INTERNATIONAL PERCEPTION OF COMPETENCE

Needs For Clinical Research Education

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Survey Objectives

To validate JTF domains/competencies through perceptions of clinical research professionals.

How do the competencies relate to:

• Roles, Job Titles
• Perceptions of competence and relevance
• Educational Levels
• Educational Needs
• Identify gaps for future study and workforce development
Demographics by region and function

<table>
<thead>
<tr>
<th>Role</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Coordinator/Research Nurse</td>
<td>559</td>
</tr>
<tr>
<td>Research Administrator/Project Manager</td>
<td>357</td>
</tr>
<tr>
<td>Principal Investigator/Co-investigator</td>
<td>354</td>
</tr>
<tr>
<td>Clinical Research Associate/Monitor</td>
<td>177</td>
</tr>
<tr>
<td>Regulatory Affairs Professional</td>
<td>90</td>
</tr>
<tr>
<td>Data Management Professional</td>
<td>47</td>
</tr>
<tr>
<td>Others</td>
<td>154</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1738</strong></td>
</tr>
</tbody>
</table>

Regional Participants (n=1584)
- Latin America/Caribbean: 41%
- US/Canada: 31%
- Western Europe: 24%
- Asia/Australia: 4%
Scale of Self-Assessed Responses

**Competence:**

0  Never been exposed to this content
1=  Aware of the content, but never needed to become further informed;
2= Exposed and sufficiently aware of content that I can look up what might be necessary for my job;
3= Competent–Able to interpret or discuss concepts and use knowledge to solve simple problems based on application concepts;
4 = Mastery–able to apply knowledge to complex problems, integrate information and create solutions

**Relevance:**

0 = unnecessary, no relevance to my role;
1 = has some relevance to my role, but not my responsibility;
2 = relevant to my role, but not a major component;
3 = significant to my role and part of my job responsibilities;
4 = major part of my responsibility or supervisory expectations
<table>
<thead>
<tr>
<th>Domain</th>
<th>Need for Training (% yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PI</td>
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<td>Scientific Concepts and Research Design</td>
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<td>Ethical and Participant Safety Considerations</td>
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<td>Medicines Development and Regulation</td>
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<td>Study and Site Management</td>
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<td>Data Management and Informatics</td>
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<tr>
<td>Leadership and Professionalism</td>
<td>62</td>
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<tr>
<td>Communication and Teamwork</td>
<td>57</td>
</tr>
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</table>
Scientific Concepts and Research Design

- High level of competence/relevance in Latin America; low in Western Europe

Medicines Development and Regulation

- Low levels of competence/relevance in all regions, but even lower in Asia

ANOVA: Comparison between regions, *p<0.05, **p<0.01, *** p< 0.001
Ethical and Participant Safety Considerations

Clinical Operations Domain

Higher perception of competence/relevance in Latin America
Study and Site Management

Data Management and Informatics

Lower competence/relevance in Asia

- Asia/Australia (n = 65)
- Latin America and the Caribbean (n = 653)
- USA/Canada (n = 489)
- Western Europe (n = 377)

Current Level of Competence

Significance of my Position

Lower competence/relevance in Western Europe

- Asia/Australia (n = 65)
- Latin America and the Caribbean (n = 653)
- USA/Canada (n = 489)
- Western Europe (n = 377)

Current Level of Competence

Significance of my Position
Leadership and Professionalism

Communication and Teamwork

Lower relevance in the USA and Europe
Comments to regional differences

- Need to confirm regional findings (focus groups) or surveys among representative samples from participating countries.
- Need to explore further according to source of employment (academic, industry, CROs).
- Questionnaire was conducted in English. Need for language validation to confirm full understanding of the individual competency.
- In spite the large sample size, internal regional demographics could skew the interpretation of results.
- Several hypothesis can be formulated.