Clinical Trials Industry Report: Beyond the Hype
Clinical trials are continually evolving, particularly in light of increasing pressures from new technologies and other disruptors. Trends ranging from artificial intelligence (AI) and mHealth to patient-centricity are challenging the industry to innovate against the backdrop of looming regulatory changes and shifting competitor landscapes resulting from M&A activity. However, are these issues truly impacting clinical trials today, or is all the buzz simply white noise?

To determine how the industry views these trends, and to what extent they are being incorporated into clinical trials today, KNect365 conducted a survey across clinical trials professionals from within pharma, contract research organizations (CROs), sites, service providers, consultancies, academia and patient groups. The survey collected 199 responses across these organization types, from a variety of job functions, regions, and therapeutic areas of focus.

The increasing volume of the patient voice has clearly affected survey respondents, who rated patient-centricity as most important among the key areas included in the survey for their companies to embrace. Although one wrote “patient-centricity is the most hyped thing”, the vast majority (78%) felt otherwise and rated it as ‘very’ or ‘extremely important’ for incorporation into their companies.

Despite this perceived importance, and key benefits of greater patient integration and retention, integration of the patient voice into clinical trials across the industry as a whole still has room to grow. Luckily, the level of effective execution should rise across the industry as nearly half of respondents felt patient-centric practices were successfully being implemented at the company-level, and it is very likely that their company will increase its emphasis on patient-centricity in the next two years.

Technology has also commanded significant attention, with new developments and IT capabilities looking to transform the various industries, including clinical trials. In fact, 53% of respondents felt that mHealth and AI will have the biggest impact on clinical trials by 2030.

Between these two tech-driven trends, mHealth edged out AI as more important for their companies to embrace. Despite difficulties in incorporating mHealth into trials as well as data security, evidence supporting adoption of mHealth products, such as mobile apps and activity trackers, continues to grow, paving the way for this technology to realize key benefits, including real-time data acquisition and improved data quality.

This survey also touches on other issues with the potential to transform the landscape of clinical trials, including the regulatory considerations of GDPR, ICH E6 R2, European Clinical Trial Regulation, and Brexit, as well as the trend of mergers and acquisitions within the industry. Is the industry prepared for more change, and what's the perceived impact?

Preparations for or implementation of each issue addressed within the survey generally require additional investments in time and costs. However, as one respondent noted “a bit of upfront planning reaps enormous downstream benefits”, which will ultimately result in a “better, more efficient clinical trial making those costs pale”.

Introduction brought to you by Citeline
PATIENT-CENTRICITY

On a scale of 1-10 how well does your company implement patient-centric practices?

Average: 6.73

By Region

Europe: 6.62

N America: 6.88
PATIENT-CENTRICITY

On a scale of 1-10, how well do you think the industry as a whole uses patient-centric practices?

**Average:** 4.97

- **2%** rated it 1 (not at all well)
- **5%** rated it 2
- **12%** rated it 3
- **18%** rated it 4
- **27%** rated it 5
- **21%** rated it 6
- **13%** rated it 7
- **3%** rated it 8
- **1%** rated it 9
- **1%** rated it 10 (perfectly)

By Region

- **Europe:** 5.29
- **N America:** 4.75

Corporate management respondents gave the highest score for their company’s implementation, but the lowest for the industry as a whole.

**Company Implementation:** 7.27

**Industry Implementation:** 4.69
Which of the following is the primary benefit to a patient-centric approach?

- Greater patient engagement: 38%
- Higher patient retention: 21%
- Increased patient compliance: 21%
- More successful patient recruitment: 16%
- Other: 4%

How does your company measure patient-centricity?

- Qualitative patient feedback: 38%
- Patient engagement metrics: 35%
- Patients satisfaction scores: 33%
- Reduced patient responsibilities: 25%

When implementing a patient-centric approach, which of the following represents the area most adversely affected?

- Other: 13%
- Efficiency: 25%
- Time: 34%
- Cost: 28%

In the next two years, how likely is it that your company will increase its emphasis on patient-centricity?

- 84% Replied “Likely” or “Very Likely”

How important is it that your company embraces patient-centricity?

- 78% Replied “Very Important” or “Extremely Important”
On a scale of 1-10, how well does your company implement mHealth technologies?

Average: 5.69

By job role:
- Clinical operations: 4.89
- Corporate management: 6.43

By organization:
- Service provider/Consultancy/Medical device company: 6.09
- Pharma/Biotech company: 4.91
- CRO: 5.49
What is the primary benefit derived from the use of mHealth technologies?

- Real-time data acquisition: 42%
- Improved data quality: 30%
- Increased patient compliance: 19%
- Larger patient pool: 4%
- Reduced costs: 2%
- Other: 3%

What is the primary concern from the use of mHealth technologies?

- Decreased regulatory acceptance: 9%
- Patient or physician resistance: 28%
- Data security: 16%
- Difficulty in incorporation: 20%
- Other: 27%

How important is it that your company embrace mHealth technologies?

- 39% replied "Moderate" to "Not at all" importance

In the next two years, how likely is it that your company will increase its use of mHealth?

- 79% replied "Likely" or "Very Likely"
**DATA AND AI**

On a scale of 1-10, how well does your company currently manage and utilise the clinical data it gathers?

![Bar chart showing the distribution of responses from 1 (not at all well) to 10 (perfectly). The average score is 7.27.]

**How important is it that your company embrace AI in clinical trials?**

- Extremely Important - 5: 13%
- Very Important - 4: 35%
- Moderate Importance - 3: 32%
- Low Importance - 2: 13%
- Not at all Important - 1: 8%

**Average**: 3.32

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

- Best in Class - 5: 4%
- Above Average - 4: 18%
- Average - 3: 26%
- Below Average - 2: 26%
- Not at all - 1: 26%

**Average**: 2.49
REGULATORY CHANGES

How well prepared is your company for ......?

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<thead>
<tr>
<th>Regulation</th>
<th>Rating</th>
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<tbody>
<tr>
<td>ICH E6 R2 implementation</td>
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<tr>
<td>European Clinical Trial Regulation</td>
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<tr>
<td>GDPR</td>
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</table>

Average rating from a 1-5 scale, with 1 = not at all prepared and 5 = completely prepared

What overall impact do you think these regulatory changes will have on the clinical trials you are involved in?

- Average: 3.50
- 40% Major Negative
- 36% Neutral
- 13% Major Positive
- 10% Moderately Negative
- 5% Major Positive
- 1% Neutral

40%
REGULATORY CHANGES

What impact do you think Brexit will have on the clinical trials you are involved in?

Average 2.82

What impact do you think Brexit will have on the clinical trials you are involved in?

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<thead>
<tr>
<th>ORGANIZATION</th>
<th>JOB ROLE</th>
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On a scale of 1-10, to what extent does your company implement RBM?

Average: 6.80

- CRO: 7.30
- Pharma/Biotech: 7.07
- Service provider/Consultancy/Medical device company: 6.00
On a scale of 1-10, to what extent does your company carry out Real World studies or use Real World Evidence?

Average: 6.09

Which innovative trial design will have the biggest impact on the future of clinical trials?

- Other: 40%
- Pragmatic/Low interventional: 35%
- Precision: 13%
- Adaptive: 9%
- Virtual: 3%
What impact has/will the recent trend of mergers and acquisitions had/have on clinical trials you’re working on?

**Average**

- Major Negative: 4%
- Moderately Negative: 26%
- Neutral: 49%
- Moderately Positive: 15%
- Major Positive: 6%

**Major Positive**

- CRO: 3.21
- Pharma/Biotech: 2.86
- Service provider/Consultancy/Medical device company: 2.78

**Moderate Positive**

- Average: 2.95
What do you think will have the biggest impact on clinical trials by 2030?

- AI: 28%
- Mobile health: 25%
- Regulatory changes: 20%
- Patient-centric approaches: 19%
- Adaptive design: 7%
- Other: 2%