporation: 16%
- Decreased regulatory acceptance: 9%
It’s ‘ Likely’ or ‘ Certain’ your company will increase its use of AI in the next two years

- Europe: 48%
- North America: 55%
- Asia: 68%
- Average: 54%

To what extent is your company currently using AI in clinical trials?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>38%</td>
</tr>
<tr>
<td>Rarely</td>
<td>17%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>26%</td>
</tr>
<tr>
<td>Often</td>
<td>10%</td>
</tr>
<tr>
<td>Fully</td>
<td>8%</td>
</tr>
</tbody>
</table>

TOP 5 What do you see as the biggest limitations of using AI in clinical trials?

1. Data standards and safety
2. Regulatory acceptance
3. Cost
4. Lack of patient acceptance
5. Lack of industry understanding

Rate in order of importance (from 1-5) where you see the biggest benefits of AI applications in clinical trials

<table>
<thead>
<tr>
<th>Application</th>
<th>Average Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient recruitment</td>
<td>2.6</td>
</tr>
<tr>
<td>Predictive Analytics</td>
<td>2.7</td>
</tr>
<tr>
<td>Electronic Health Records</td>
<td>3.4</td>
</tr>
<tr>
<td>Novel biomarkers</td>
<td>3.5</td>
</tr>
<tr>
<td>RPA</td>
<td>4.4</td>
</tr>
<tr>
<td>NLP</td>
<td>4.5</td>
</tr>
</tbody>
</table>
EARLY CLINICAL DEVELOPMENT

Which of the following are you using in Early Phase Protocol Designs?

<table>
<thead>
<tr>
<th>Design Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive trials</td>
<td>65%</td>
</tr>
<tr>
<td>Umbrella trials</td>
<td>33%</td>
</tr>
<tr>
<td>Basket trials</td>
<td>30%</td>
</tr>
<tr>
<td>Platform trials</td>
<td>28%</td>
</tr>
<tr>
<td>Virtual trials</td>
<td>23%</td>
</tr>
<tr>
<td>Other novel designs</td>
<td>8%</td>
</tr>
</tbody>
</table>

How do you think AI can be utilised for early phase clinical development?

- Patient identification & safety profiles: 52%
- Patient stratification: 30%
- Novel biomarkers: 42%
- Predictive Analytics: 55%

What does successful patient-centricity in early phase studies mean to you? (Selected responses)

- Collaboration and empowerment
- Engagement in the promise of our technology to destigmatise their suffering
- Fast interaction between patient, trial center, lab and study monitoring
- High retention rates and high PRO data entry compliance
- Less burden to patients and better compliance, therefore improving safety and giving better data quality and outcomes
- Identifying the right patient for the right trial