Trends, Opportunities and Challenges in Site and Patient Recruitment
Executive Summary

Methodology
- Web-based, quantitative survey
- Quota: n=120
  - 1Large companies n=59
  - 2Small/Mid-size co’s n=61
- Locations:
  - U.S./Canada n=67
  - Europe n=53
- Additional survey information:
  - Dec-2022 — Jan-2023
  - Conducted by Industry Standard Research (ISR) using the proprietary ISR Health Panel*.
  - PPD was not identified as the research sponsor.

Screening Criteria
- Employed by a pharmaceutical, biopharmaceutical, or biotechnology company.
- Job level: Manager or higher.
- Outsourcing: Company outsourced 20% or more of its site and patient recruitment activities in the past two years.
- Decision-maker: Sole decision-maker or part of a team selecting providers for site and/or patient recruitment services.

1Annual R&D budgets = $1 billion or more
2Annual R&D budgets = less than $1 billion
*Participants were compensated according to their agreement to participate in the ISR Health Panel

Trends to Address
- For participants from large sponsors the key issues providers should address are:
  - Patient diversity
  - Site capacity/under resourcing at sites
  - Managing site burden
  - Patient centricity
  - Decentralized clinical trials
- Respondents at small/mid-size sponsors are most concerned about:
  - Site capacity/under resourcing at sites
  - Managing site burden
  - Decentralized clinical trials

Patient Diversity
- Improving patient diversity is significantly more important to large company participants than it is to their counterparts at small/mid-size companies (63% vs. 33%).
- However, views on how to improve patient diversity are similar among both segments; topping the list are:
  - Building relationships with patient advocacy groups
  - Offering patient assistance resources (e.g., patient concierge, travel reimbursement, etc.)
  - Providing patient education
  - Conducting research in more countries

Patient Retention
- Patient retention is not viewed as an overall concern, generally speaking.
- Most participants say it is only slightly or somewhat problematic, and this is the case among participants from both large and small/mid-size companies.
- But, for those trials where retention is an issue, it is an urgent problem.
- Participants believe these solutions will most improve patient retention:
  - Patient assistance resources
  - Home visits
  - Patient education
  - Virtual/telehealth visits
Key Selection Criteria for Site and Patient Recruitment Services

Whether for site or patient recruitment services, when choosing providers the must-haves are therapeutic area experience and a proven track record of success.

**CRITERIA FOR SITE RECRUITMENT SERVICES**

- **Tier 1**
  - Therapeutic area experience
  - Track record of success
  - Strong site relationships
  - Established site network

- **Tier 2**
  - Flexing to meet individual site needs
  - Accurate feasibility data/site metrics
  - Plan to meet site activation timing

**CRITERIA FOR PATIENT RECRUITMENT SERVICES**

- **Tier 1**
  - Track record of success
  - Therapeutic area experience
  - Plan to meet enrollment timelines

- **Tier 2**
  - Customized recruitment strategies
  - Patient advocacy group relationships
  - Plan for patient retention

**Desired Technology and Specialized Capabilities**

- Topping the list of technologies or other specialized capabilities sought by decision makers for site and patient recruitment services are:
  - Database with accurate site metrics
  - Real-time access to data

- Other capabilities form a second tier of capabilities that are important to provider selection:
  - Access to registries
  - Remote/virtual patient visits
  - Recruitment website/app building
  - eCOA/ePRO
Top Trends

Patient Diversity

Patient Retention

Provider Selection Criteria
Top Trends Providers Should Address

- Addressing patient diversity is the top priority among participants from Large companies.
-Respondents at Small/Mid-size sponsors want site/patient recruitment providers to focus on solving the problem of site capacity and under resourcing.

Most Important Trends for Site/Patient Recruitment Providers to Address

- Patient diversity
- Site capacity/under-resourcing at sites
- Managing site burden
- Patient centricity
- Decentralized clinical trials (DCT)
- Managing patient burden
- Social media for patient engagement/retention
- Social media for patient recruitment

Base = Total participants; Large companies n=59, Small/Mid-size companies n=61
* Indicates statistically significant difference between Large and Small/Mid-size companies at the 90% confidence level.
Patient Diversity

- Patient diversity is a greater concern among those from Large sponsors.

**Importance of Improving Patient Diversity**

<table>
<thead>
<tr>
<th></th>
<th>Large companies (n = 59)</th>
<th>Small/Mid-size companies (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely important</td>
<td>63% *</td>
<td>33%</td>
</tr>
<tr>
<td>Very important</td>
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</table>

- Engaging patient advocacy groups is seen as key to improving patient diversity.

**Solutions Most Needed to Improve Patient Diversity** (mentions >20%)

* Relationships with patient advocacy groups
  - Large companies
  - Small/Mid-size companies

Patient assistance resources
  - Large companies
  - Small/Mid-size companies

Patient education
  - Large companies
  - Small/Mid-size companies

Conducting research in more countries
  - Large companies
  - Small/Mid-size companies

Using more sites
  - Large companies
  - Small/Mid-size companies

Virtual/telehealth visits
  - Large companies
  - Small/Mid-size companies

Patient-centric platforms/apps
  - Large companies
  - Small/Mid-size companies

Regulatory guidance in patient diversity
  - Large companies
  - Small/Mid-size companies

Base = Patient diversity rated slightly/somewhat/very/extremely important; Large companies n=58, Small/Mid-size companies n=60

* Indicates statistically significant difference between Large and Small/Mid-size companies at the 90% confidence level.
Patient Retention

- Neither segment indicates patient retention is a major problem overall, but for studies encountering this difficulty retention is a more urgent issue to address.

Concern About Patient Retention

Note: no one rated patient retention “extremely problematic”

- Offering patient assistance and home visits are considered the best ways to address patient retention.

Solutions Most Needed to Improve Patient Retention
(mentions >20%)

- Patient assistance resources
- Home visits
- Patient education
- Virtual/telehealth visits
- Remote monitoring
- Patient-centric platforms/apps
- Relationships with patient advocacy groups

Base = Patient retention rated slightly/somewhat/very/extremely problematic; Large companies n=58, Small/Mid-size companies n=54
No statistically significant differences between Large and Small/Mid-size companies at the 90% confidence level.
Provider Selection Criteria: Site Recruitment Services

- Therapeutic area experience and a successful track record are critical to provider selection for site recruitment services.
- Site relationships and an established site network are also key considerations.

Top 10 Selection Criteria for Site Recruitment Services

- Experience in my therapeutic area
- Proven track record of success
- Strong site relationships
- An established site network
- Ability to flex to meet unique needs of individual sites
- Accurate, up-to-date feasibility data, including site performance metrics
- Plan for meeting site activation timelines
- Ability to solve problems
- A one-stop shop for all the site and patient recruitment services I need
- Plan to keep site staff/investigators invested in my study

Base = Total participants; Large companies n=59, Small/Mid-size companies n=61
No statistically significant differences between Large and Small/Mid-size companies at the 90% confidence level.
Likewise, a proven record of success and therapeutic area expertise also top the list of criteria in choosing providers for patient recruitment services. Providers’ plans for meeting enrollment timelines and their ability to customize patient recruitment strategies are also likely to factor into provider selection.

Top 10 Selection Criteria for Patient Recruitment Services

- Proven track record of success
- Experience in my therapeutic area/indication
- Plan for meeting patient enrollment timelines
- Customized patient recruitment strategies
- Relationships with patient advocacy groups/organizations
- Plan for patient retention
- A one-stop shop for all the site and patient recruitment services I need
- * Plan to address patient diversity
- Ability to solve problems
- Large geographic footprint

Base = Total participants: Large companies n=59, Small/Mid-size companies n=61

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Provider Selection Criteria: Technology and Specialized Capabilities

- When choosing site and patient recruitment providers, participants indicate that the site metric database along with the ability to provide real-time access to data are important in their selection decisions.

Top Selection Criteria for Technology / Specialized Capabilities (mentions >20%)

- Database with accurate site metrics
- Real-time access to data
- Remote/virtual patient visits
- eCOA/ePRO
- Access to EHR data
- * Access to registries
- Direct-to-patient delivery (e.g., study drugs, supplies)
- Decentralized trial platform
- * Recruitment website/app building
- EDC
- Wearables/Remote monitoring
- Moderated, online community of enrolled patients
- Social media capabilities

Base = Total participants; Large companies n=59, Small/Mid-size companies n=61

* Indicates statistically significant difference between Large and Small/Mid-size companies at the 90% confidence level.
Appendix
# Participant Profile

<table>
<thead>
<tr>
<th>Region</th>
<th>Large Companies (n = 59)</th>
<th>Small/Mid-size Companies (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>41%</td>
<td>48%</td>
</tr>
<tr>
<td>U.S./Canada</td>
<td>59%</td>
<td>52%</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Job Level</th>
<th>Large Companies (n = 59)</th>
<th>Small/Mid-size Companies (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manager</td>
<td>17%</td>
<td>13%</td>
</tr>
<tr>
<td>Associate Director/Director</td>
<td>71%</td>
<td>43%</td>
</tr>
<tr>
<td>Vice President</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>President/C-level</td>
<td>--</td>
<td>31%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Functional Responsibility</th>
<th>Large Companies (n = 59)</th>
<th>Small/Mid-size Companies (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical operations/Project manager/CTL</td>
<td>32%</td>
<td>25%</td>
</tr>
<tr>
<td>Data management</td>
<td>3%</td>
<td>--</td>
</tr>
<tr>
<td>Executive management/C-suite</td>
<td>2%</td>
<td>34%</td>
</tr>
<tr>
<td>Late-phase/HEOR/Registries</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Medical</td>
<td>20%</td>
<td>10%</td>
</tr>
<tr>
<td>Outsourcing/Purchasing management</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td>Patient recruitment/Feasibility/Site ops</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>R&amp;D management</td>
<td>25%</td>
<td>21%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Development Categories (company)</th>
<th>Large Companies (n = 59)</th>
<th>Small/Mid-size Companies (n = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Biologics</td>
<td>95%</td>
<td>52%</td>
</tr>
<tr>
<td>* Biosimilars</td>
<td>34%</td>
<td>11%</td>
</tr>
<tr>
<td>* Cell/gene therapies (CGT)</td>
<td>68%</td>
<td>28%</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>24%</td>
<td>16%</td>
</tr>
<tr>
<td>* Small molecule drugs – novel</td>
<td>86%</td>
<td>67%</td>
</tr>
<tr>
<td>Small molecule drugs – generic</td>
<td>17%</td>
<td>20%</td>
</tr>
<tr>
<td>* Vaccines</td>
<td>56%</td>
<td>10%</td>
</tr>
</tbody>
</table>

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Whether your needs are to increase patient diversity or manage site burden, our experts stand ready with the right site and patient recruitment solution for you.

LET’S ACCELERATE YOUR SUCCESS, TOGETHER.

www.ppd.com/how-we-help/site-patient-recruitment