



# DECENTRALIZED CLINICAL TRIALS SURVEY REPORT

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# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

## **1. Introduction**

# 1. Introduction

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This survey was conducted in 2020 among companies that outsource clinical research services or operations to contract research organizations (CROs). The objectives of the study were to gain current insights into the status of trends in the clinical trials market, including the threat to trials, patients and data presented by the global progression of the COVID-19 pandemic. The data also covers how existing trends are being accelerated by the need to sustain trials, and new strategies and regulatory measures that have been employed since news of the SARS-CoV-2 virus broke in early 2020.

## Demographics

The research study was global in scope, with 60% of respondents working in North America, 30% in Europe and 10% in Asia-Pacific. It reflects a mix of large pharma/biopharma, mid-size pharma/biopharma, and small pharma/biopharma, with some weighting towards the large and small categories. Respondents mainly work in clinical operations or management, or clinical trials development, and over 90% of them are in C-suite or Director-level roles. The same high proportion have more than 10 years of experience – representing a respondent panel of high relevance and strong data integrity.

A large percentage of the full survey demographic represents a company that is active in outsourcing clinical research services or operations to CROs, and over three quarters of respondents are directly involved in decision-making relating to that process.

## Therapeutic Areas Represented

- |                              |                          |
|------------------------------|--------------------------|
| 1. Oncology & Hematology     | 8. Cardiovascular        |
| 2. Rare Diseases             | 9. Metabolic & Endocrine |
| 3. Immunology & Rheumatology | 10. Gastroenterology     |
| 4. Neuroscience              | 11. Women's Health       |
| 5. Infectious Disease        | 12. Critical Care        |
| 6. Respiratory               | 13. Pediatrics           |
| 7. Vaccines                  | 14. Urology              |

## Trends: COVID-19 Pandemic, Decentralized Clinical Trials and Digital Solutions

Questions in the study generated insights on the impact of the COVID-19 pandemic on clinical trials globally – namely concerns over delays, interruptions and continuity; patient enrollment / retention; site operations / capacity; supply chain interruptions; patient safety and access; and regulatory changes.

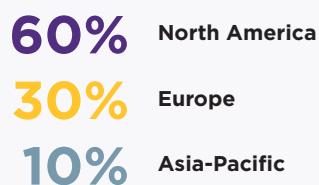
Mitigation strategies are also covered, as is data on the extent to which decentralized trials were already a growing trend in the clinical trials market, and how much the COVID-19 pandemic will alter or accelerate that trend. The depth of implementation of flexible protocols, direct-to-patient services, and digital solutions is also explored.

# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

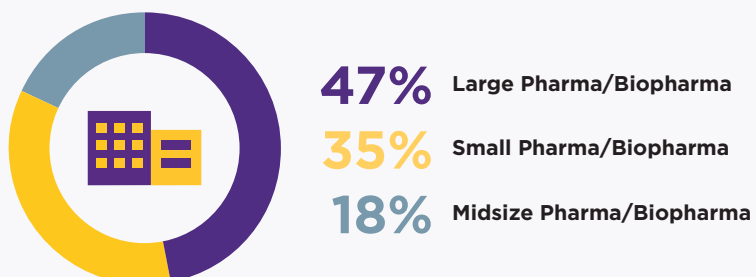
## **2. Demographics**

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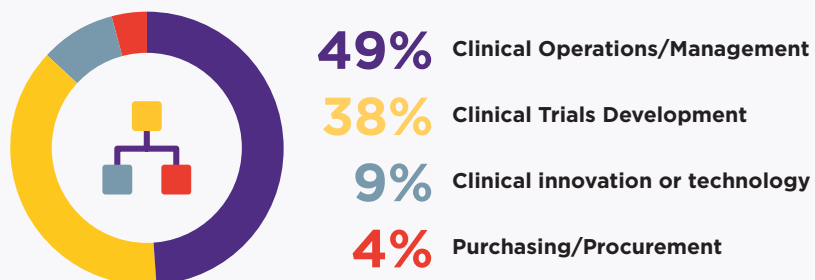
### 2.1 Survey of Participant's Regional Location



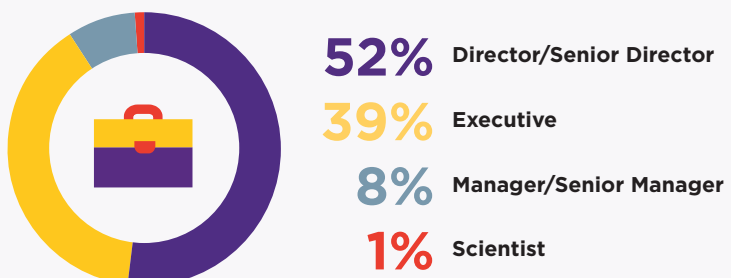
### 2.2 Survey of Participant's Organization Type



### 2.3 Survey of Participant's Department



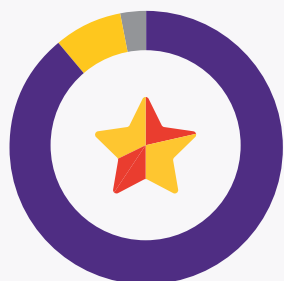
### 2.4 Survey of Participant's Job Title



**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 2. Demographics

### 2.5 Survey of Participant's Industry Experience



**89%** More than 10 years

**8%** 5-10 years

**3%** 3-5 years



### 2.6 Relationship with CRO

Survey Participant's Company's Relationship with Contract Research Organizations (CROs)



**96%**

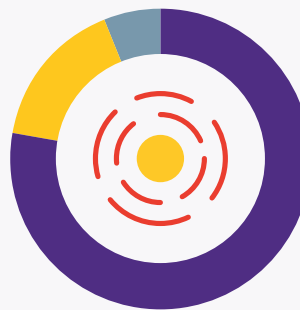
My company currently outsources clinical research services or operations to contract research organizations (CROs).

**4%**

My company does not currently outsource clinical research services or operations, but is in the process of evaluating CROs — likely to need within the next 24 months.

### 2.7 Influence with CRO

Survey Participant's Influence in the CRO Selection Process



**78%**

I am part of the decision-making unit that selects the CROs.

**16%**

I am part of a team that establishes criteria / makes recommendations on the selection of CROs.

**6%**

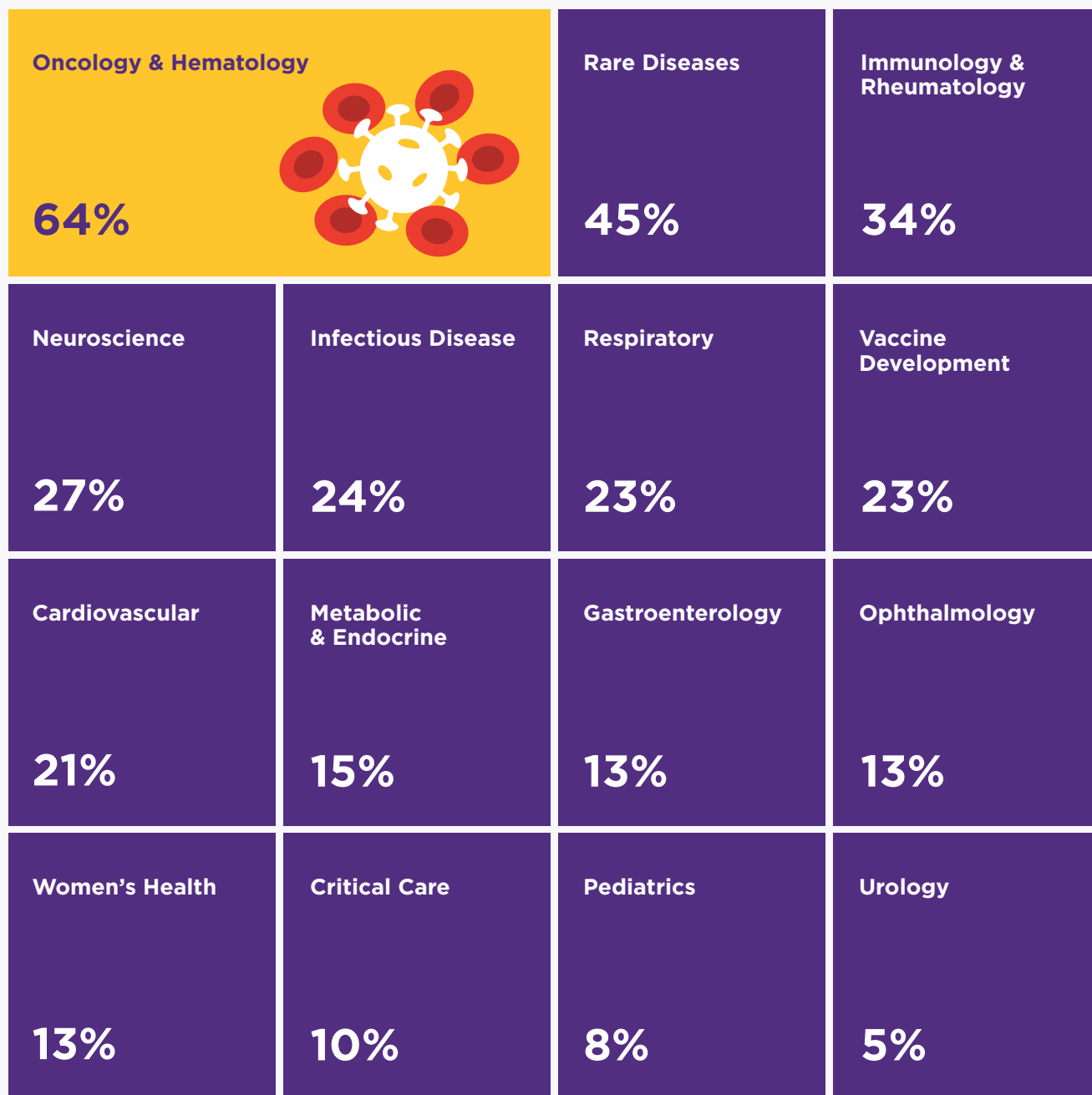
I supervise or coordinate with CROs.

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## 2. Demographics

### 2.8 Therapeutic Focus of Drug Pipeline

Survey Participant's Ongoing Clinical Trials' Therapeutic Focus



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# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

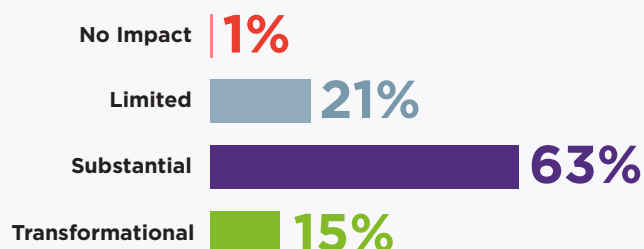
## **3. COVID-19 Impact and Mitigation**



## 3. COVID-19 Impact and Mitigation

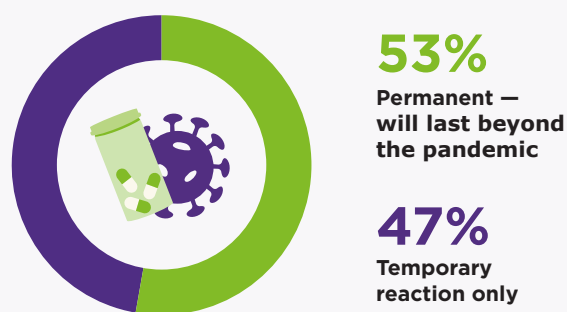
### 3.1 Covid-19 Impact on Ongoing Trials

How has the current COVID-19 crisis impacted your ongoing clinical trials?



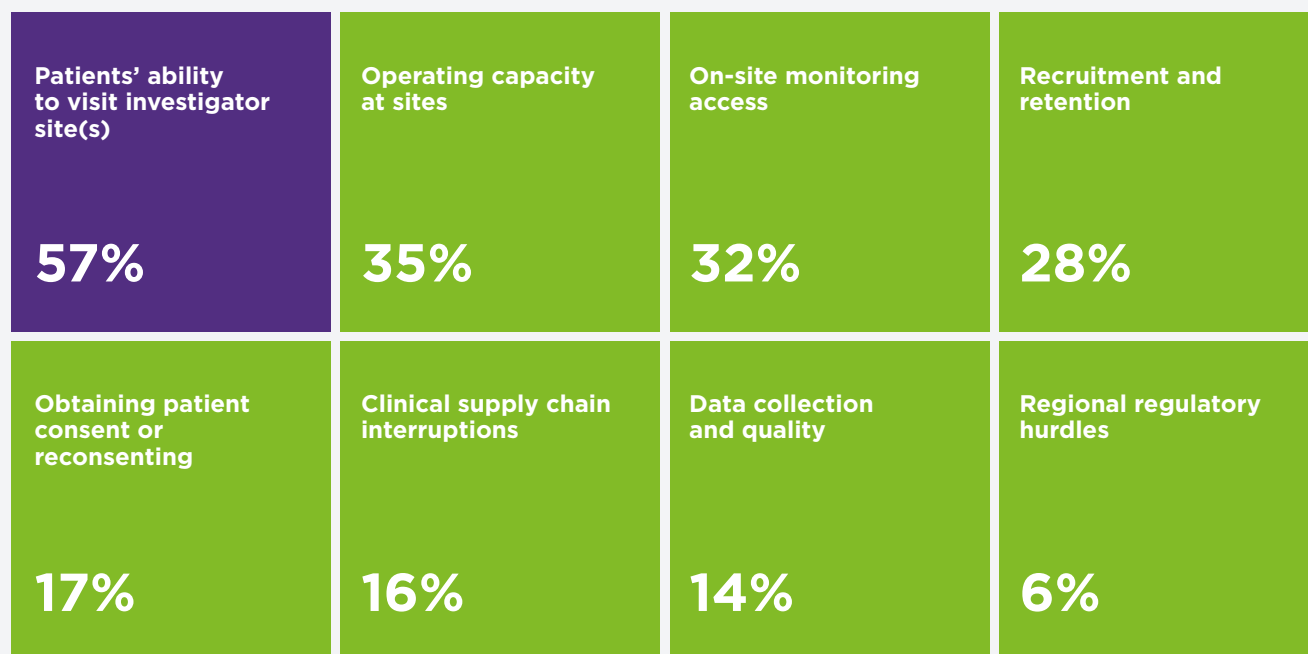
### 3.2 Impact Timeline

Do you anticipate the COVID-19 impact your clinical trials to be permanent or temporary?



### 3.3 Covid-19 Impact on Ongoing Trials

What are the most impacted areas of clinical trial operations caused by COVID-19?



Percentages in the above chart represents the top 2 boxes of the impact scale

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

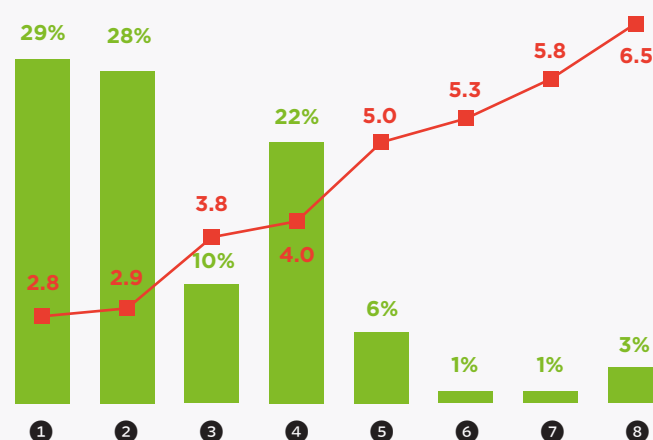
## 3. COVID-19 Impact and Mitigation

### 3.4 Most Concerning Aspect of COVID-19 Impact

Looking ahead, what are the most concerning aspects of the Covid-19 Impact?

- ① Trial delays, interruptions and continuity
- ② Patient enrollment and retention
- ③ Limited site operating capacity
- ④ Patient safety and access
- ⑤ Clinical supply chain interruptions
- ⑥ Endpoint collection and data quality
- ⑦ Obtaining patient consent
- ⑧ Regulatory changes

■ Ranked First  
—●— Mean Rank



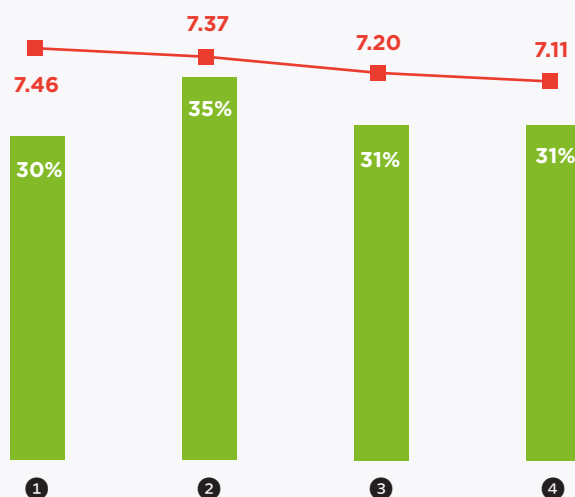
Percentages in the above chart represents the top 2 boxes of the impact scale

### 3.5 COVID-19 Regional Impact

How have your clinical operations been impacted by the pandemic across different regions?

- ① Trials in North America
- ② Trials in EMEA
- ③ Trials in Asia-Pacific
- ④ Trials in rest of world

■ T2B Most Impact  
—●— Mean



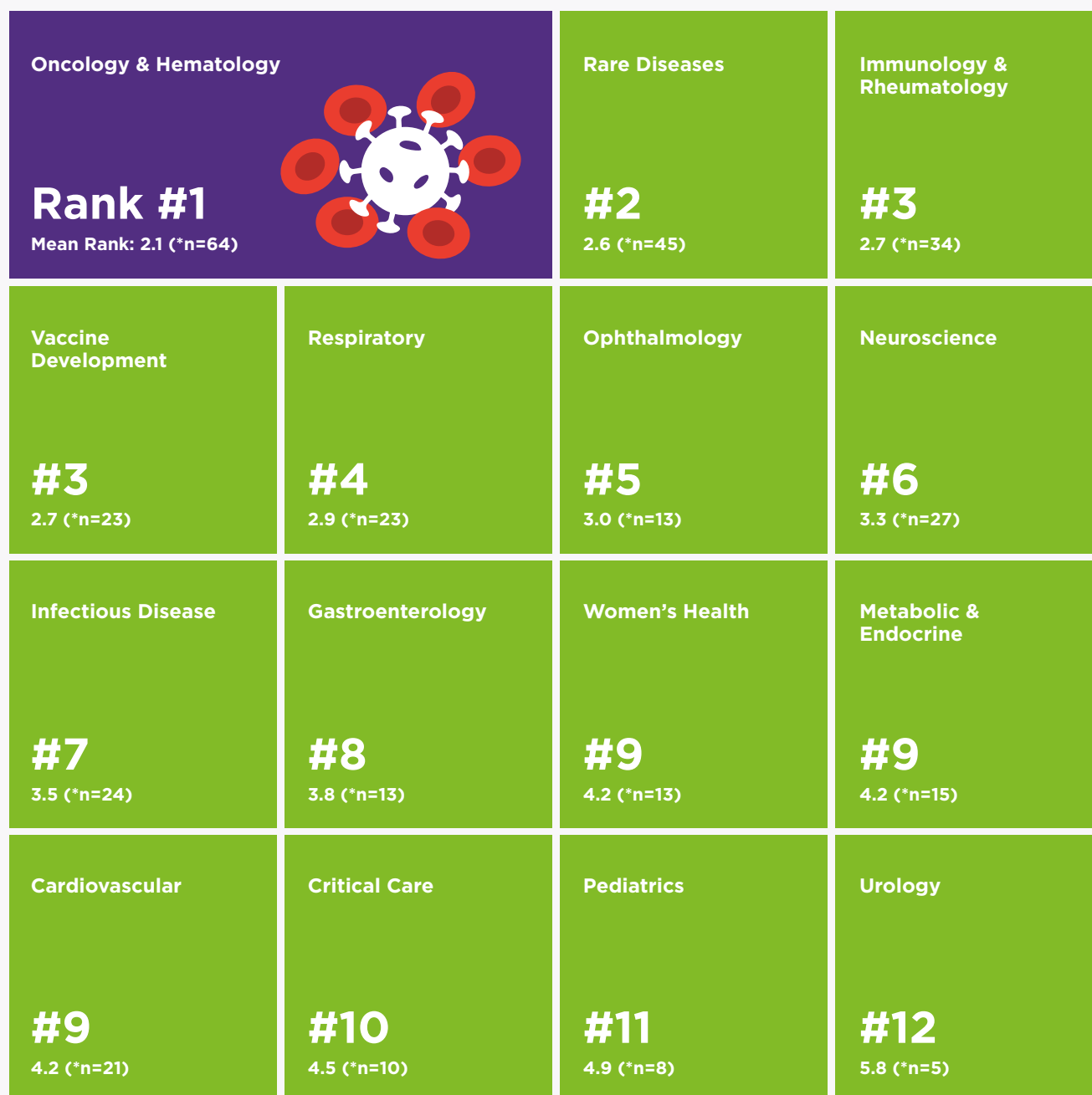
Percentages in the above chart represents the top 2 boxes of the impact scale

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## 3. COVID-19 Impact and Mitigation

### 3.6 Therapeutic Areas Impacted — Ranked

Within your current pipeline, which therapeutic area(s) have been impacted the most?



\*n indicates the sample size

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 3. COVID-19 Impact and Mitigation

### 3.7 Mitigation Strategies Implemented

To mitigate the impact of the pandemic, what are some of the technologies or strategies being implemented or planned by your organization?

Remote site visits/ monitoring	Risk assessments and mitigation plans	Reduced site visits	Replacing paper with digital clinical outcome assessments
69%	66%	60%	54%
Virtual pre-site selection visit	Ensure remote eConsent is available	Amending existing SOPs and alliance agreements	Remote safety lab collections
51%	49%	47%	42%
Remote EMR Access	Deferring trials	Setting up home health care options for patients	Creating flexible protocols to incorporate decentralized/ hybrid trials
39%	35%	32%	32%
Avoiding immune- compromised regimens	Establishing direct-to- patient (DTP) options for patients	Shifting trials to other locations/ sites	Reduced number of sites
27%	26%	23%	23%

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 3. COVID-19 Impact and Mitigation

### 3.8 Mitigation Strategies Initiated Not Implemented

To mitigate the impact of the pandemic, what are some of the technologies or strategies being implemented or planned by your organization?

Setting up home health care options for patients  <b>27%</b>	Establishing direct-to-patient (DTP) options for patients  <b>27%</b>	Creating flexible protocols to incorporate decentralized/hybrid trials  <b>26%</b>	Remote safety lab collections  <b>25%</b>
Shifting trials to other locations/sites  <b>24%</b>	Remote EMR Access  <b>24%</b>	Amending existing SOPs and alliance agreements  <b>24%</b>	Virtual pre-site selection visit  <b>23%</b>
Replacing paper with digital clinical outcome assessments  <b>23%</b>	Risk assessments and mitigation plans  <b>22%</b>	Reduced number of sites  <b>19%</b>	Deferring trials  <b>18%</b>
Ensure remote eConsent is available  <b>16%</b>	Remote site visits/monitoring  <b>16%</b>	Reduced site visits  <b>15%</b>	Avoiding immune-compromised regimens  <b>12%</b>

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 3. COVID-19 Impact and Mitigation

### 3.9 Mitigation Strategies Planned But Not Initiated

To mitigate the impact of the pandemic, what are some of the technologies or strategies being implemented or planned by your organization?

Creating flexible protocols to incorporate decentralized/hybrid trials  <b>28%</b>	Establishing direct-to-patient (DTP) options for patients  <b>24%</b>	Setting up home health care options for patients  <b>23%</b>	Reduced number of sites  <b>21%</b>
Shifting trials to other locations/sites  <b>21%</b>	Virtual pre-site selection visit  <b>21%</b>	Avoiding immune-compromised regimens  <b>20%</b>	Remote EMR Access  <b>20%</b>
Ensure remote eConsent is available  <b>20%</b>	Reduced site visits  <b>20%</b>	Remote safety lab collections  <b>3%</b>	Replacing paper with digital clinical outcome assessments  <b>13%</b>
Amending existing SOPs and alliance agreements  <b>12%</b>	Risk assessments and mitigation plans  <b>12%</b>	Deferring trials  <b>10%</b>	Remote site visits/monitoring  <b>10%</b>

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## 3. COVID-19 Impact and Mitigation

### 3.10 Mitigation Strategies Not Planned

To mitigate the impact of the pandemic, what are some of the technologies or strategies being implemented or planned by your organization?

Avoiding immune-compromised regimens  <b>41%</b>	Reduced number of sites  <b>37%</b>	Deferring trials  <b>37%</b>	Shifting trials to other locations/sites  <b>32%</b>
Establishing direct-to-patient (DTP) options for patients  <b>24%</b>	Remote safety lab collections  <b>20%</b>	Setting up home health care options for patients  <b>18%</b>	Remote EMR Access  <b>17%</b>
Amending existing SOPs and alliance agreements  <b>17%</b>	Ensure remote eConsent is available  <b>15%</b>	Creating flexible protocols to incorporate decentralized/hybrid trials  <b>14%</b>	Replacing paper with digital clinical outcome assessments  <b>10%</b>
Virtual pre-site selection visit  <b>5%</b>	Reduced site visits  <b>5%</b>	Remote site visits/monitoring  <b>5%</b>	Risk assessments and mitigation plans  <b>0%</b>

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 3. COVID-19 Impact and Mitigation

### 3.11 Importance of Mitigation Strategies

Importance of your clinical trials pandemic mitigation strategies.

Remote site visits/ monitoring  <b>Rank #1</b> Mean Rank: 5.28 (*n=95)	Risk assessments and mitigation plans  <b>#2</b> 5.31 (*n=100)	Creating flexible protocols to incorporate decentralized/hybrid trials  <b>#3</b> 6.24 (*n=86)	Reduced site visits   <b>#4</b> 6.64 (*n=95)
Setting up home health options for patients  <b>#5</b> 7.09 (*n=82)	Ensure remote eConsent is available  <b>#6</b> 7.16 (*n=85)	Establishing direct- to-patient (DTP) options for patients  <b>#7</b> 7.17 (*n=76)	Virtual pre-site selection visit   <b>#8</b> 7.26 (*n=95)
Replacing paper clinical outcome assessments with digital ones  <b>#9</b> 7.56 (*n=90)	Amending existing SOPs and alliance agreements  <b>#10</b> 7.95 (*n=83)	Remote EMR Access   <b>#11</b> 8.00 (*n=83)	Remote safety lab collections   <b>#12</b> 8.31 (*n=80)
Shifting trials to other locations/ sites  <b>#13</b> 8.45 (*n=68)	Avoiding immune- compromised regimens  <b>#14</b> 8.66 (*n=59)	Reduced number of sites   <b>#15</b> 9.01 (*n=63)	Deferring trials   <b>#16</b> 9.73 (*n=63)

\*n indicates the sample size

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.



# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

## **4. Decentralized Trials Implementation**

## 4. Decentralized Trials Implementation

### 4.1 Average Implementation Time

On average, how long has it taken for your organization to implement a hybrid or decentralized trial (i.e., from protocol redesign to first patient TeleVisit)?

**7.5 Months**

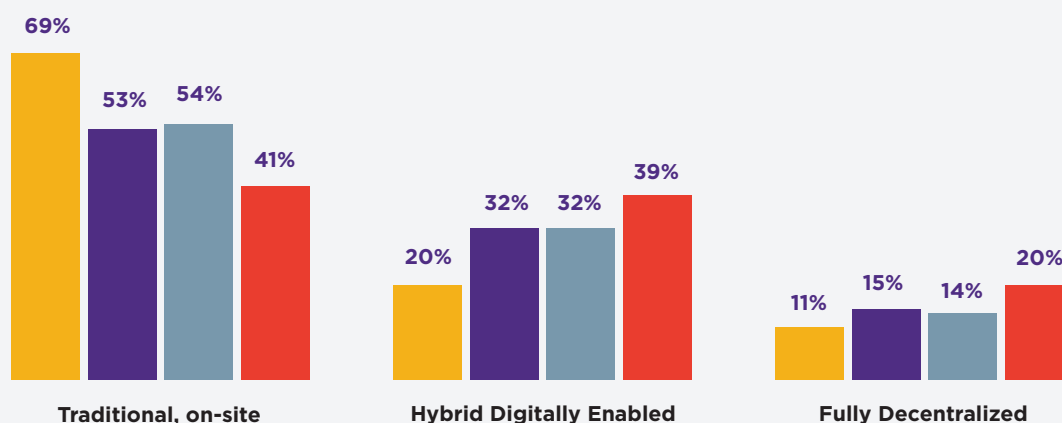
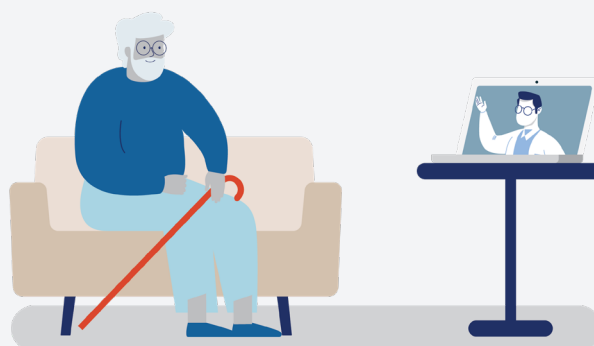


The average number from 100 respondents

### 4.2 Type of Trials 2019-2021

Of the clinical trials sponsored by your company from 2019-2021, please indicate the breakdown of trials (in percentages) — onsite, decentralized, or hybrid?

- 2019
- 2020 H1
- Pandemic ends in Q4 2020
- Pandemic continues in Q1 2021



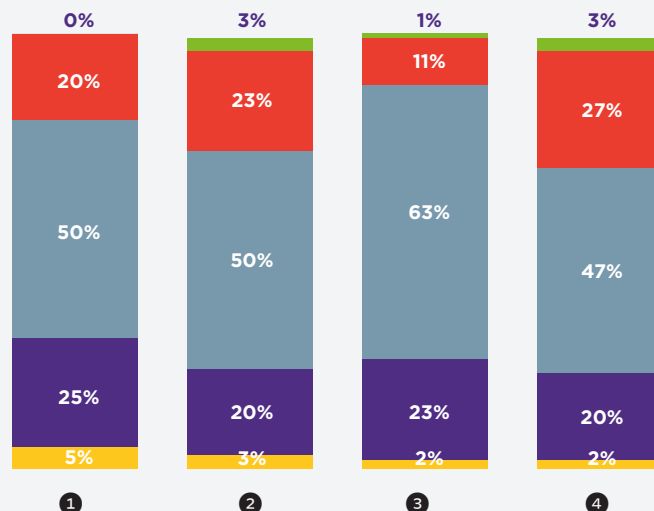
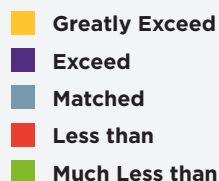
**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 4. Decentralized Trials Implementation

### 4.3 Expectations with Decentralized Trials

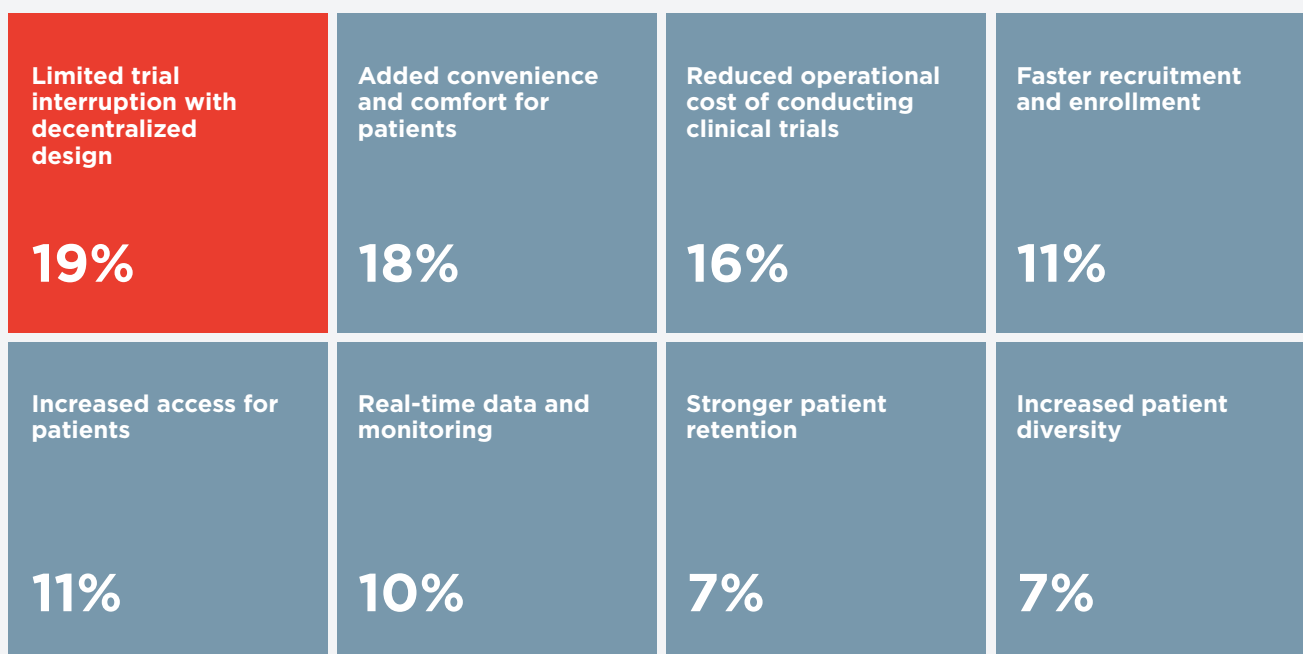
Rate how decentralized trials and tools have helped meet expectations for your organization?

- ① Increase patient access and diversity
- ② Reduce study footprint (less sites & countries)
- ③ Reduce burden for patient participation
- ④ Accelerate timelines



### 4.4 Decentralized Trials Benefits

What would you consider to be the primary benefit your organization has seen from its decentralized trials?

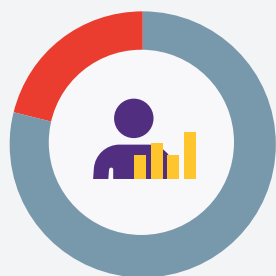


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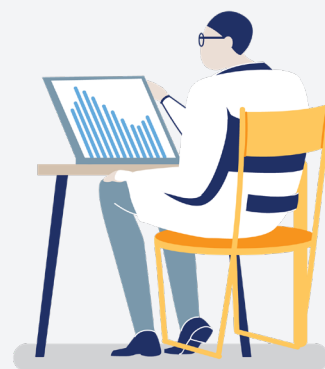
## 4. Decentralized Trials Implementation

### 4.5 Data Quality & Quantity: DCT VS Traditional

Do you think decentralized trials can have at least the same [or higher] level of data quality and quantity when compared to traditional trials?



**Yes 79%**  
**NO 21%**



### 4.6 Research Improvements for DCTs

What would you improve or change about decentralized trial solutions to make them more effective for each of the categories below?

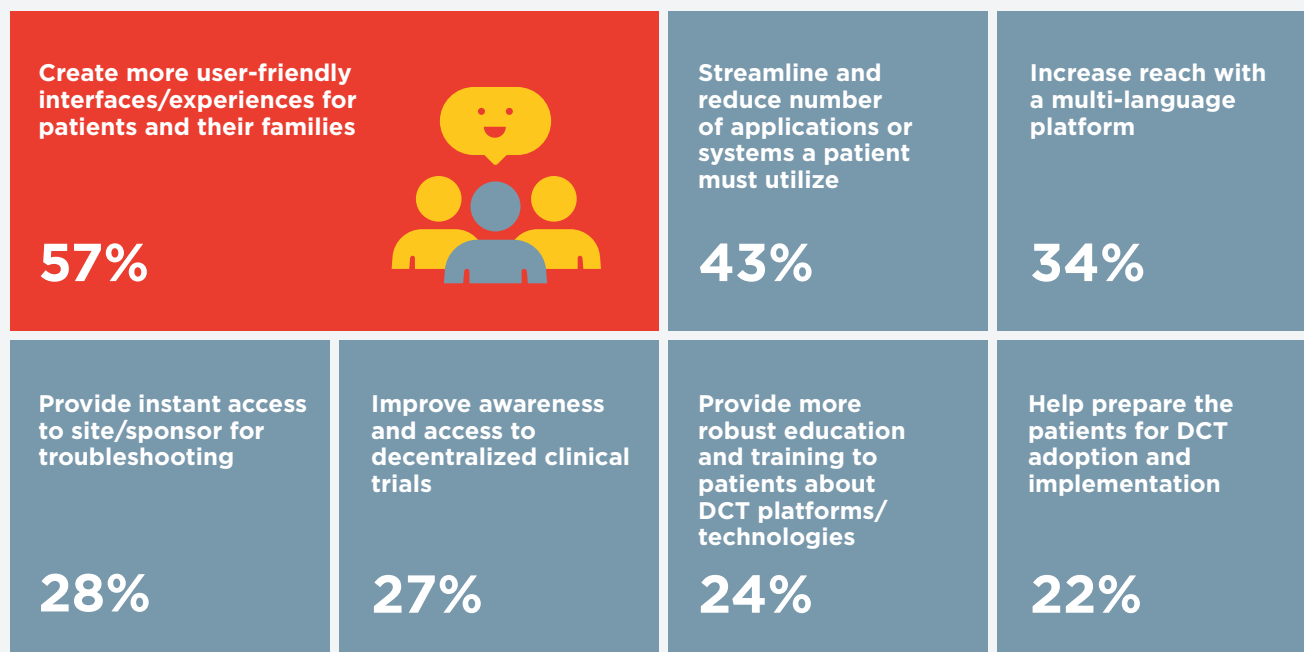
Create more user-friendly interfaces/experiences for investigator sites <b>44%</b>	Provide more robust education and training to the clinicians about DCT platforms/technologies <b>32%</b>	Reduce the cost of conducting clinical trials <b>31%</b>	Improve quality of study data <b>28%</b>
Provide better regulatory support <b>26%</b>	Help prepare the sites for DCT adoption and implementation <b>25%</b>	Increase reach with a multi-language platform <b>24%</b>	Provide the entire spectrum of digital services <b>23%</b>

**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

## 4. Decentralized Trials Implementation

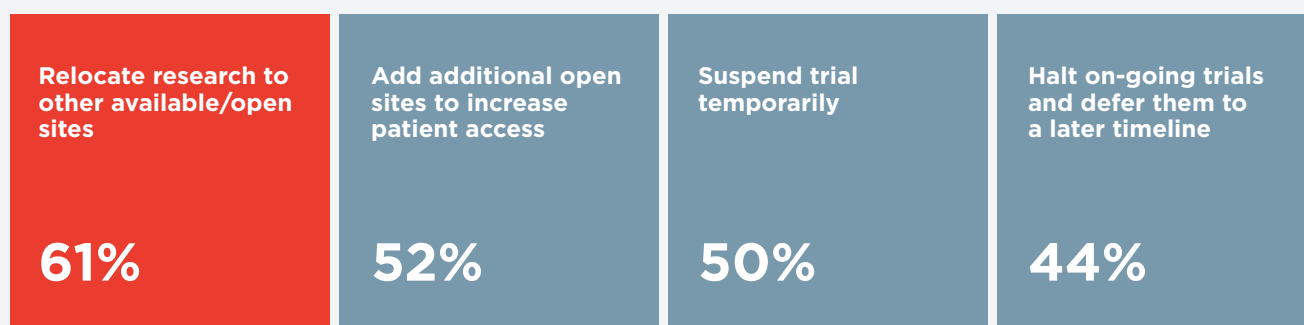
### 4.7 Patient Experience Improvements for DCTs

What would you improve or change about decentralized trial solutions to improve patient experience?



### 4.8 Alternate Options Considered Prior to DCT

Before opting for a decentralized trial, what other options did you consider to mitigate challenges stemming from the pandemic?

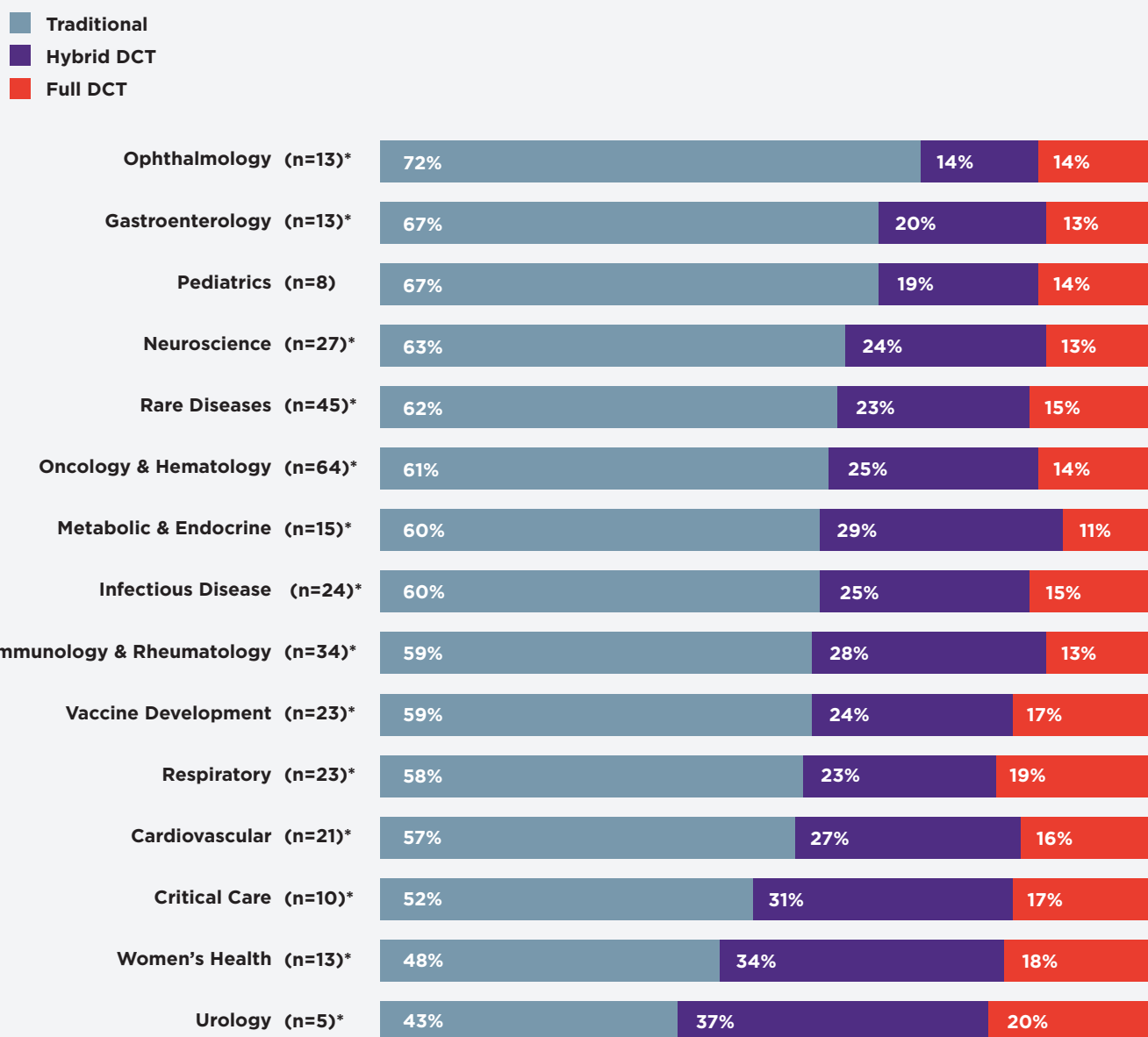


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## 4. Decentralized Trials Implementation

### 4.9 Clinical Trial Type for Therapeutic Area

Rank of type of Clinical Trial Design for Therapeutic Areas



\*n indicates the sample size

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## 4. Decentralized Trials Implementation

### 4.10 CRO DCT Evaluation Factors

Importance of the following attributes when evaluating the hybrid or decentralized solutions offered by CROs.



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# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

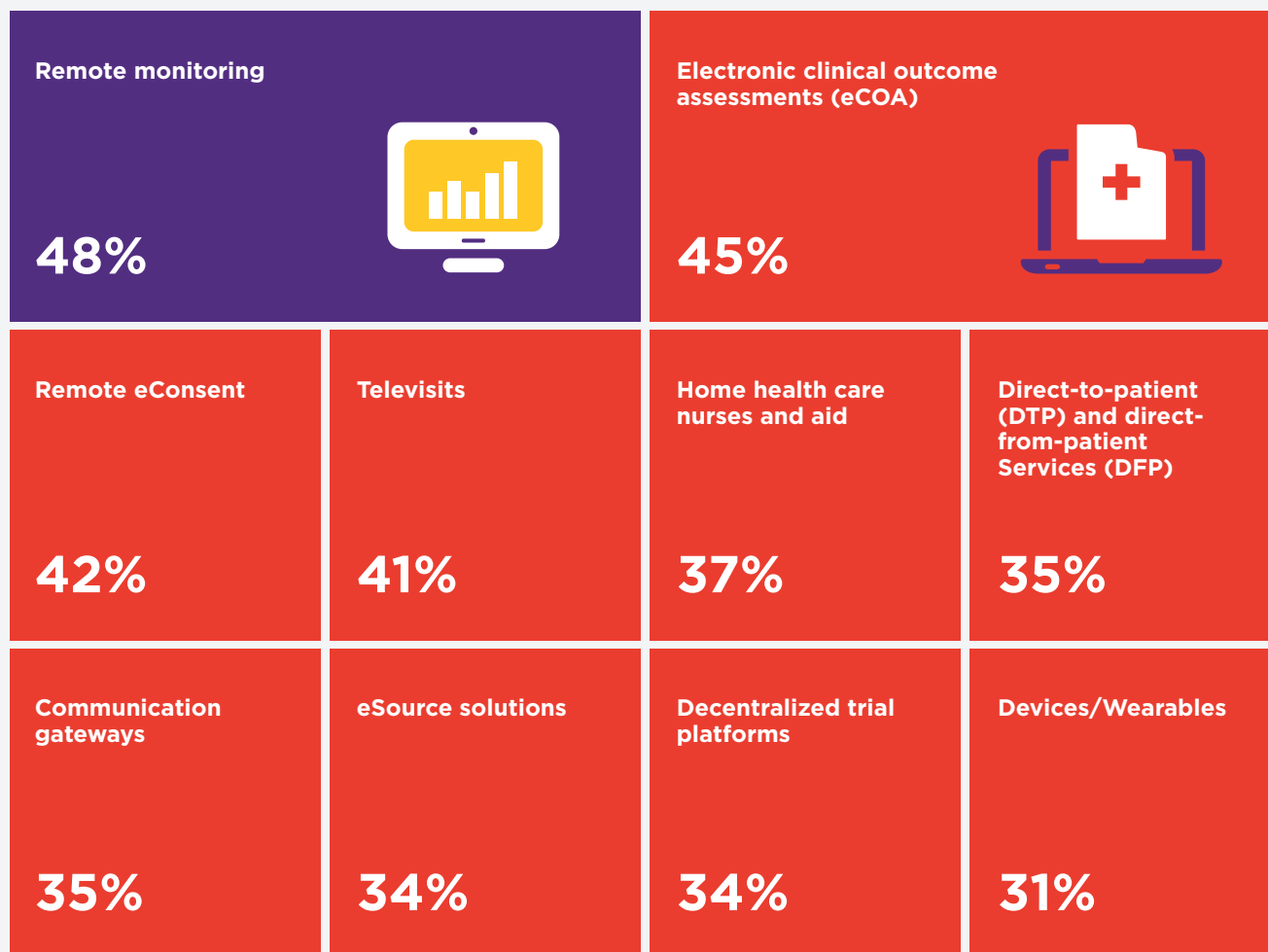
## **5. Technologies in Clinical Trials**



## 5. Technologies in Clinical Trials

### 5.1 Technologies, Tools and Platforms for Trials

Percentage of respondents rated the following strategies, tools, and platforms as having the most positive impact on trial performance.



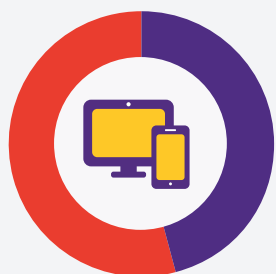
Percentages in the above chart represents the top 2 boxes of the impact scale

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## 5. Technologies in Clinical Trials

### 5.2 Work with Tech Solution Providers

Do you work directly with tech, software or clinical trial platform companies to improve or digitize aspects of your clinical trials operations?

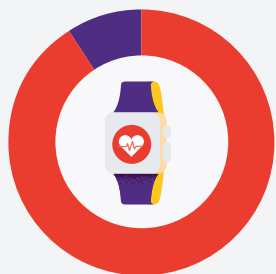


**NO 54%**  
**Yes 46%**



### 5.3 Try New Solution Platform with Trial

If you were given access to try a new feature, product or platform with your trial, would you be willing to test it?



**Yes 91%**  
**No 9%**



**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.

# **DECENTRALIZED CLINICAL TRIALS SURVEY REPORT**

## **6. Feedback on Decentralized Trials**

## 6. Feedback on Decentralized Trials

### 6.1 The top 10 most common responses regarding Decentralized Trials: Clinicians

- 1 Education and training are essential especially for older patients
- 2 Efficiency improvement, less time consuming
- 3 Excitement about advanced technology
- 4 Convenience for mitigate pandemic situation
- 5 Regulatory support need data and information privacy control
- 6 Compliance involvement
- 7 Cost concerning household and recruitment
- 8 Complexities, prefer face to face-to-face traditional sites
- 9 Time to get used to new processes
- 10 Others include regulators like FDA's approval on digital trials, quality concerns, etc.



### 6.2 The top 10 most common responses regarding Decentralized Trials: Patients

- 1 Patients' big willingness of adoption and excitement about new experiences
- 2 Efficiency improvement, less time consuming
- 3 Education and training are essential for older adults
- 4 Easy to access, more directly in the process
- 5 Take time to get used to the new process
- 6 Regulatory support need data and information privacy control
- 7 Time to get used to new processes
- 8 Requirement on patient-friendly interface
- 9 Complicated and challenging to participate
- 10 Others include cost saving, traditional site preference, etc.



**NOTE:** Total sample size of this study is 100. The sample size varies for each question based respondents' qualifications.