Tigermed

Research Report

Decentralized clinical trials: Decoding Industry Dynamics 2023

A sub project on "Research on domestic and foreign regulations and technical guidelines for drug development"

Customer-centric and globally adaptive DCT solutions

Release date: 2024.1.3

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Introduction

This survey is a sub-project undertaken by the NMPA, as part of the < Research on domestic and foreign regulations and technical guidelines for drug development>, focuses on exploring the present adoption, challenges, regulatory aspects and industry expectations.

The aim of this initiative is to engage various stakeholders in the clinical trials domain in a collective discourse on the regulatory policies and requisite infrastructure for the implementation of digitalized/decentralized clinical trials in China. The anticipated outcome is to contribute valuable insights that will facilitate the advancement of clinical trials and the research and development of biopharmaceutical products in China. The research involves active participation from regulatory bodies in the clinical trials domain, industry experts, medical institutions, research organizations, patient advocacy groups, and individuals. Their collective involvement is expected to deepen our understanding of the digitalized/decentralized clinical trials domain, providing robust support for the industry's future development.

A total of 889 responses were collected. Among these, research institutions/hospitals contributed 497 responses, while the remaining 392 responses were gathered from other sources. The diverse backgrounds of the respondents and their cross-functional collaboration can address the challenges in the field of digitalized/decentralized clinical trials, ultimately enhancing the efficiency and quality of clinical research.

Project Initiator:

China National Medical Products Administration- NMPA

Project Undertaking Unit:

China Society for Drug Regulation- CSFDR

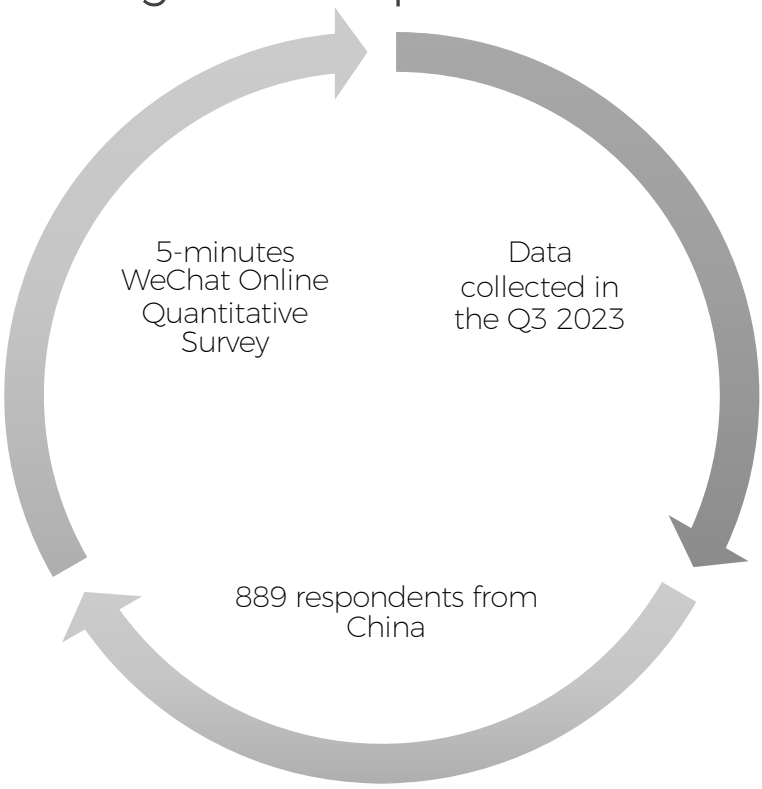
Project Lead Unit:

Hangzhou Tigermed

Project Participating Units:

- Beijing Tsinghua University Changgeng Hospital
- Peking University First Hospital
- Beijing Youan Hospital
- Syneos Health
- Fortrea
- 3D Medicines

Questionnaire design and implementation



Main Content

- Respondent Demographics
- Industry practice
- Technical issues
- Regulatory considerations

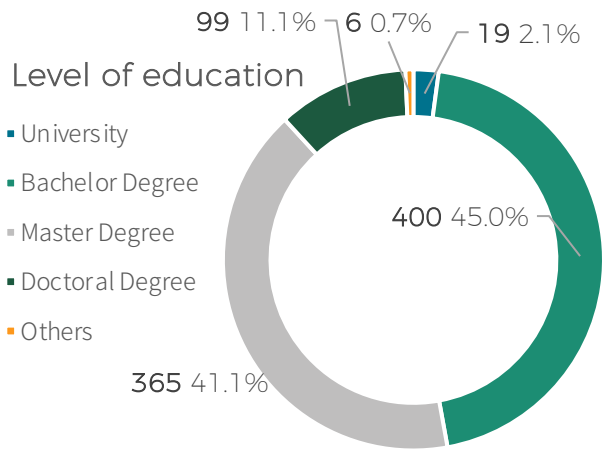
01

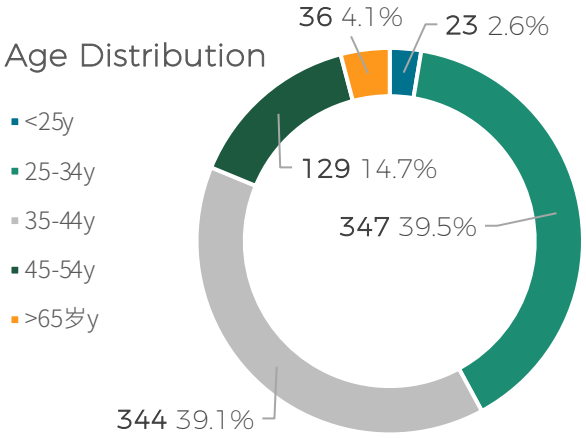
Respondent Demographics

Respondent Demographics

The age distribution of surveyed participants, the majority fall within the 25-44 age group, particularly among those aged 25-34 and 35-44, constituting approximately 39.5% and 39.1% of the total respondents, respectively. This suggests a notable interest in digitalized/decentralized clinical trials among individuals in this age range, indicating that they may be key contributors in this field.

The vast majority of participants hold a bachelor's or master's degree, accounting for approximately 45% and 41.1% of the total respondents, respectively. This indicates that, in the realm of digitalized/decentralized clinical trials, participants with higher education levels play a dominant role. Additionally, there is a noteworthy presence of doctoral degree holders, comprising approximately 11.1%, highlighting the involvement of individuals with advanced academic qualifications.





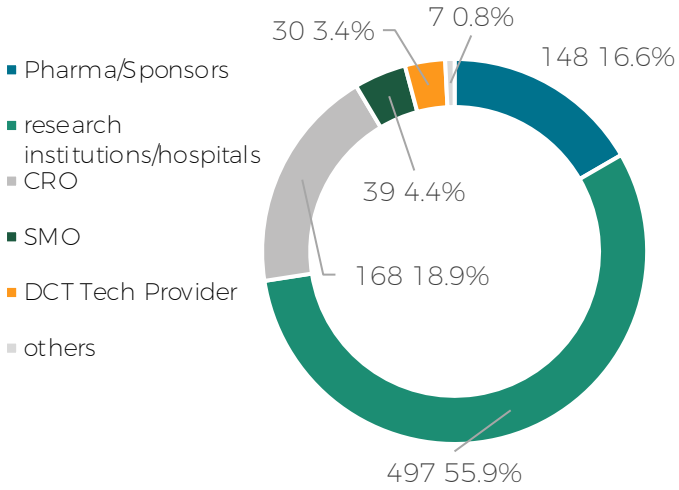
Digitalized/decentralized clinical trials in China has attracted a diverse range of participants, particularly those who are younger and have higher education. Medical and research institutions play crucial roles in digitalized/decentralized clinical trials, and participants with higher educational backgrounds hold significant positions. These findings contribute to understanding the characteristics of various stakeholders in clinical trials, providing valuable insights for future research and policy formulation.

The majority of participants come from research institutions and hospitals, accounting for approximately 55.9% of the total respondents. This indicates that medical and research institutions play a central role in digitalized/decentralized clinical trials. Additionally, Contract Research Organizations (CROs) and pharmaceutical companies / sponsors also contribute significantly, constituting approximately 18.9% and 16.6% of the total respondents, respectively, and they play pivotal roles. While participants from Site Management Organizations (SMOs), DCT technology providers, and other organizational types are fewer in number, their contributions remain significant.

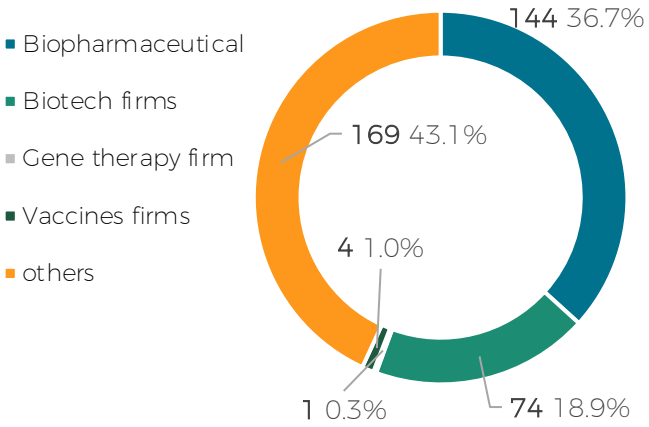
In term of company types, other categories of companies constitute the largest proportion, accounting for approximately 43.1%. Biopharmaceutical companies represent 36.7%, and biotechnology firms account for 18.9%. This indicates that the field of digitalized/decentralized clinical trials has attracted participation from diverse types of companies, with a notable presence from biopharmaceutical entities.

The distribution of company sizes is relatively even, with companies employing fewer than 500 people constituting 36.5%, and those with over 10,000 employees representing 19.1%. This suggests that the field of digitalized/ decentralized clinical trials has attracted participation from companies of varying sizes, ranging from small to medium enterprises to large multinational corporations.

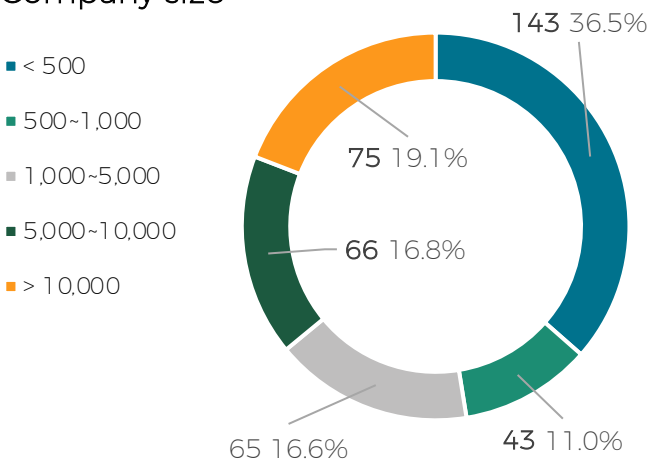
Type of organization



Company type



Company size

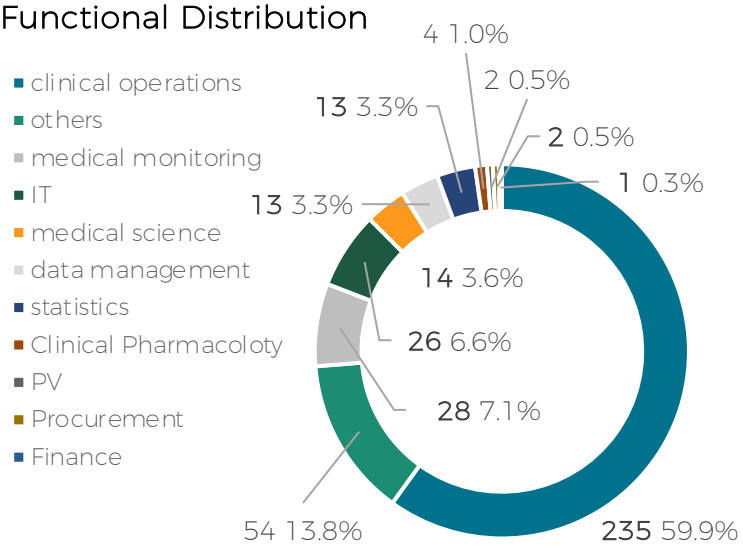


These findings contribute to the understanding of the characteristics of organization details, providing valuable insights for future research and policy formulation.

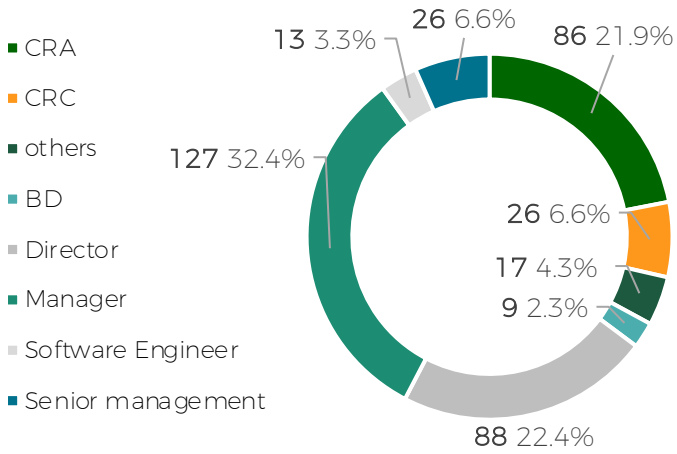
The functional distribution of research participants reveals that individuals engaged in clinical operations represent the largest proportion, accounting for approximately 59.9%. Participants from other functional areas also contribute, including roles in medical monitoring, IT, medical sciences, data management, statistics, and other fields. This suggests that clinical operations play a pivotal role in the digitalized/decentralized clinical trials domain, while professionals from various functional areas are equally indispensable.

In terms of positions within companies, managers constitute the largest proportion at approximately 32.4%, closely followed by directors at around 22.4%. The proportion of Clinical Research Coordinators (CRC) and senior management (Vice Presidents and above) is relatively lower, at approximately 6.6% and 4.3% respectively. Additionally, individuals in business-related and other roles also comprise a certain percentage. This indicates that participants in the digitalized/decentralized clinical trials domain span various positions, both in managerial and non-managerial roles.

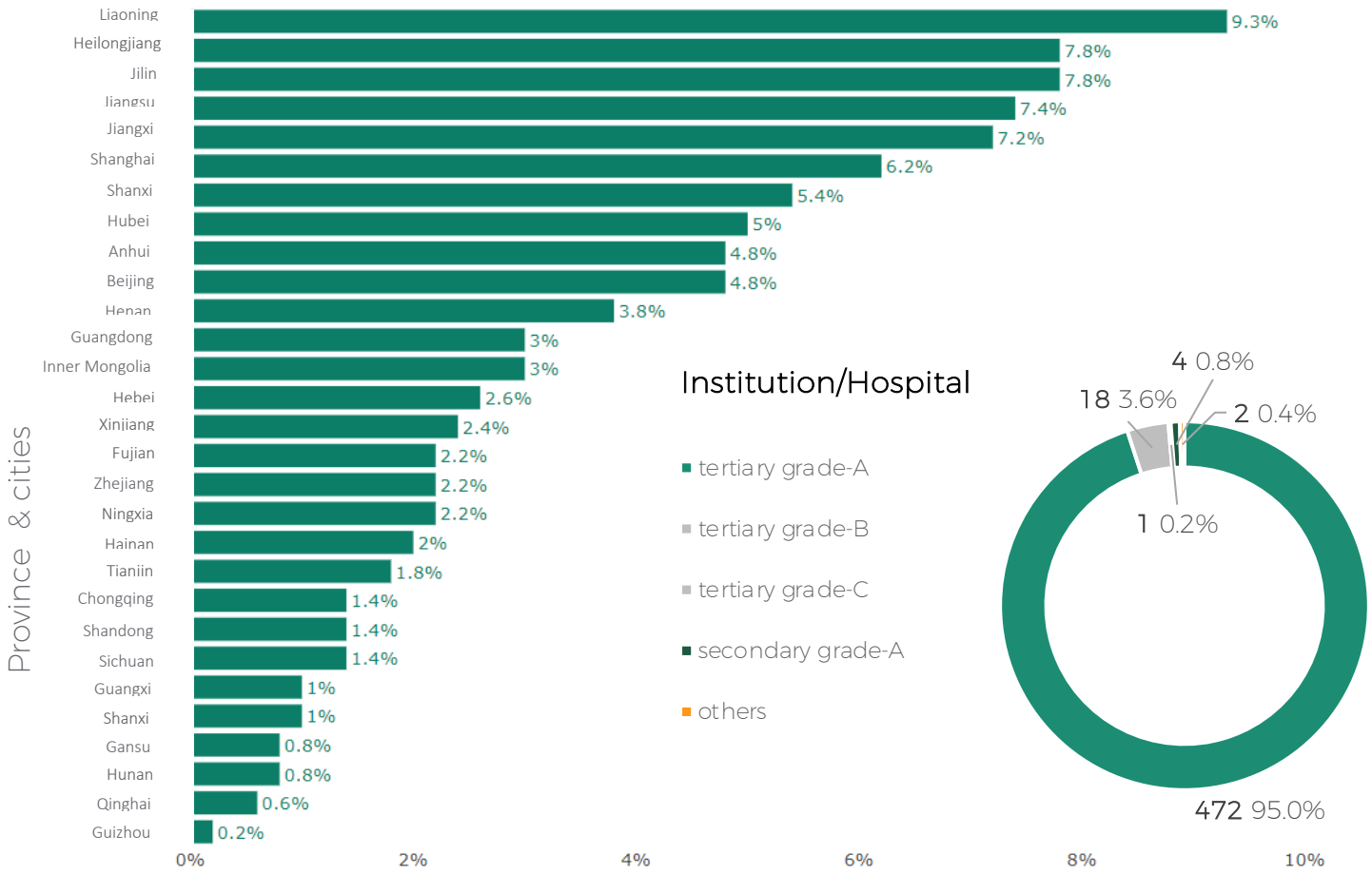
Functional Distribution



Positions



The functional and positional distribution of research participants in digitalized/decentralized clinical trials highlights the diverse roles and responsibilities within the domain. Clinical operations emerge as a crucial component, with professionals from various functional areas also playing indispensable roles. Moreover, the distribution across managerial and non-managerial positions underscores the breadth of expertise and experience contributing to the advancement of these trials. Overall, these findings deepen our understanding of stakeholder familiarity and development in clinical trials concerning DCT, and they underscore the vitality needed for the continued growth and evolution of the clinical trials industry ecosystem.



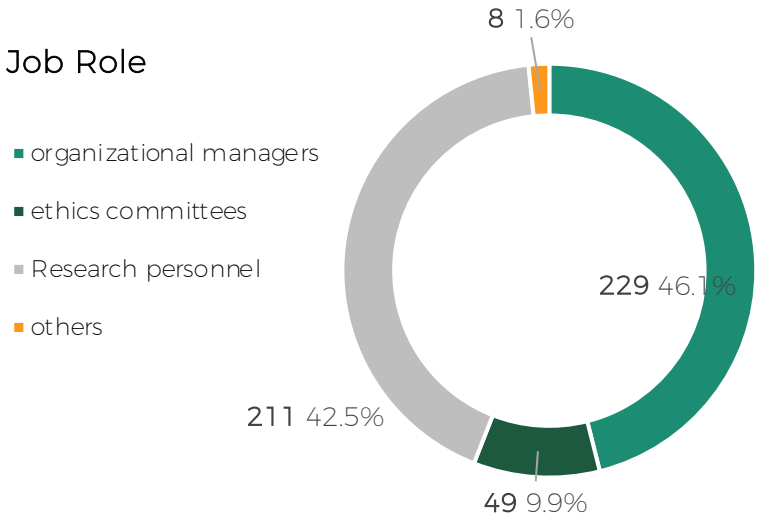
Percentage of institutions/hospitals by location

The vast majority of respondents are affiliated with tertiary hospitals, constituting the overwhelming majority at approximately 94.8%. A small percentage of participants are from secondary grade-A and tertiary grade-B hospitals, accounting for approximately 3.6% and 0.8%, respectively. Tertiary grade-C hospitals and other types of hospitals have relatively lower representation, at around 0.2% and 0.4% respectively.

The distribution of institutions/hospitals by location indicates that Liaoning has the highest proportion, approximately 9.3%, followed by Heilongjiang and Jilin at 7.8% each. The proportions vary in other regions, including Jiangsu, Jiangxi, Shanghai, Shaanxi, Hubei, and others.

The distribution of institutions/hospitals by location reveals that while digitalized/decentralized clinical trials are dispersed to some degree across various regions in China, certain areas exhibit a higher concentration of participants. Liaoning, Heilongjiang, and Jilin display the highest proportions, with other regions such as Jiangsu, Jiangxi, Shanghai, Shaanxi, and Hubei also demonstrating varying levels of participation. This suggests the importance of paying closer attention to these regions to ensure equitable access and participation in digitalized/decentralized clinical trials across China.

The distribution of research participants by job role reveals that organizational managers and research personnel constitute the largest proportions, accounting for approximately 46.1% and 42.4%, respectively. Members of ethics committees represent a relatively smaller proportion at about 9.9%. Participants in other roles account for 1.6%. This indicates that the field of digitalized/decentralized clinical trials has attracted widespread participation from organizational managers and research personnel.



In addition to the substantial participation from organizational managers and research personnel in digitalized/decentralized clinical trials, the involvement of members from ethics committees underscores a holistic engagement within the field. This diverse participation sheds light on the varied stakeholders involved and offers valuable insights for shaping future research and policy. The inclusivity of professionals from different roles emphasizes the multidimensional nature of DCT development. Moving forward, optimizing collaboration and innovation will require concerted efforts to integrate resources and expertise across diverse roles effectively.

02

Industry practice

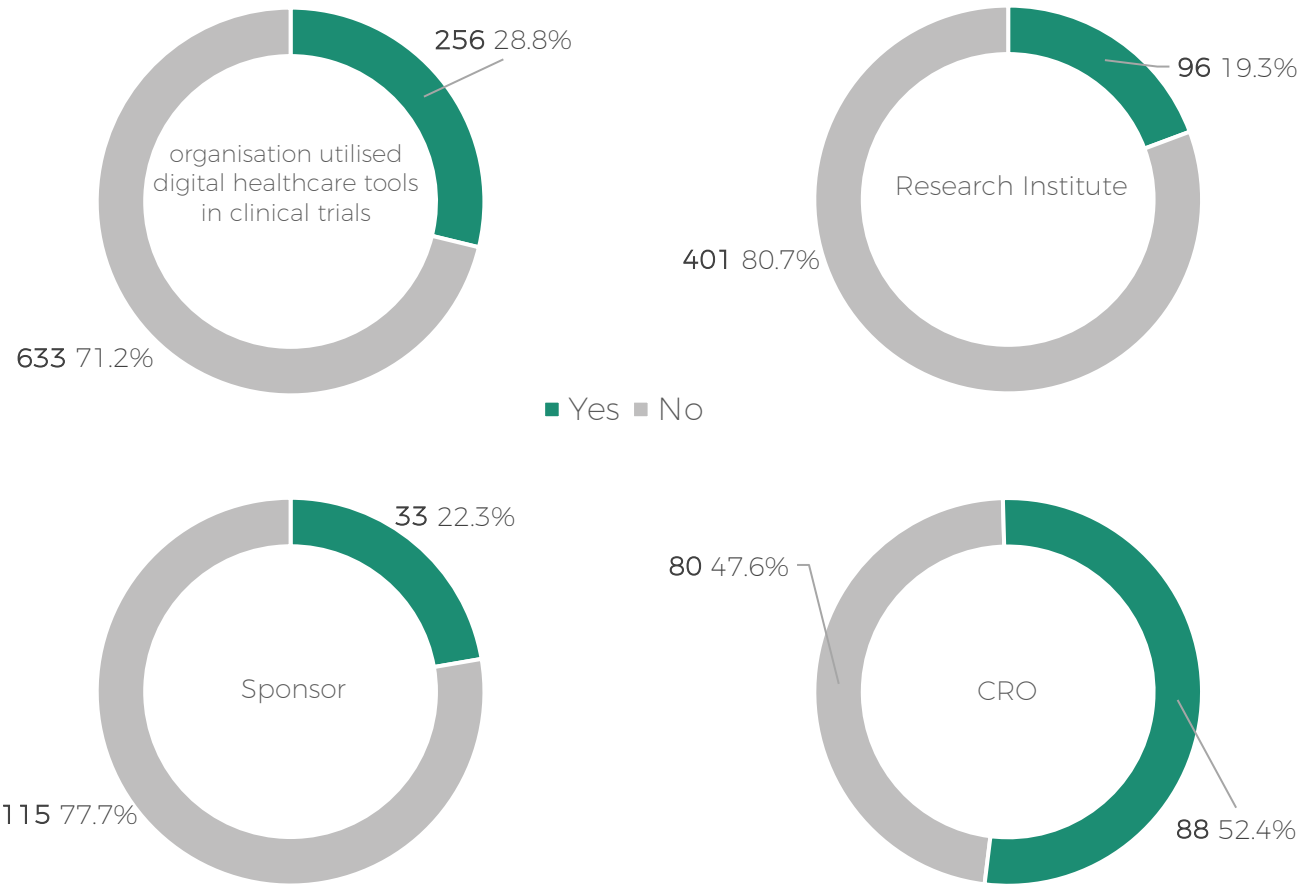
Industry practice

Question:

Has your organisation utilised any digital healthcare tools in clinical trials (from 2013-now)

The analysis indicates that only a minority of the surveyed organizations, comprising 28.8% of the total, have chosen to utilize DCT elements. This reflects that, since 2013, digital/decentralized clinical trials are still in the early stages of development in China, with potential for further growth. In comparison to research institutions and sponsors, Contract Research Organizations (CROs) are leading the way with a usage rate exceeding 52.4%.

The adoption of DCT elements by organizations indicates the necessity for further promotion and popularization in the field. Concurrently, the development of digital/decentralized clinical trials would benefit from the implementation of supportive policies and comprehensive training programs to enhance understanding and utilization of these innovative approaches.



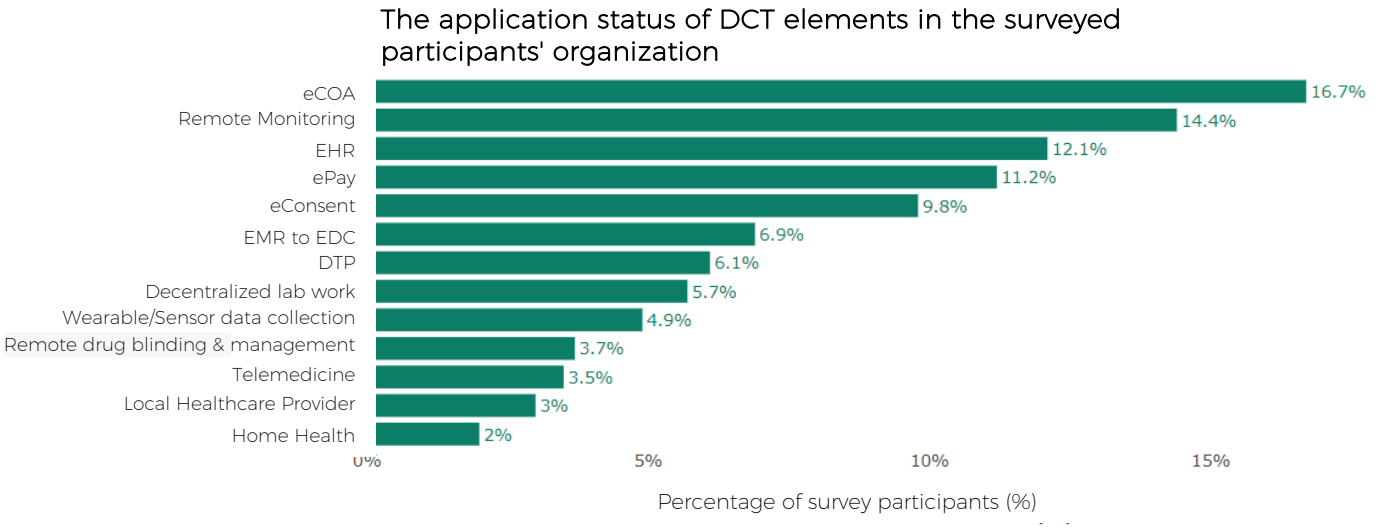
Question:

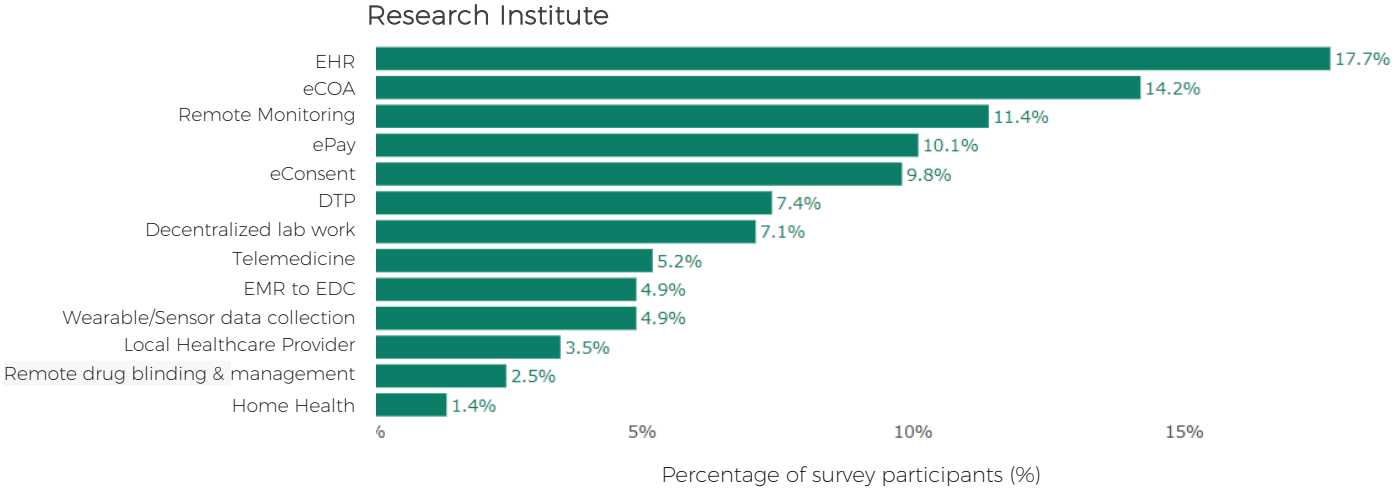
Please select the elements that the organization used in clinical trials related to DCT

The application of DCT elements shows that electronic Clinical Outcome Assessments (eCOA), remote monitoring, electronic medical records (EMR), EHR data integration, electronic payments (ePay), and electronic Informed Consent (eConsent) are among the forefront. They are currently used in participant trials with proportions ranging from one-third to half, occupying 16.7%, 14.4%, 12.1%, 11.2%, and 9.8%, respectively.

Elements with lower current usage rates include Remote drug blinding & management , Telemedicine, Local healthcare provider, and Home Health.

While these figures may not necessarily represent the entire clinical research and development market, it is still noteworthy that two-thirds of the participants in research institutions have already applied DCT technologies and models. This includes integration of electronic medical records (EMR) and electronic health record (EHR) data , eCOA, remote monitoring, ePay, and eConsent.



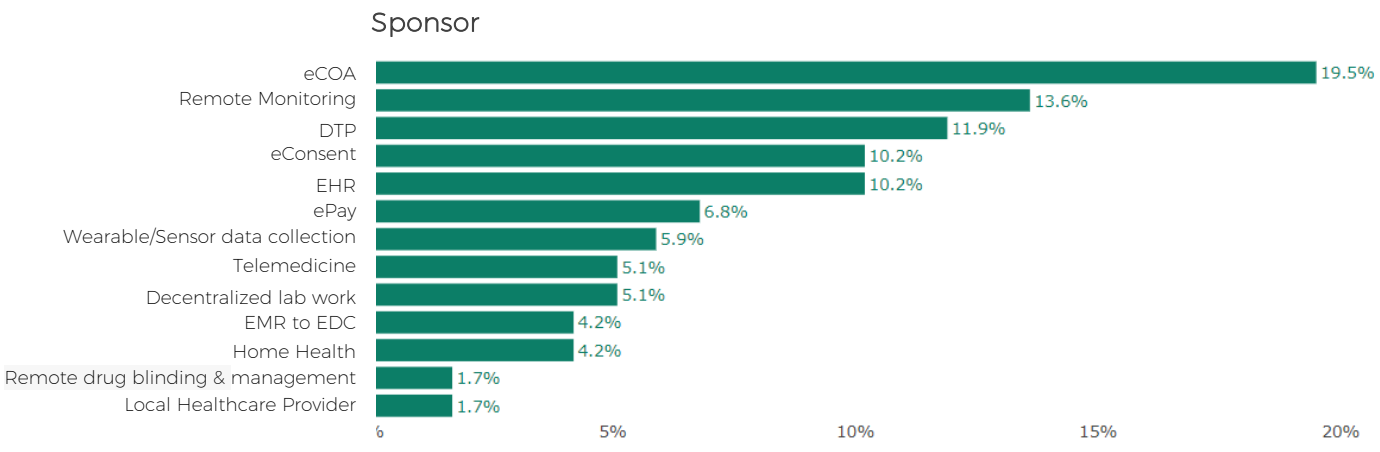


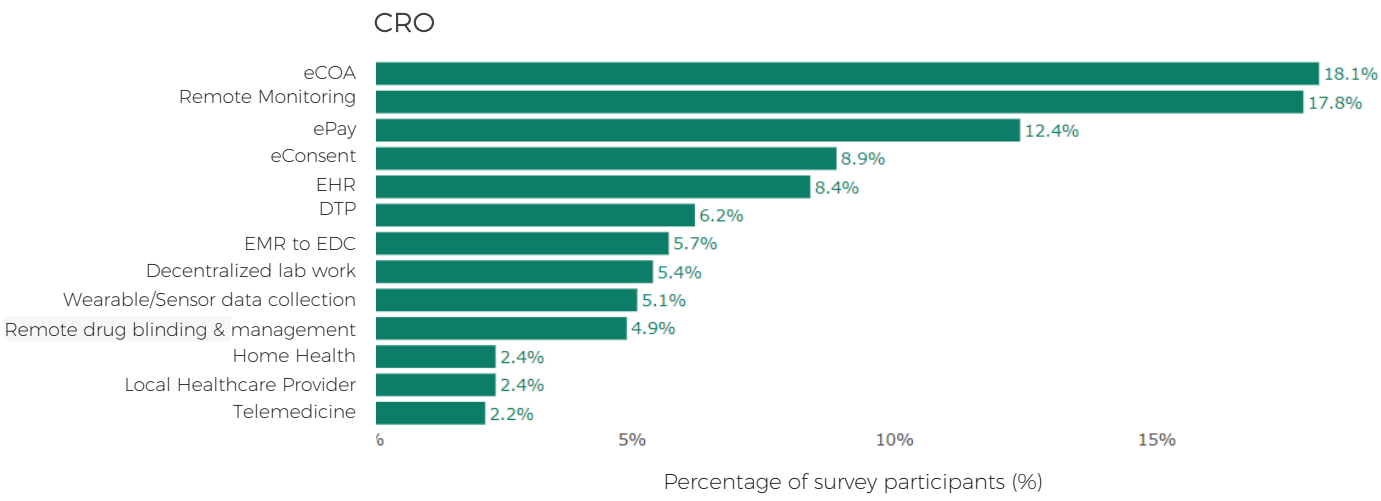
Question:

Please select the elements the organization used in clinical trials related to DCT

Among the elements widely used by sponsors' surveyed participants in DCT, eCOA stands out as the most prevalent at 19.5%, with remote monitoring following closely at 13.6%, and Direct-to-Patient (DTP) services at 11.9%. Additionally, eConsent (10.2%), integration of EMR and EHR data (10.2%), and ePay (6.8%) also demonstrate substantial application. In contrast, Remote drug blinding & management and the utilization of Local healthcare provider have relatively lower usage rates, each accounting for 1.7%.

The analysis suggests that among the surveyed participants from CROs, there is a significant level of familiarity and usage, exceeding fifty percent, for eCOA, remote monitoring, ePay, and eConsent in the implementation of DCT technologies and models.



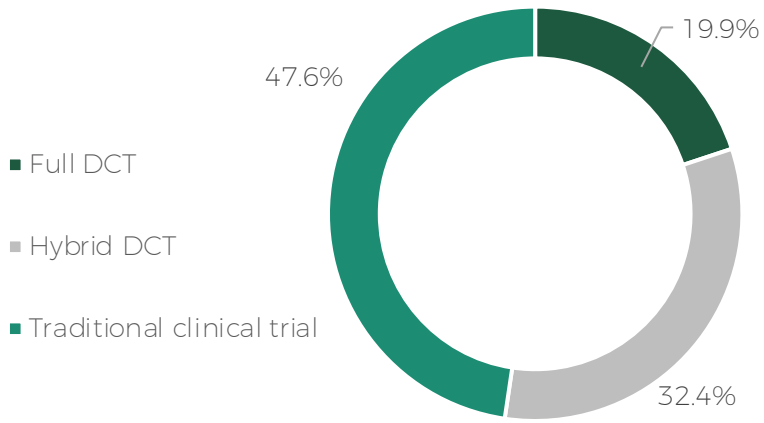


Question:

Please indicate the distribution of clinical trial models being used in your company's current ongoing trials, (The total will add up to 100%)

The choices made by the surveyed participants' organizations regarding clinical trial models show that traditional clinical trials still constitute the primary trial mode, accounting for 47.6% of the total. In comparison, fully decentralized clinical trials make up only 19.9%, while the usage proportion of hybrid models is relatively high, at approximately 32.4%.

The analysis highlights the continued dominance of traditional clinical trials, comprising 47.6% of the surveyed organizations' choices. However, there is a notable trend towards the adoption of digital/decentralized clinical trials, which collectively represent 52.3% of the selections. While fully decentralized trials currently constitute a smaller percentage, hybrid models are increasingly favored, comprising 32.4% of the total. This trend underscores the evolving landscape of clinical trial methodologies, with hybrid models offering a promising blend of traditional and digital approaches.

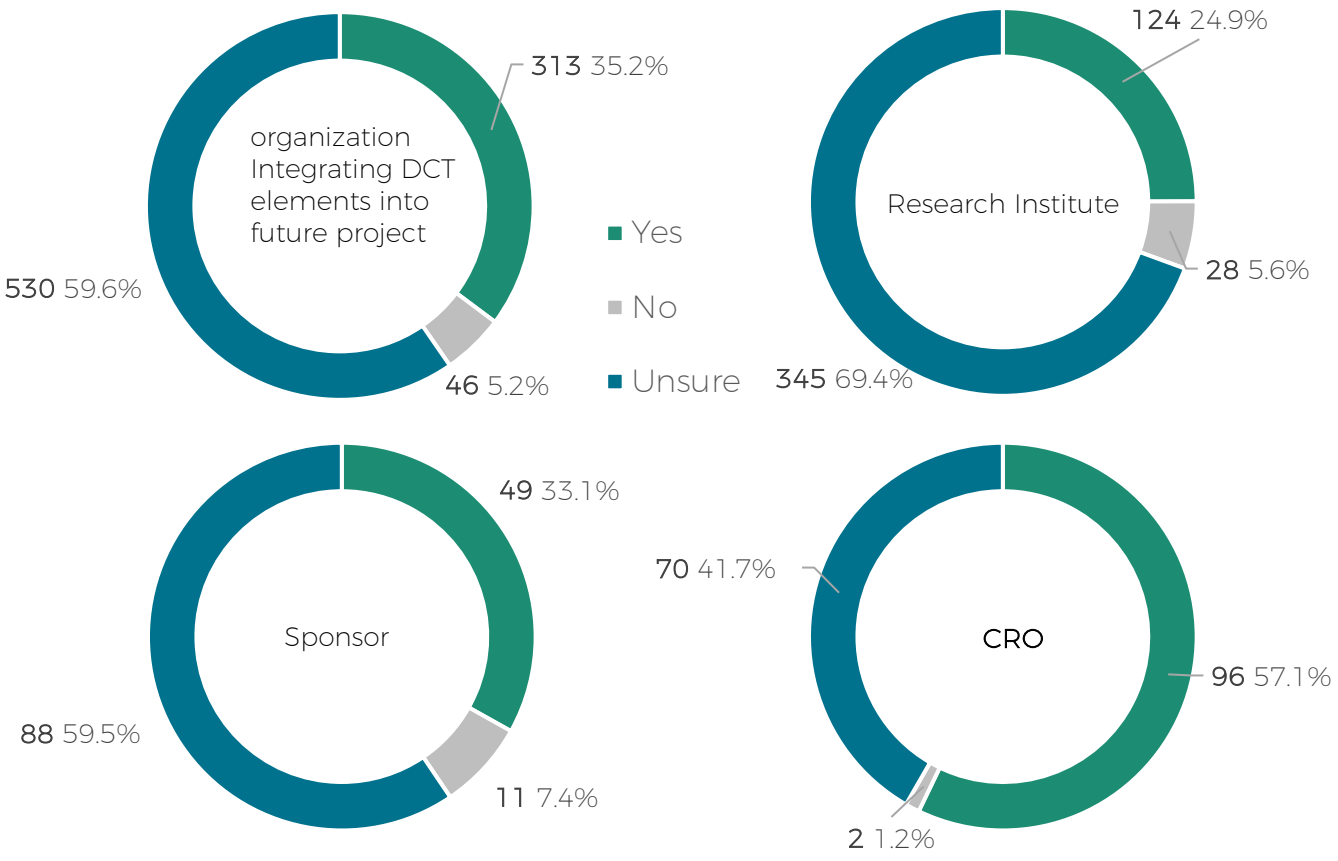


Question:

Will your organization be integrating DCT elements into your future project over the next 3 years (2024-2026)

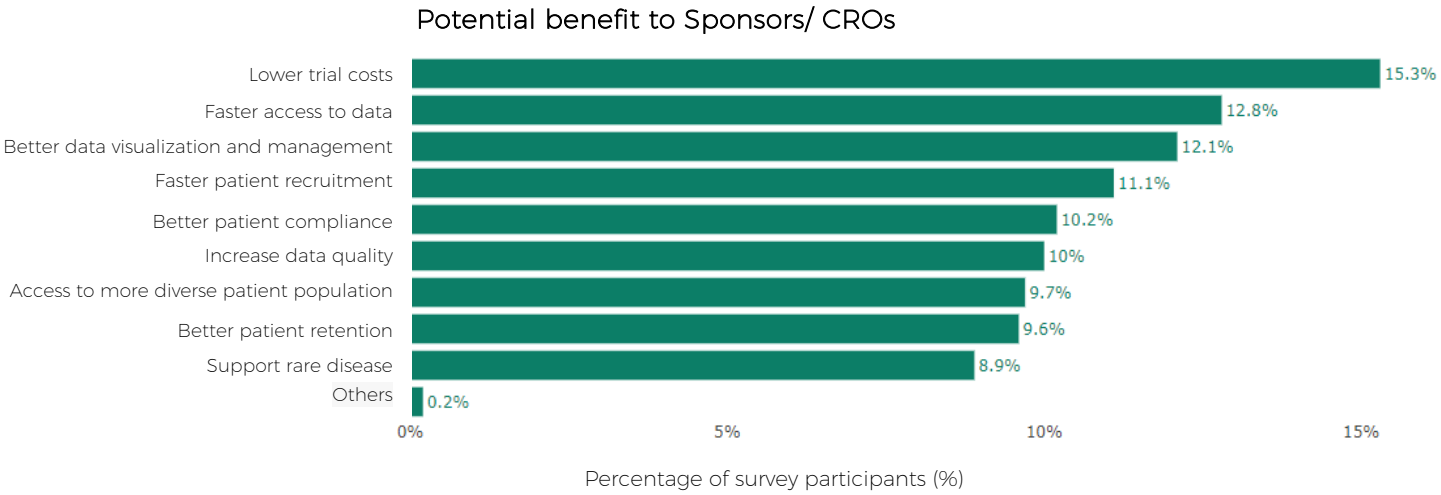
For the integration of DCT elements into future projects, the majority of surveyed participants express uncertainty about the development within the next three years (59.6%). About 35.2% believe it is possible to integrate DCT elements into future projects, with only 5.2% of participants expressing a negative view. This indicates a certain level of uncertainty in the DCT field that warrants further exploration. From the perspective of organizational types, 24.9% of participants from research institutions predict the integration of DCT elements into future projects, compared to 33.1% for sponsors and 57.1% for CROs.

The willingness to integrate DCT elements into future projects in the Chinese DCT field reflects a certain exploratory and positive attitude among stakeholders. However, uncertainties in this regard necessitate comprehensive efforts, including the provision of more information, education, and training. Addressing regulatory and compliance issues, emphasizing data security and privacy, and offering support to mitigate technological complexity and cost concerns are crucial steps. Furthermore, establishing industry standards and sharing best practices can help alleviate uncertainties and foster confidence in adopting DCT. Notably, CROs demonstrate a relatively higher willingness to embrace DCT elements in the future, potentially positioning them as leaders in driving the development of digital/decentralized clinical trials.

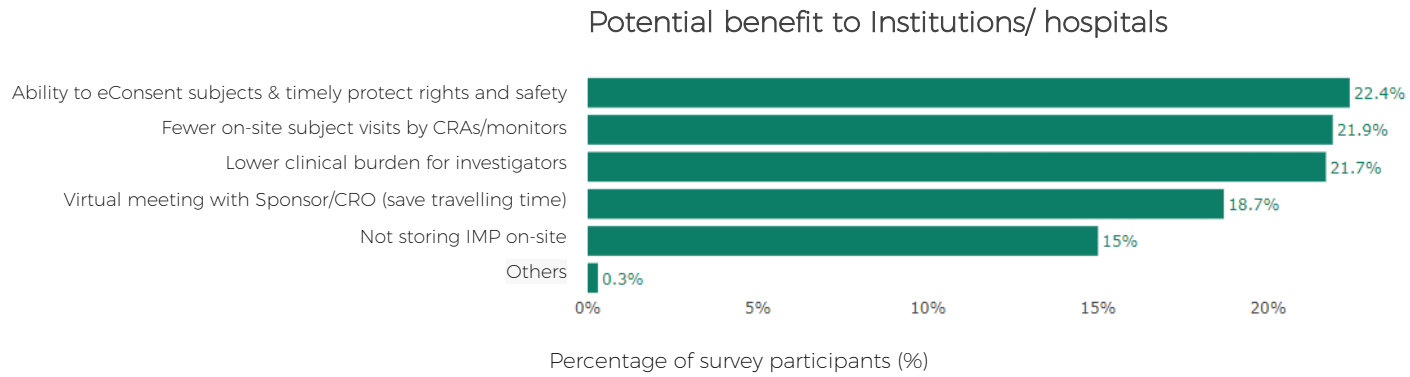


Question:

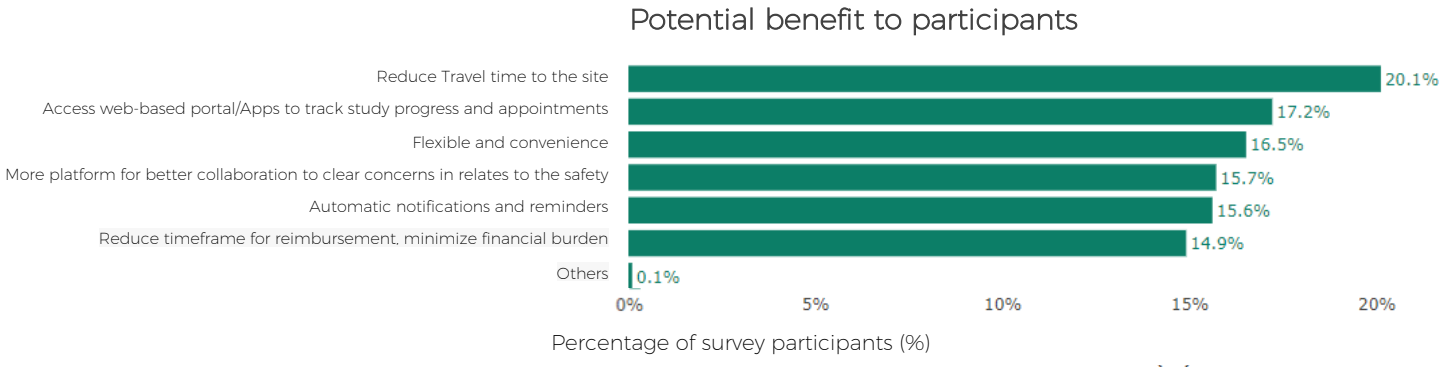
What are the potential benefits to Sponsors/CROs, Sites, and Patients in conducting a DCT (including Hybrid DCT) as opposed to a traditional clinical trial? Please rank the top 3 (1 = biggest benefit, 2 = second biggest benefit, 3 = third biggest benefit) potential benefits to:



Compared to traditional clinical trials, the industry's expectations for DCT, particularly from sponsors/CROs, are predominantly centered on the primary advantage of reducing trial costs. Other advantages, such as rapid data collection, improved data management, faster recruitment of participants, enhanced participant compliance, and improved data quality, show relatively minor differences.



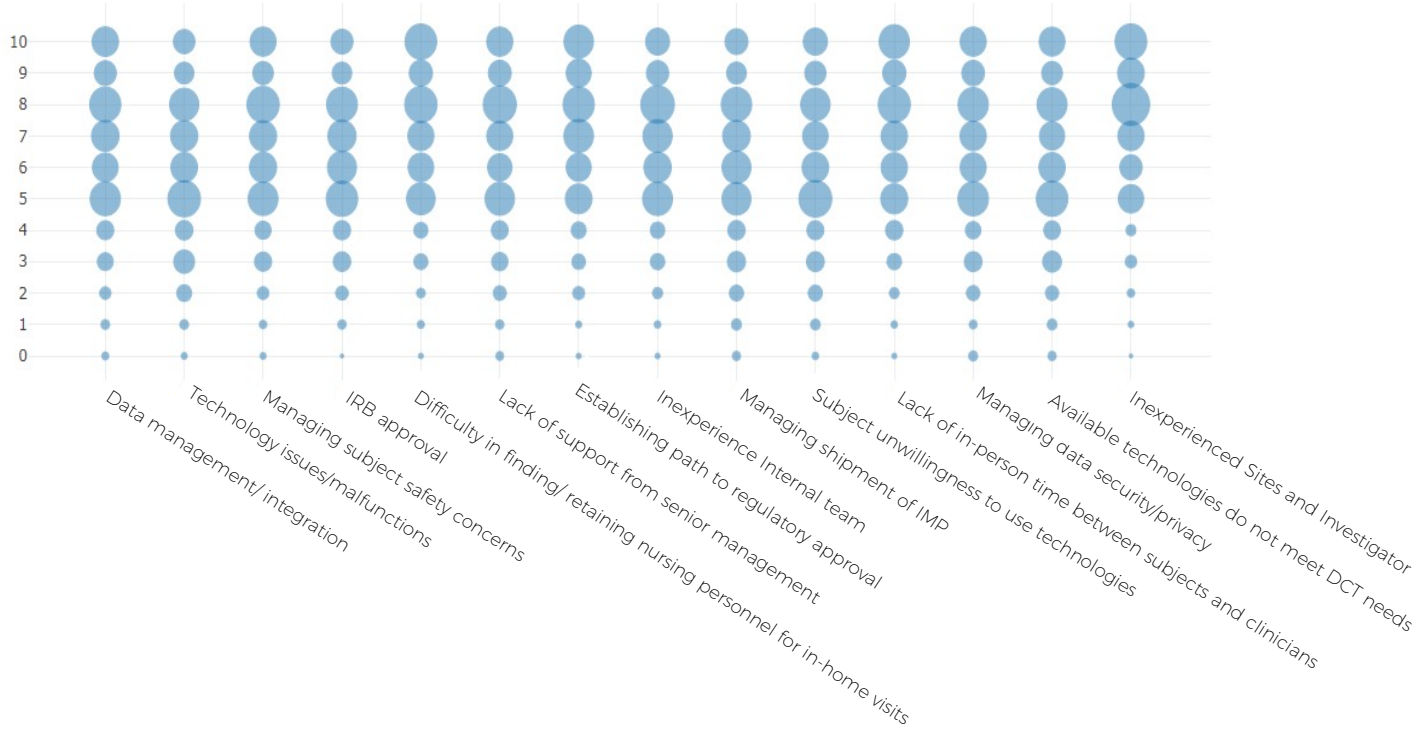
For institutions and hospitals, the leading advantages include the ability to promptly obtain eConsent from participants, thereby better protecting participant rights and safety, as well as alleviating the on-site monitoring burden for Clinical Research Associates (CRAs) and clinical researchers.



The most significant benefit for participants is the time saved on commuting, accounting for 20.1%. This is achieved through online platforms and applications, which enable participants to track study progress, make appointments, and engage in trials in a more flexible and convenient manner, thereby enhancing overall convenience and comfort.

Question:

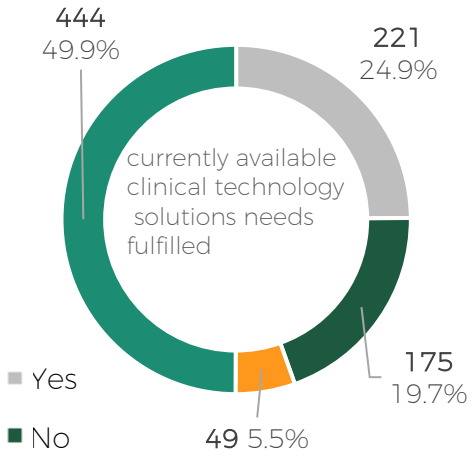
What are the potential challenges associated with running DCTs? Please rate each challenge on a scale of 0-10, where 0 represents 'not at all challenging' and 10 represents 'extremely challenging'.



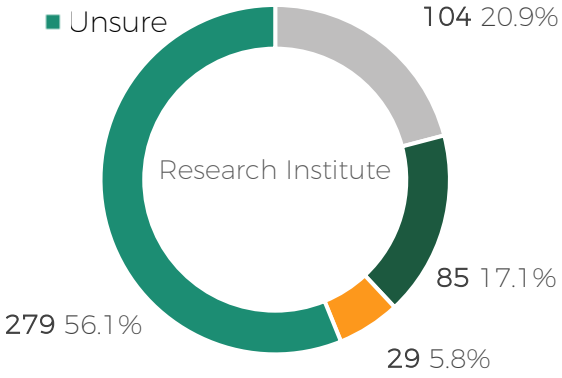
While participants in the survey were asked about potential challenges perceived in DCT, there is no clear consensus on a specific major challenge. Various opinions exist among the respondents, and no singular difficulty stands out prominently.

Question:

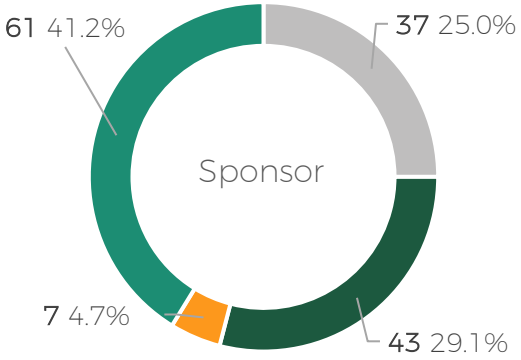
Do you believe that currently available clinical technology solutions adequately meet your needs to successfully execute a DCT?



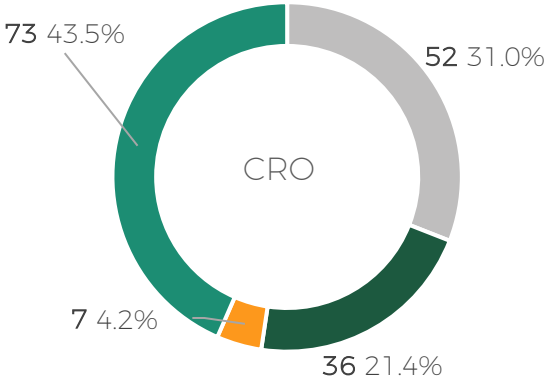
In terms of the perception of whether clinical technology solutions adequately meet needs, 24.9% of survey participants believe they meet the requirements, while 19.7% think they do not. Additionally, 49.9% of participants are uncertain about whether their needs are met, and 5.5% indicated that it is not applicable.



From the perspective of organizational types, 20.9% of participants in research institutions believe their needs are met, compared to 25% of sponsors and 31% of CRO participants. Conversely, 29.1% of sponsors believe their needs are not met, while 17.1% of participants in research institutions share the same sentiment. Moreover, there is a relatively high level of uncertainty across all organizational types.



Based on the provided data, a notable portion of participants exhibit uncertainty regarding whether current clinical technology solutions effectively fulfill their needs. This uncertainty could stem from inadequate communication among stakeholders and operational challenges in aligning with these solutions. Furthermore, organizations may lack confidence in their capacity to implement and manage these technologies effectively, including ensuring data security, obtaining technical support, managing costs, and optimizing resource allocation. Uncertainties also extend to factors such as ensuring compatibility with existing systems and devices and ensuring patient willingness to engage with these technologies. Addressing these uncertainties will be essential for fostering confidence and maximizing the potential benefits of clinical technology solutions in healthcare settings.

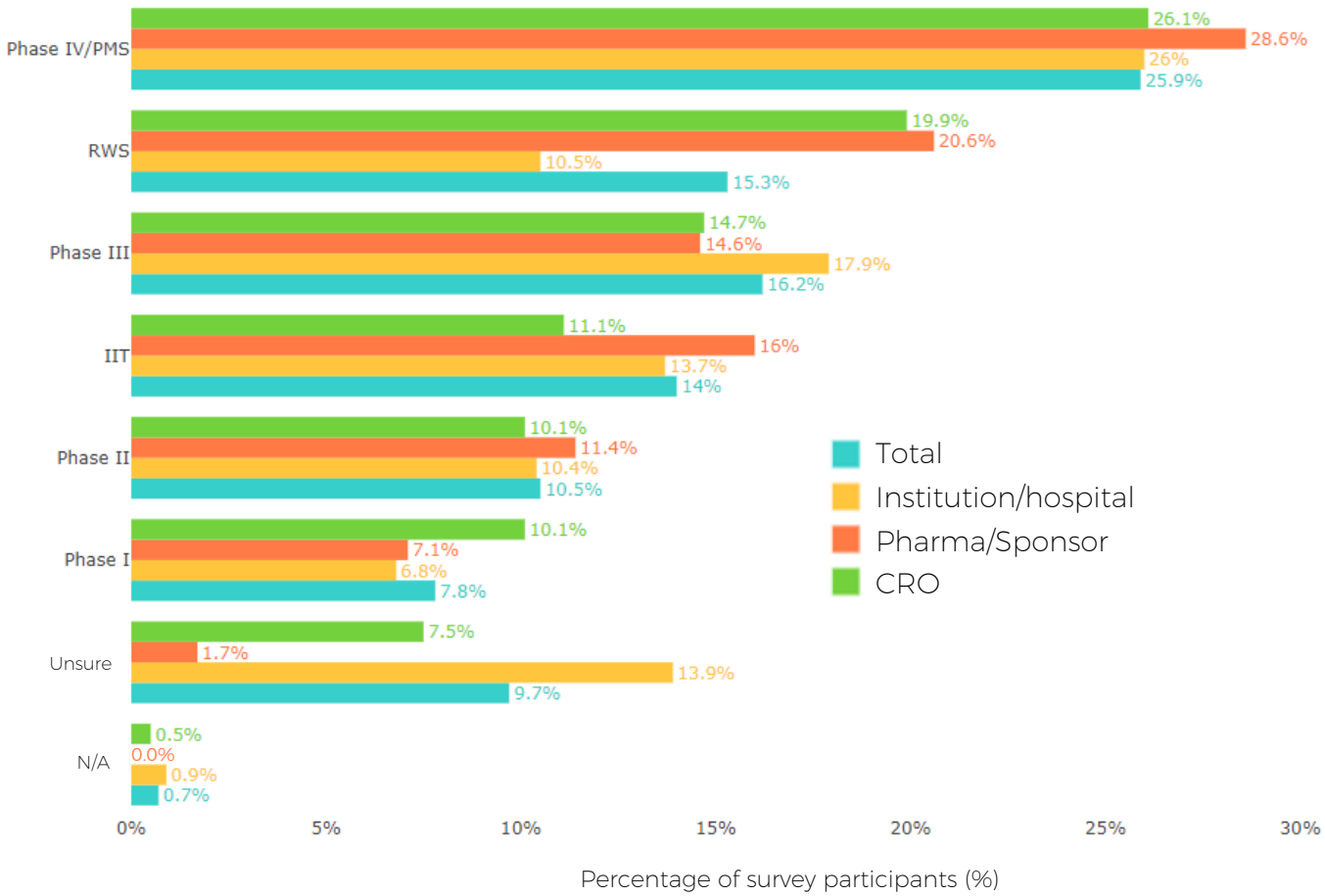


Question:
In which phases of clinical trials were DCT trials mainly conducted?

According to the survey results, there is a certain degree of divergence in opinions regarding the suitability of adopting DCT for different types of trials. For Phase IV/PMS trials, 25.9% of participants believe DCT is suitable, while for RWS (Real-World Evidence Studies) trials, the belief in DCT suitability is at 15.3%. Regarding Phase III trials, a significant proportion of participants (16.2%) consider DCT to be suitable.

In contrast, the belief in DCT suitability is relatively lower for Investigator-Initiated Trials (IIT), Phase II, and Phase I trials, at 14%, 10.5%, and 7.8%, respectively. Additionally, 9.7% of participants express uncertainty about the suitability of DCT, and 0.7% indicate that it is not applicable to their trial types.

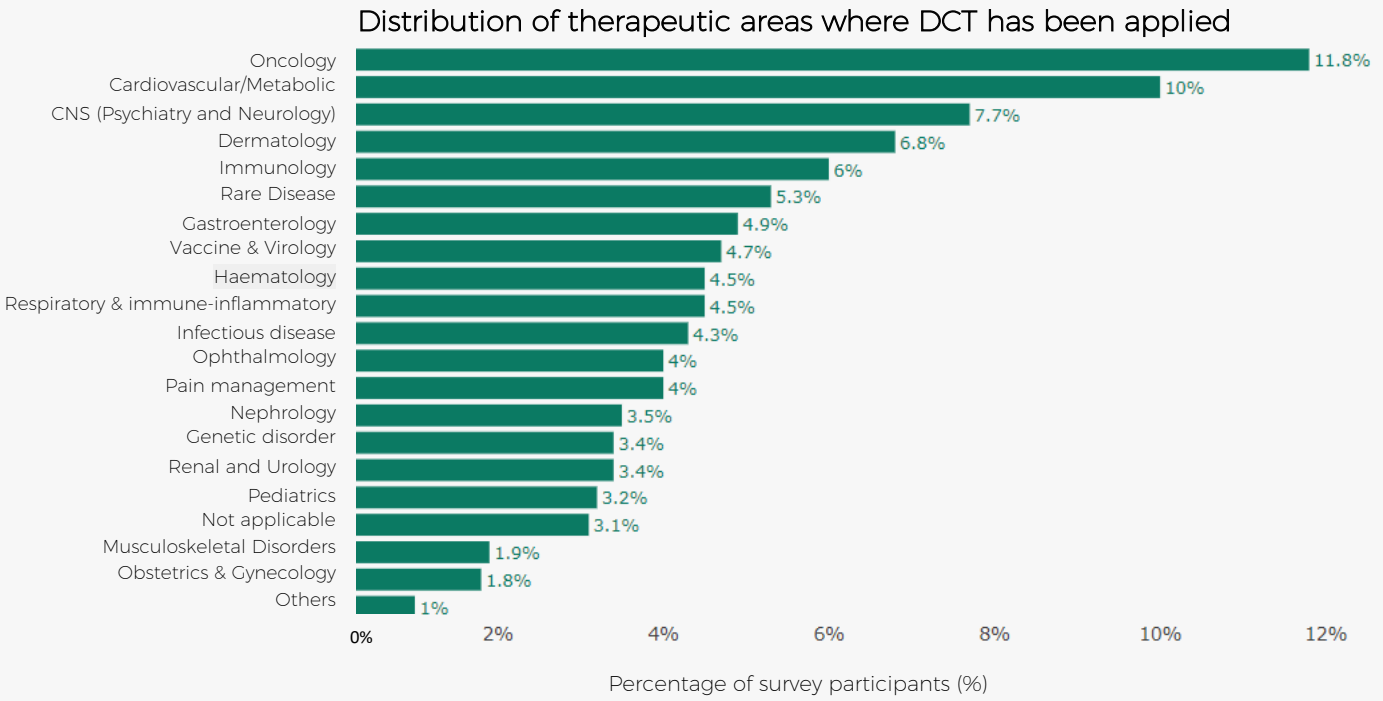
Based on this data, significant differences in the perceived suitability of DCT across different trial types are evident. Phase IV/PMS and RWS trial types have a relatively higher number of participants who believe DCT is suitable, while Phase I trials show comparatively lower acceptance. Additionally, the proportion of uncertainty is relatively high, reflecting the complexity and variability in the application of DCT across different trial types.

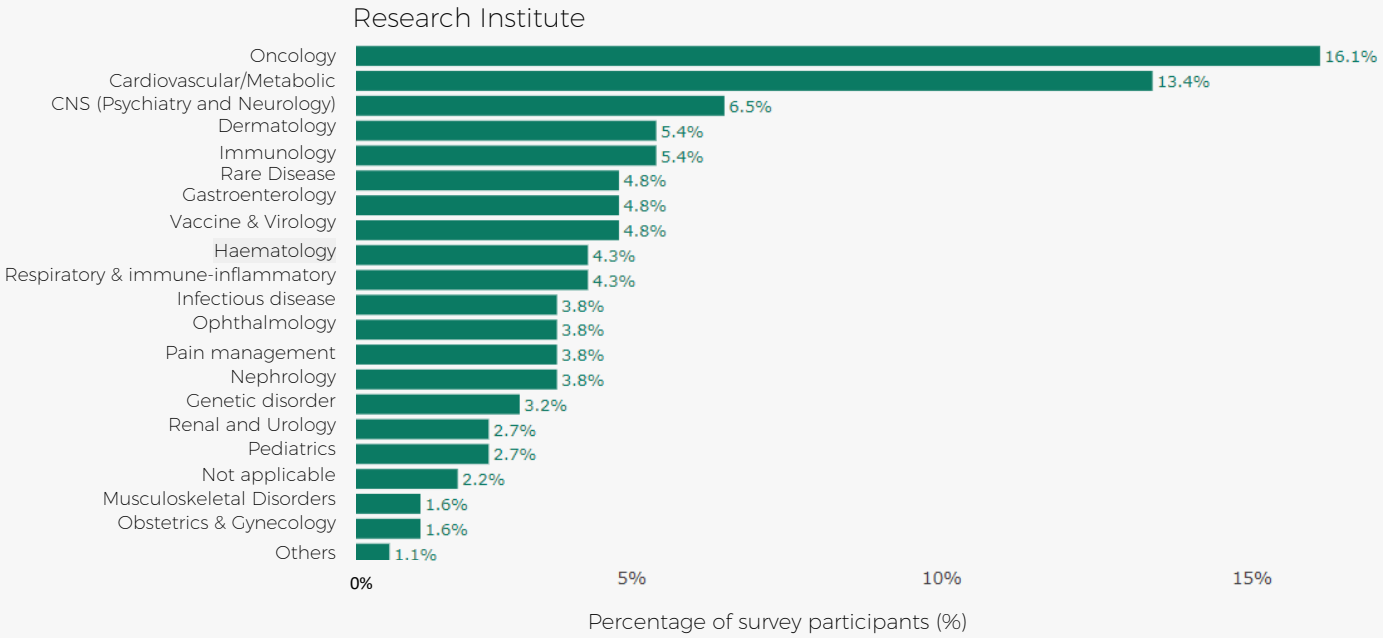


Question:
Which therapy areas adopted DCT the most?

According to the research results, noticeable differences in the distribution of DCT application across various therapeutic areas are evident. Oncology emerges as the most widely applied field for DCT, accounting for 11.8%. Following closely are Cardiovascular/Metabolism (10%) and Central Nervous System (Psychiatry and Neurology) areas (7.7%).

In certain fields, such as Obstetrics/Gynecology (1.8%) and Musculoskeletal Disorders (1.9%), the application of DCT is relatively low. In contrast, in other areas such as Dermatology, Hematology, Immunology, and Infectious Diseases, the distribution of DCT application is relatively even, ranging from 4% to 6%.

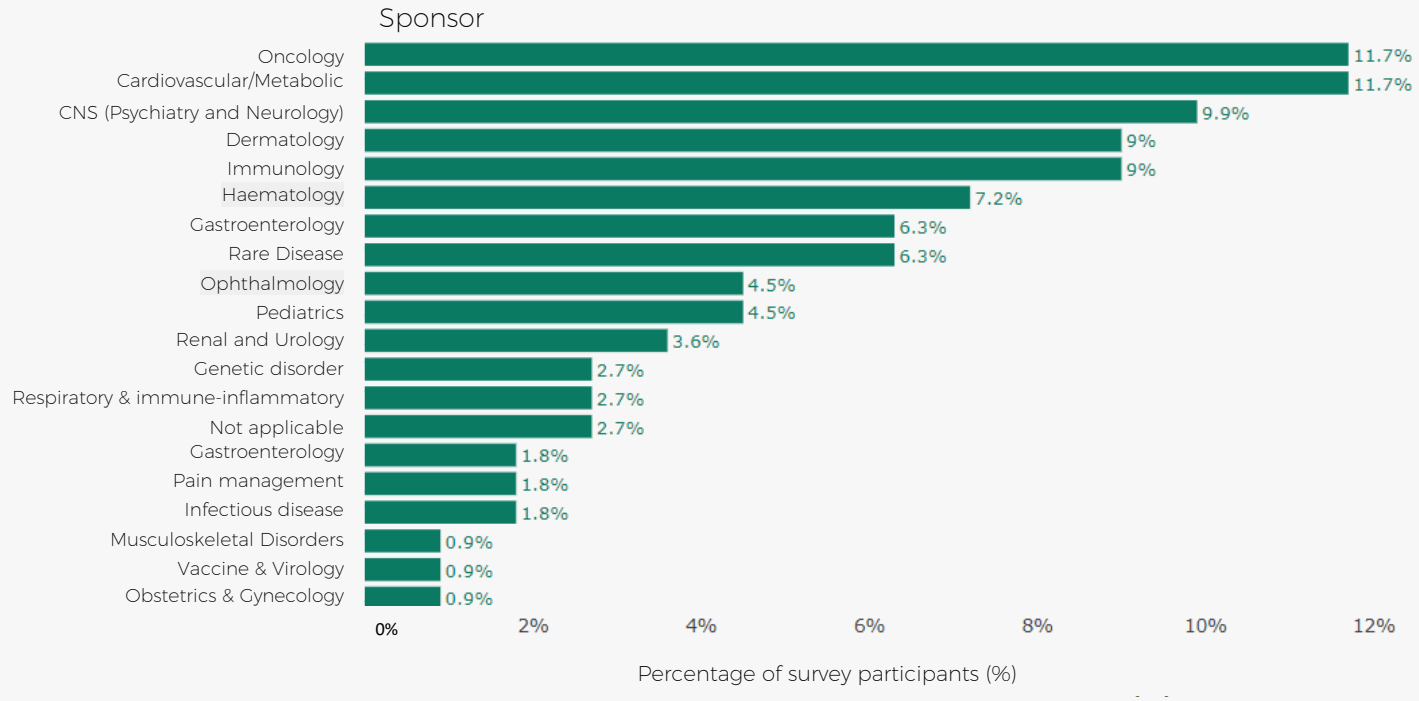


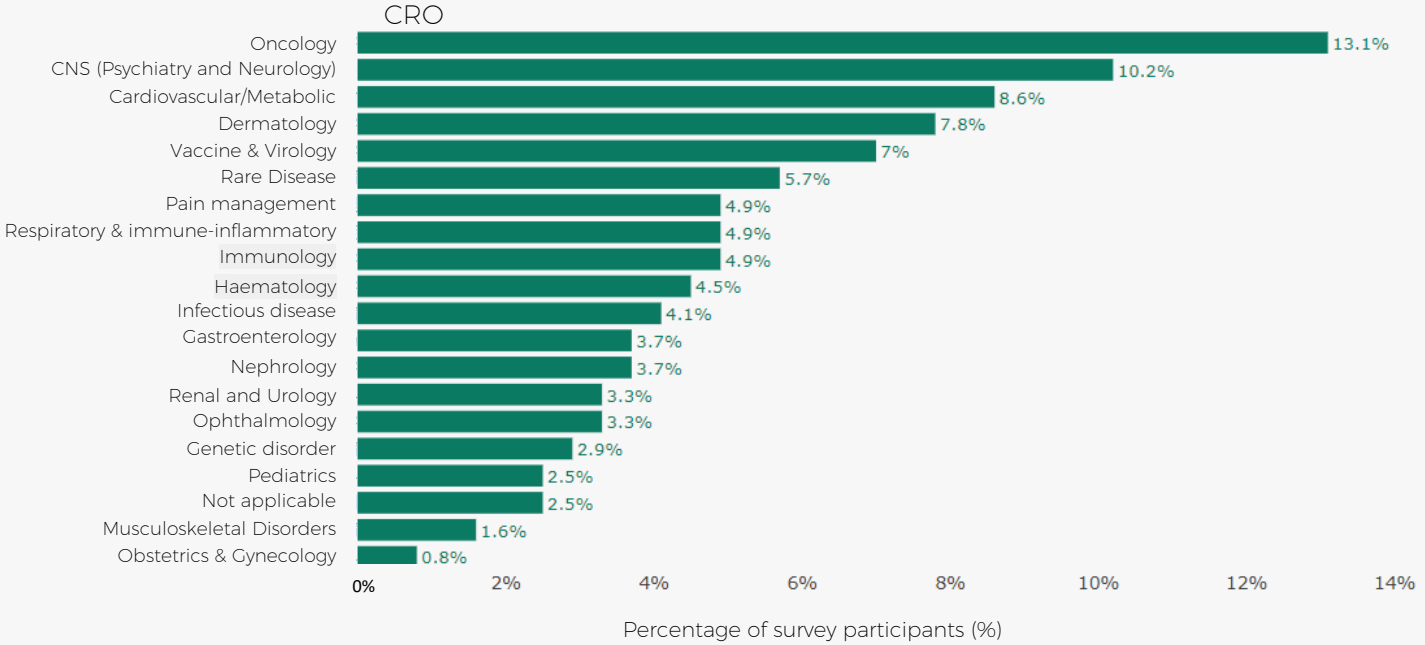


Question:
Which therapy areas adopted DCT the most?

In the survey, research institutions, sponsors, and CRO participants all agree that the use of DCT elements is most prevalent in the therapeutic areas of Oncology, Cardiovascular/Metabolism, and Central Nervous System (Psychiatry and Neurology).

In conclusion, the data reveal a diverse distribution of DCT applications across various therapeutic areas, with each field influenced by its specific needs and characteristics. Oncology, Cardiovascular/Metabolism, and Central Nervous System areas emerge as leaders in the adoption of DCT, reflecting the tailored nature of DCT implementation to meet the demands of these specialties. Meanwhile, other therapeutic areas are progressively embracing DCT as a method for conducting clinical trials, signaling a broader shift towards the integration of digital technologies in healthcare research.

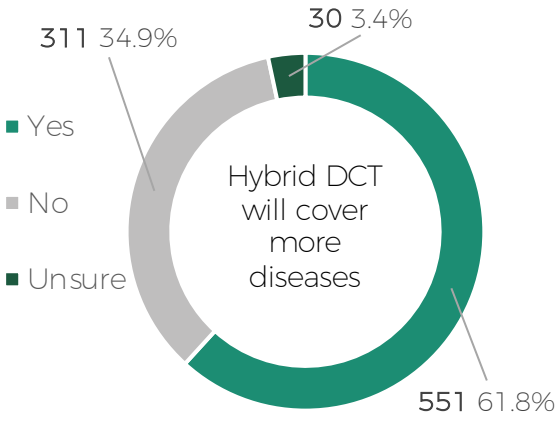


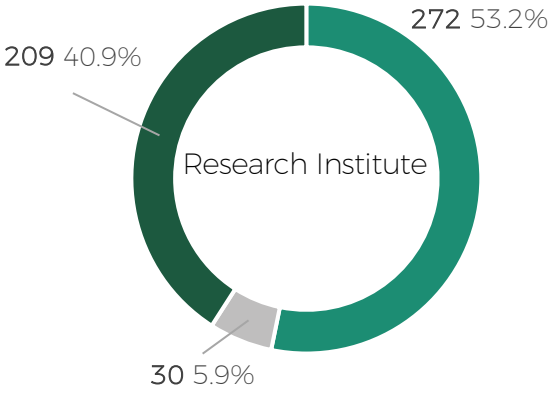


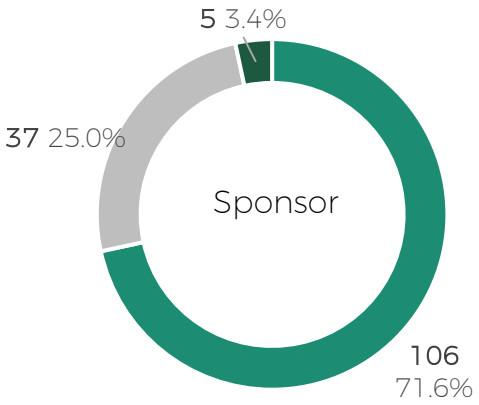
Question:
Do you think Hybrid DCT will cover more diseases?

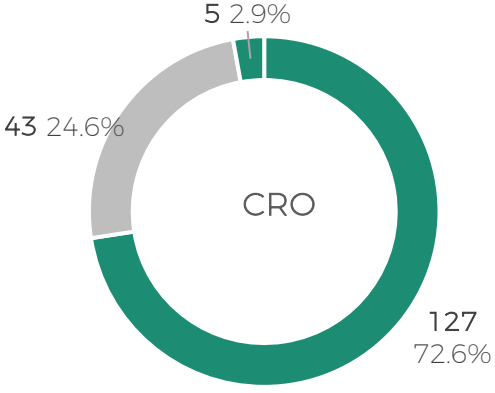
According to the research results, hybrid decentralized clinical trials (DCT) have gained high recognition for expanding disease coverage. Overall, 62% of the participants believe that hybrid DCT will cover more diseases, indicating a general optimism about its potential to broaden its application scope. When examining different types of organizations, high levels of acceptance are observed across research institutions, sponsors, and Contract Research Organizations (CROs), with CROs exhibiting the highest acceptance rate at 72.6%. This may reflect the positive role that CROs play in promoting the application of hybrid DCT.

Hybrid decentralized clinical trials (DCT) are considered to have the potential to cover more diseases, and this perception has received widespread recognition from participants. Not only is there a high overall acceptance, but also various types of organizations (including research institutions, sponsors, and Contract Research Organizations or CROs) exhibit high levels of acceptance. This suggests that the practical benefits of hybrid DCT in different disease and treatment areas could be further extended. Continued research and evaluation are necessary to ensure its effectiveness and safety.









03

Technical issues

Technical issues

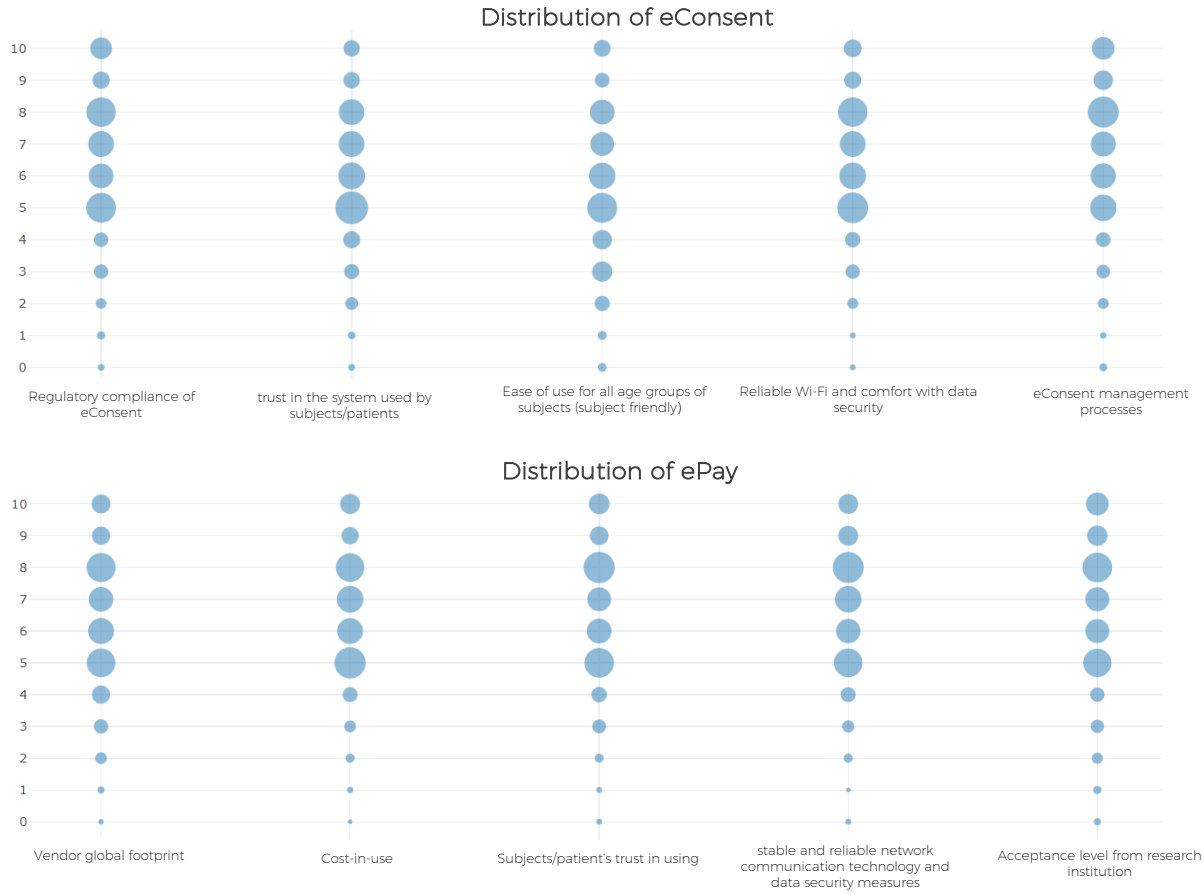
Question:

What are the unmet needs for the usage of technology solutions mentioned below in DCTs: Please rate on a scale of 0-10, where 0= "not needing improvement at all" and 10= "extremely needing improvement"

According to the survey results, participants in the research believe that there is room for improvement in various aspects of eConsent and ePay technology solutions. The average ratings for eConsent are all close to 5, indicating a general consensus that improvement is needed. Specifically, areas identified for improvement include eConsent management processes (4.81), ease of use for subjects/patients of all age groups (4.79), stable and reliable network communication technology and data security measures (4.75), trust in the system used by subjects/patients of all age groups (4.79), and a platform with functionality supporting signatures compliant with FDA 21 CFR Part 11 regulations (4.83).

Similarly, the average ratings for ePay are also close to 5, suggesting a widespread recognition of the need for improvement. Areas identified for improvement in ePay include acceptance by research institutions (5.23), trust in the system used by subjects/patients (5.13), stable and reliable devices, and data security measures (5.14), global coverage capabilities of the vendor (5.15), and usage costs (5.21)."

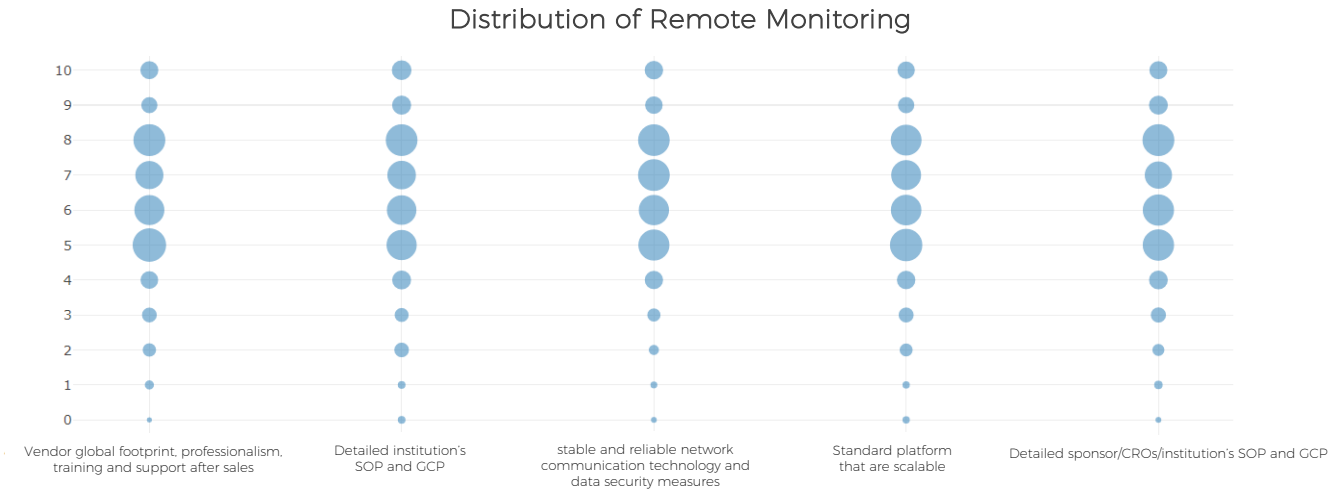
The survey results highlight clear areas for improvement in both eConsent and ePay technologies within DCTs. For eConsent, enhancing technological features, bolstering network security, and ensuring compliance with FDA regulations are imperative for improving its quality and feasibility. Conversely, ePay requires enhancements to boost acceptance, trustworthiness, security, global coverage, and cost-effectiveness. Addressing these unmet needs will be crucial for advancing the utilization of eConsent and ePay technologies in DCTs.

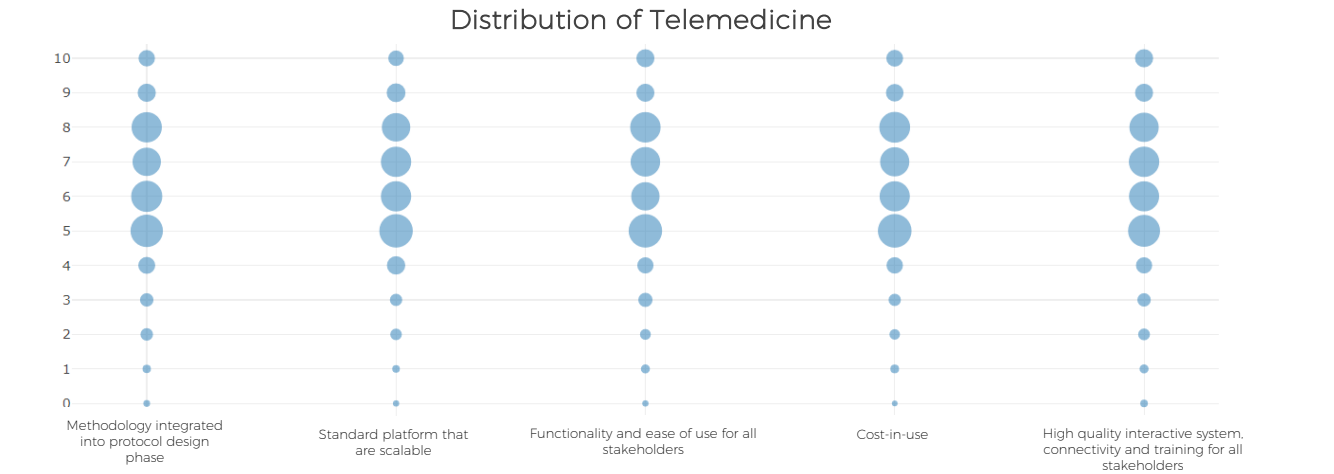


According to the survey results, participants in the research believe there is room for improvement in various aspects of remote monitoring technology and remote medical technology solutions. Regulatory agency requirements for remote monitoring (average rating of 5.38), the construction and improvement of Sponsor/CRO SOP systems (5.38), the availability of scalable standard platforms (5.30), reliable Wi-Fi and data security (5.35), and the global footprint of vendors, their professionalism, training, and post-sales support (5.25), among others, all have average scores close to 5. This indicates a general consensus that improvements are needed in these areas.

In the distribution of telemedicine, the average ratings for interface functionality and usability for all stakeholders (5.36), usage costs (5.31), the availability of scalable standard platforms (5.37), incorporating methods into the trial design phase (5.35), and providing high-quality interactive systems, connectivity, and training for all stakeholders (5.34) are all close to 5. This indicates a general consensus that improvements are needed in these areas.

The survey highlights the need for enhancements in remote monitoring and telemedicine technologies to bolster regulatory compliance, technical feasibility, data security, and global coverage, while also ensuring professional support from vendors. Strengthening these aspects is essential for improving the quality and feasibility of remote monitoring in DCT. Similarly, improvements in telemedicine are imperative to enhance interface functionality and usability, reduce usage costs, promote standard platforms, integrate methods into trial designs, provide higher-quality interactive systems, strengthen connectivity, and offer comprehensive training. These enhancements aim to enhance the effectiveness and feasibility of remote healthcare in DCT.





According to the survey results, participants in the research have identified significant unmet needs in the use of eCOA and wearable device/sensor solutions in DCT. There is a consensus that there is room for improvement in various aspects.
The average ratings for clarity of data collection understanding between subjects and clinical staff (5.50), validation of survey questionnaire setup (5.39), ease of use for subjects/patients of all age groups (5.45), compliance with completeness of filling (5.50), and readiness of platforms/software (5.56) in the distribution of eClinical outcome assessment results are all close to 5. This indicates a widespread belief that improvements are needed in these areas.

In the average ratings for wearable device/sensor solutions, aspects such as the ease of use of the interface without adding too much burden to patients (5.35), having a technical support team in case of device malfunctions (5.22), accuracy and reliability (subject education and precise data collection) (5.33), reliable network and data security (5.26), and possessing qualifications/certifications (such as medical device registration) (5.50) are all close to 5. This suggests a general consensus that improvements are needed in these areas.

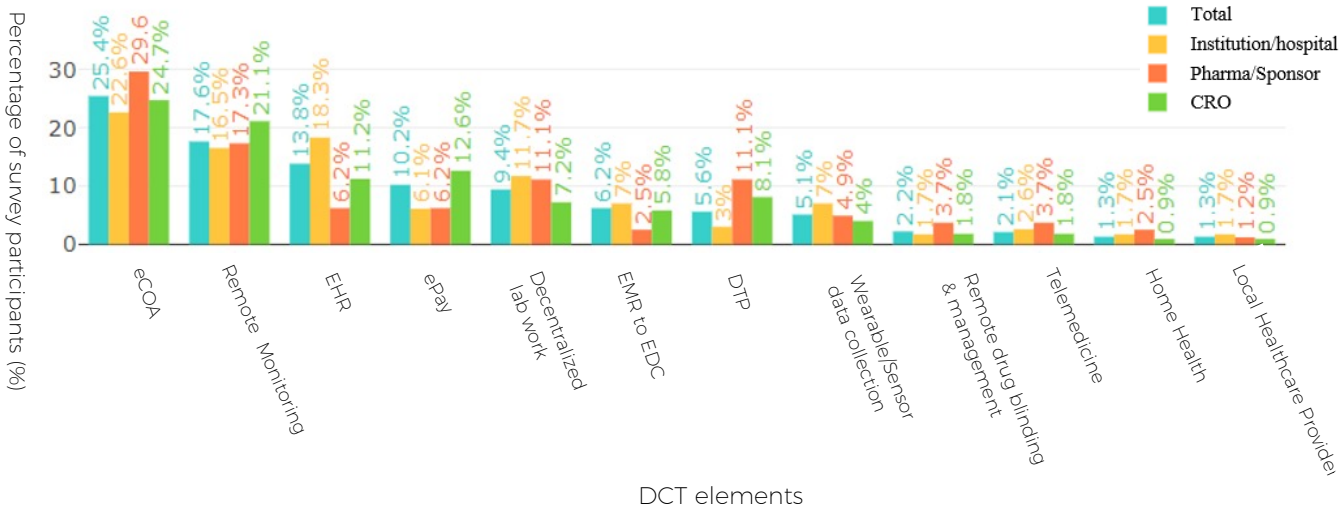
To address the identified unmet needs in utilizing electronic clinical outcome assessment (eCOA) solutions in Decentralized Clinical Trials (DCT), improvements should focus on enhancing data collection clarity, validation accuracy, user-friendliness, compliance, and platform/software readiness. These enhancements are crucial for improving the overall quality and feasibility of eCOA utilization in DCT.
Similarly, for wearable device/sensor solutions in DCT, improvements are needed in interface user-friendliness, technical support provision, data accuracy and reliability, network security, and obtaining relevant qualifications/certifications. Implementing these improvements holistically aims to effectively meet the demands of DCT requirements.

Question:

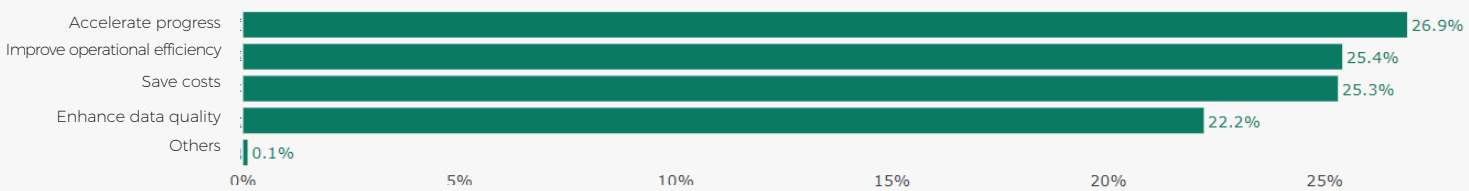
Which of the DCT elements that your organization adopted most over the last 12 months: choose ONLY 3 elements.

The participants in the survey were asked about the three elements they found most satisfying among those adopted in the past 12 months for Decentralized Clinical Trials (DCT). The top three elements were eCOA (electronic Clinical Outcome Assessment), remote monitoring with electronic medical records, and integration of electronic health record datasets. Satisfaction was attributed to the ability to accelerate progress (26.9%), improve operational efficiency (25.4%), save costs (25.3%), and enhance data quality (22.2%).

Satisfaction of survey participants with their organization's adoption of DCT



Reason behind high adoption rate



Percentage of survey participants (%)

Question:

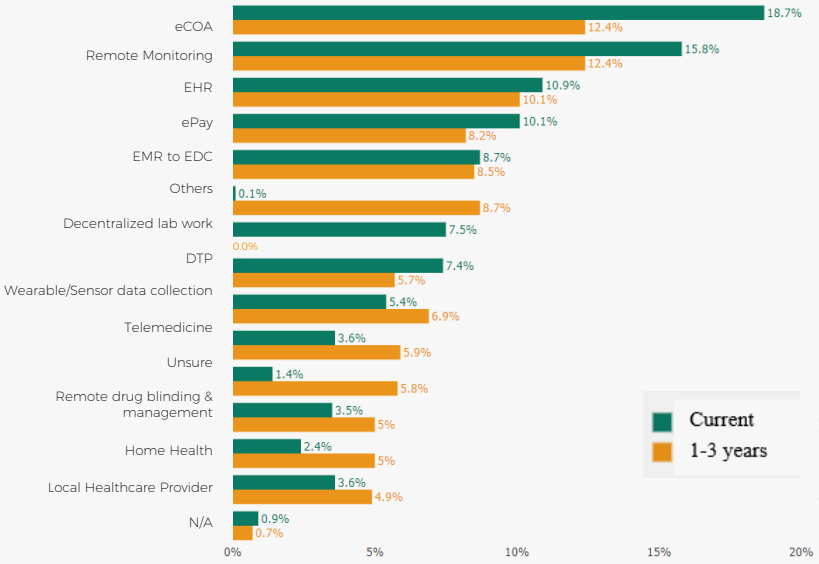
What DCT-related systems and models has your organization already developed or implemented, and what are the future plans for the next 1-3 years?

The research results indicate that eCOA (18.7%) has the highest success rate and the highest proportion of development or implementation among the organizations surveyed. Following eCOA, remote monitoring systems (15.8%) and the integration of EHR (10.9%) rank second and third, respectively.

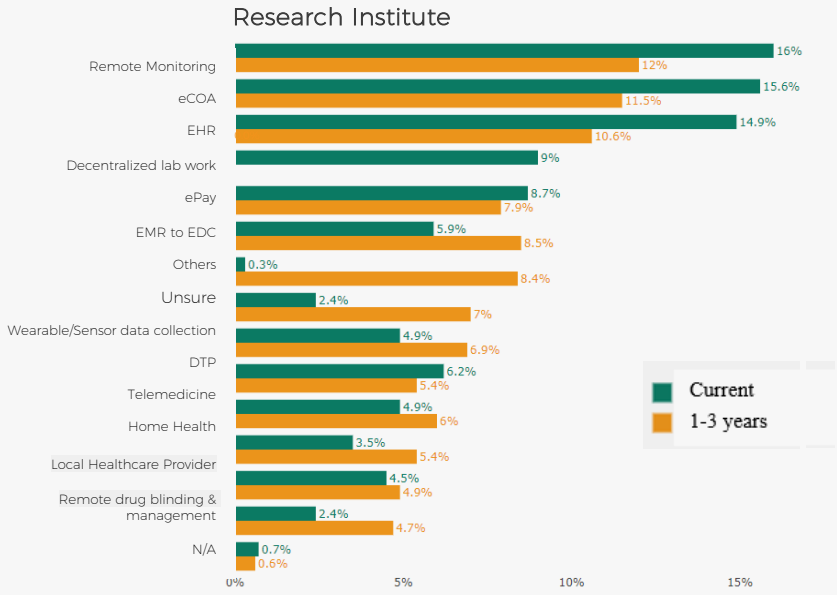
Looking ahead to the next 1-3 years, the industry's focus on DCT elements remains consistent. The top three priorities are eCOA (12.4%), remote monitoring (12.4%), and the integration of EHR (10.1%).

Furthermore, research organizations plan to allocate more funds to these three elements in both their current status and the next 1-3 years.

The current status of developed or implemented DCT elements, and future plan in 1-3 years



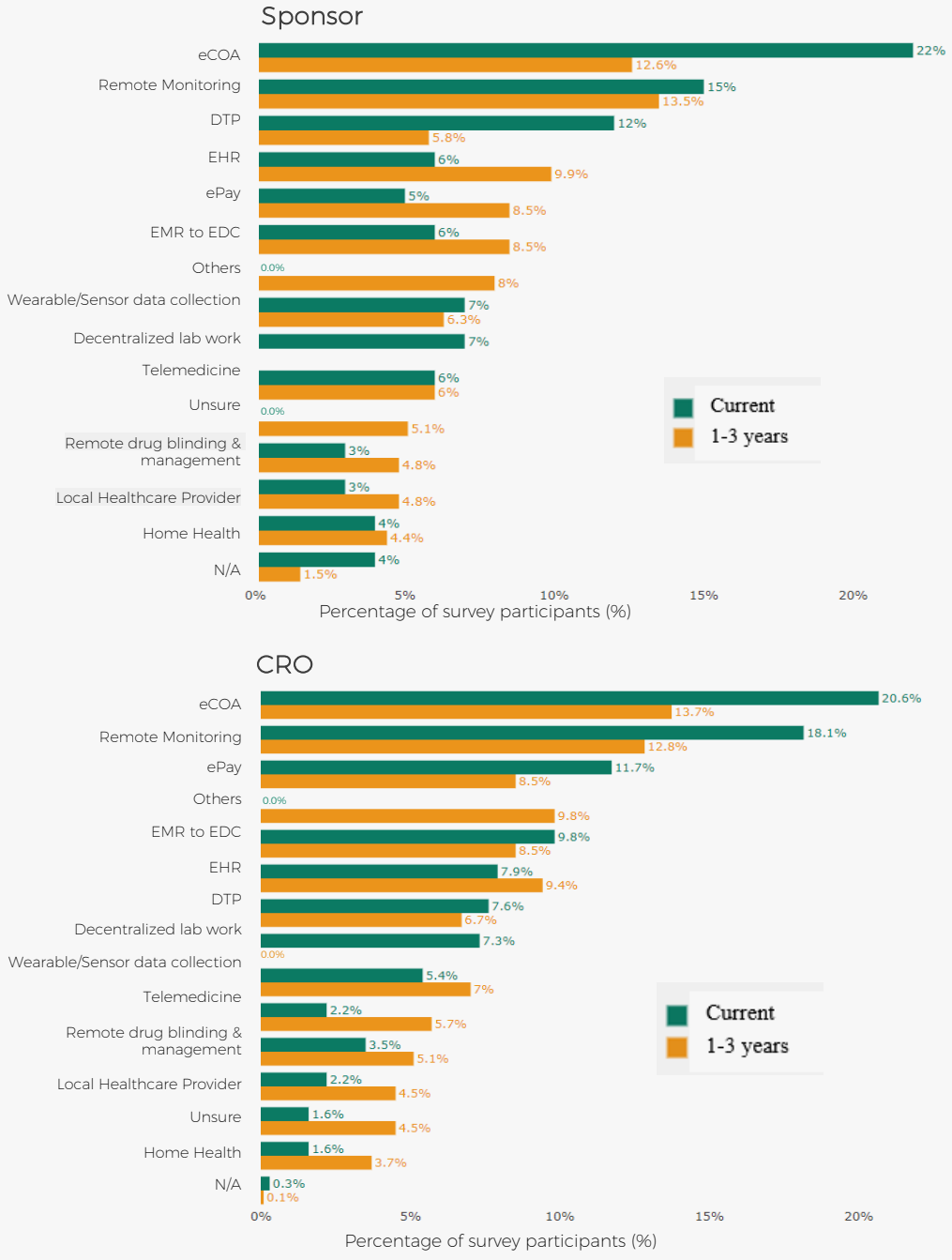
Research Institute



Based on the research findings, the top three DCT elements currently utilized by sponsors collectively account for nearly 50% of the total. These include eCOA (22%), remote monitoring systems and management processes (15%), and DTP delivery (12%).

In the next 1-3 years, sponsors intend to increase investment in several areas, with a focus on remote monitoring systems and management processes (13.5%), eCOA (12.6%), integration of EMR and EHR (9.9%), and the integration of ePay and Electronic Data Capture (EDC) for electronic medical and electronic data collection (8.5%).

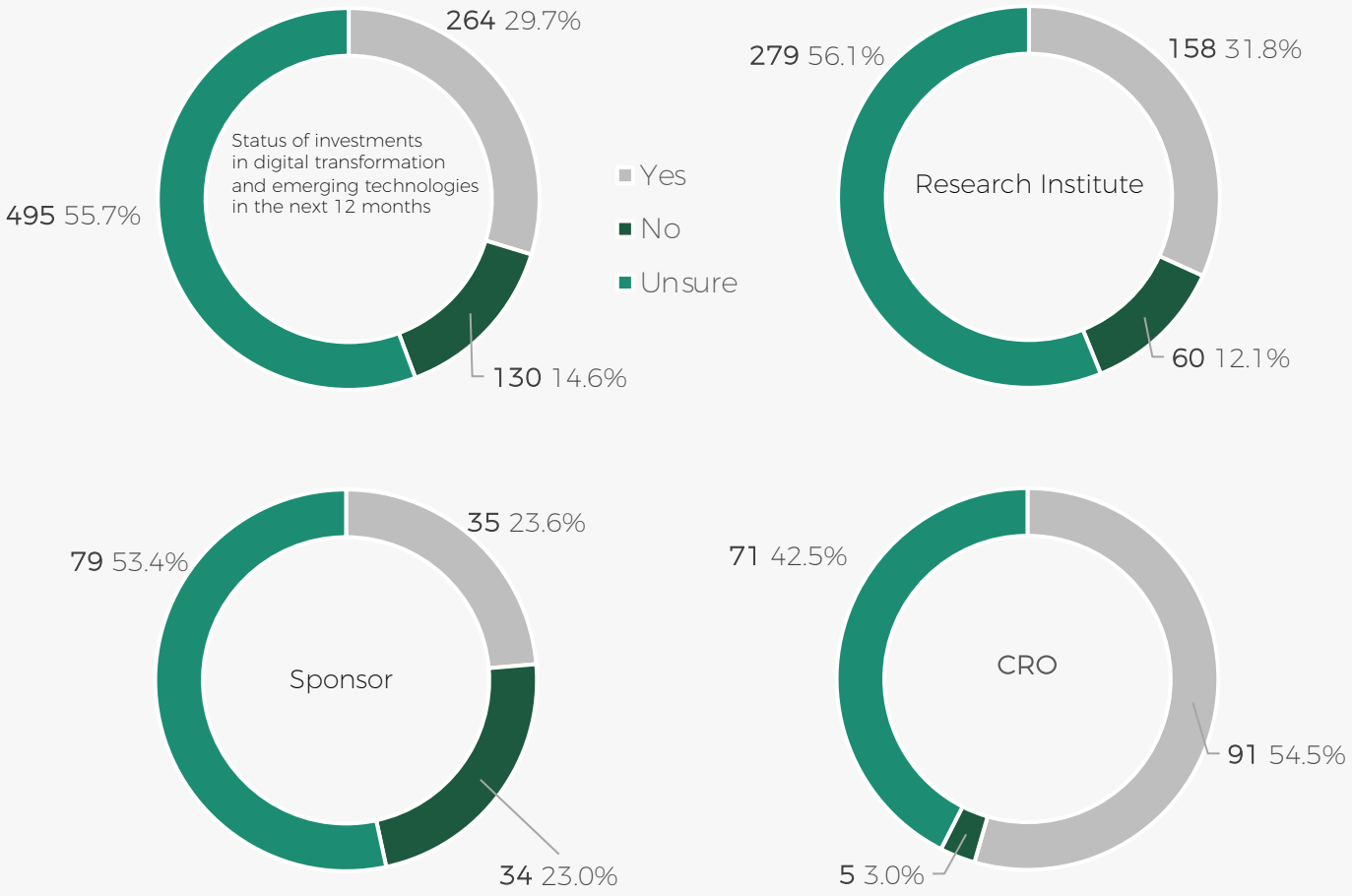
For CROs, the current usage rates of eCOA, remote monitoring, and ePay collectively contributed to over 50%, with respective proportions of 20.6%, 18.1%, and 11.7%, respectively.
In the next 1-3 years, CROs intend to allocate two-thirds of their investments as follows: 13.7% to eCOA, 12.8% to remote monitoring systems and management processes, 9.8% to other elements, 9.4% to the integration of EMR and EHR, 8.5% to the integration of ePay and EDC for electronic medical and electronic data collection, and 7% to wearable device/sensor data collection.



Question:
Will you invest in digital transformation & emerging technologies over the next 12 months?

In the organization surveyed, over half of the participants (55.7%) express uncertainty about whether the organization will invest in digital transformation and emerging technologies in the next year. This uncertainty may be related to the fact that the survey gathered responses primarily from a minority of senior management personnel (6.6%) holding "company position" roles.

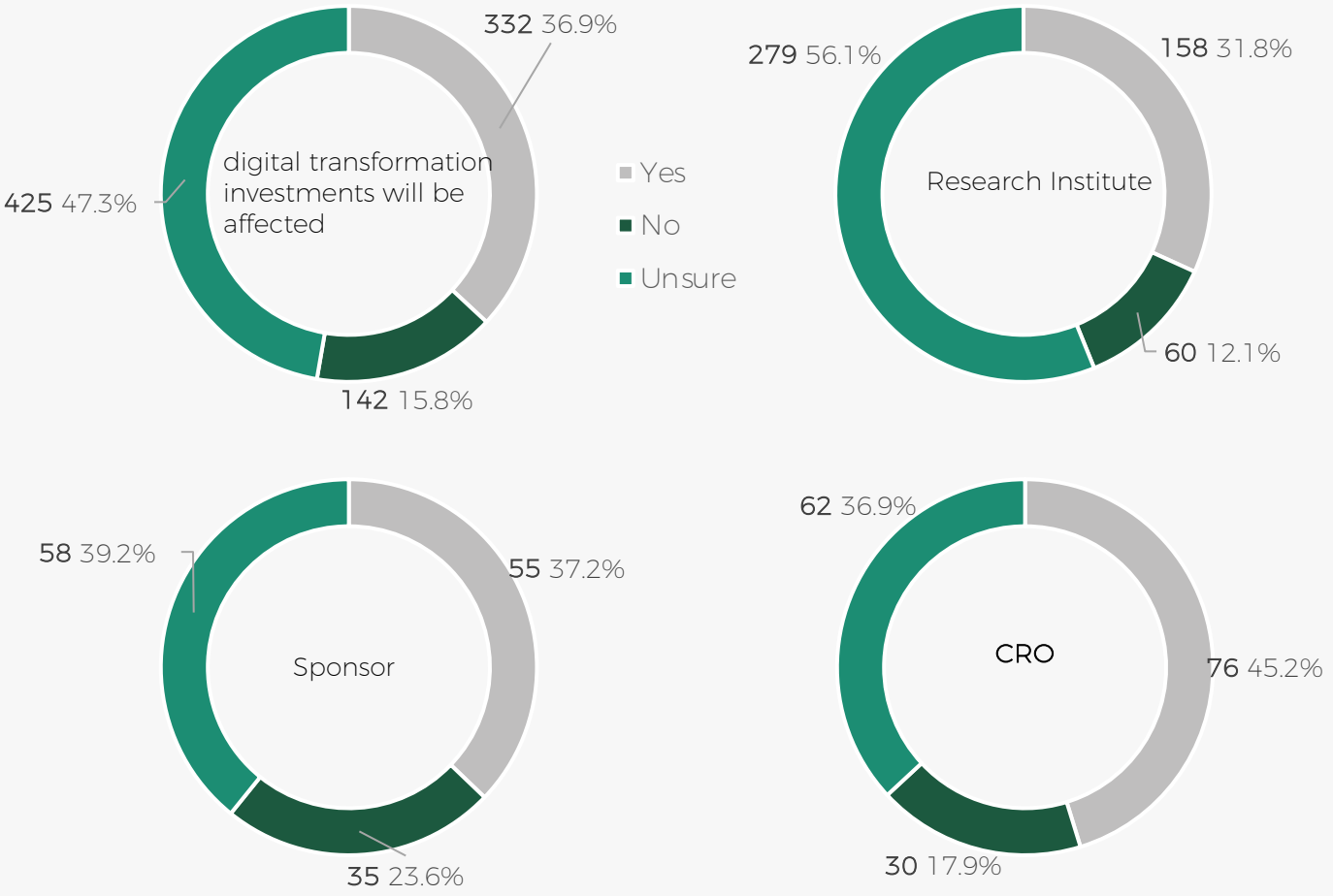
Among Contract Research Organizations (CROs), there is a significant inclination towards investing in digital transformation and implementing emerging technologies in the next 12 months, with a proportion of 54.5%.



Question:

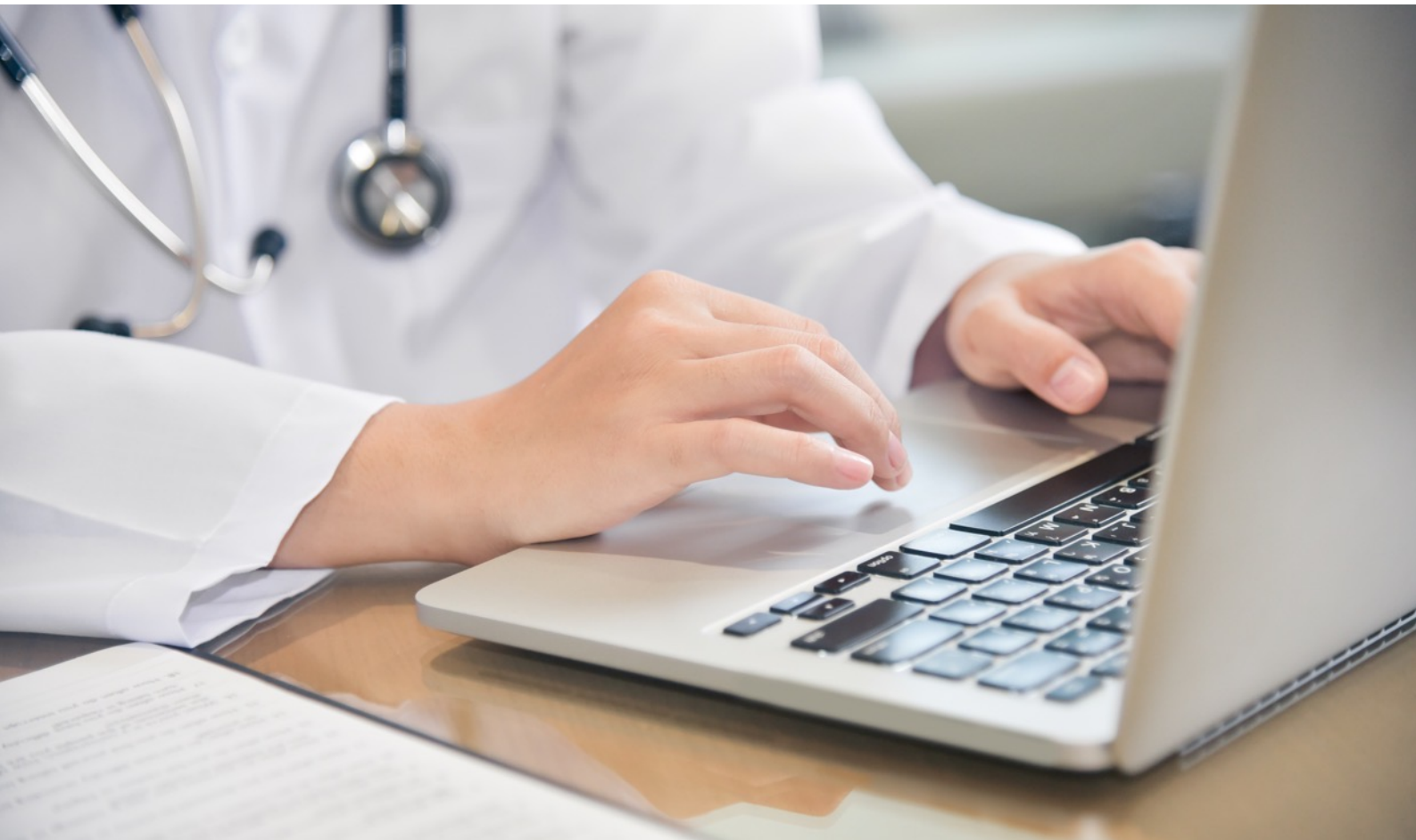
Do you think that current economic conditions, financial disruptions and inflation would impact on your investment on digital transformation?

According to the survey results, 36.9% of the participants believe that the current economic conditions, financial instability, and inflation will impact the organization's choices regarding investments in digital transformation. This poses a challenge within the observable timeframe required for the outcomes.



04

Regulatory considerations



Regulatory Considerations

Question:

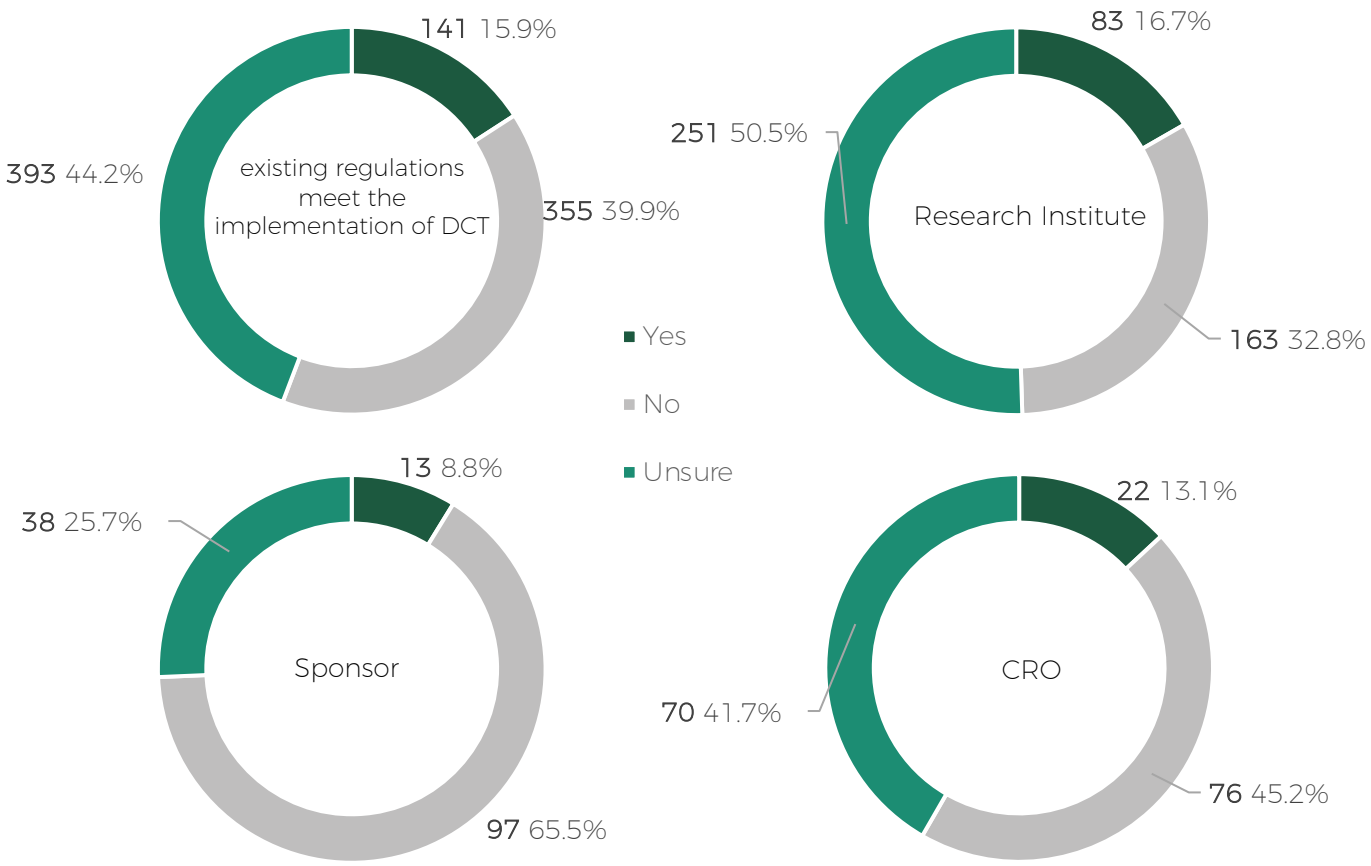
Do you believe industry-wide collaboration and education are important for enhancing the collective understanding of regulatory considerations when implementing DCT?

According to the survey results, a significant number of participants expressed dissatisfaction with existing regulations for the implementation of Decentralized Clinical Trials (DCT). Among them, 39.9% chose "No," indicating a substantial proportion. In contrast, only 15.9% selected "Yes," while 44.2% indicated "Uncertain.

Further analysis reveals that within research institutions, 16.7% believe that existing regulations meet the requirements for implementing DCT, while 32.8% express dissatisfaction, and 50.5% are uncertain. Among sponsors, 8.8% believe existing regulations are sufficient, but 65.5% feel they are inadequate,

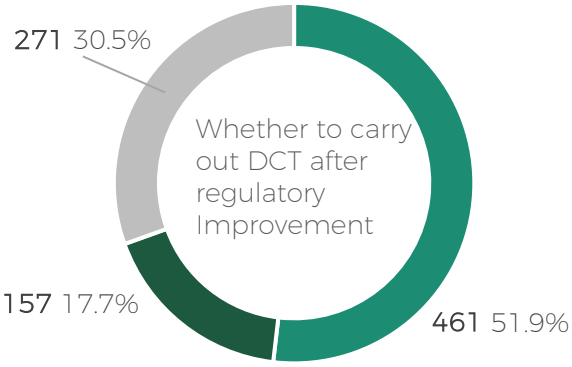
and 25.7% are uncertain. In the case of CROs, 13.1% believe existing regulations are sufficient, but 45.2% find them insufficient, and 41.7% are uncertain.

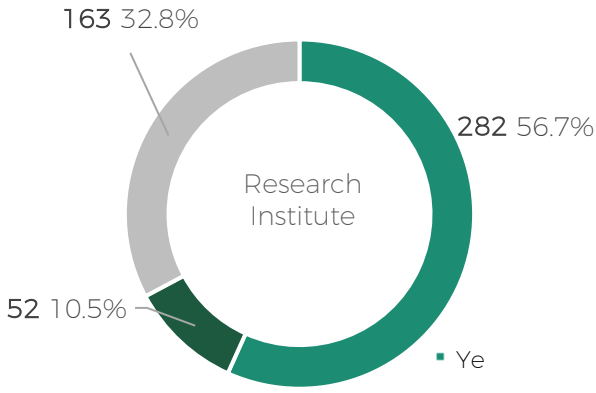
From the survey results, many participants believe that existing regulations are insufficient to meet the implementation needs of DCT. This suggests a need for improvement and adjustment of current regulations to accommodate the trends in digitalization and decentralized clinical trials. Additionally, a considerable number of participants express uncertainty, indicating a potential need for more guidance and regulatory clarity. Relevant government agencies and regulatory bodies should review existing regulations to ensure alignment with best practices in DCT. Furthermore, providing more education and guidance can enhance understanding of regulations and compliance requirements, fostering the development and implementation of DCT.

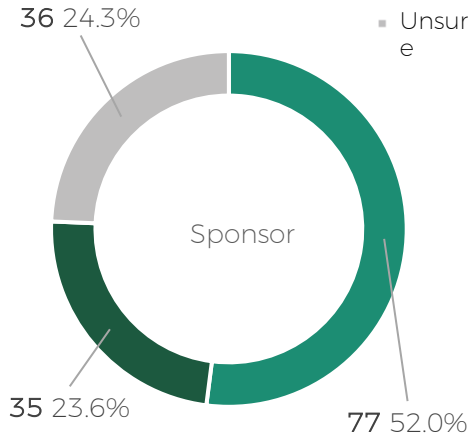


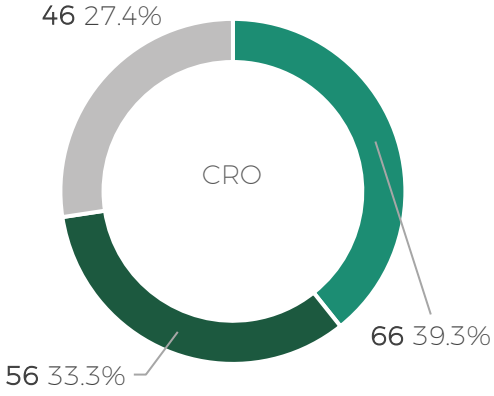
Question:

Do you believe that implementing more regulations to clarify access to health technologies and technical requirements is important given the rapid evolution of technology?









According to the survey results, the majority of participants indicate that they will only commence DCT after regulatory improvements, accounting for 51.9%. Only 17.7% selected "No," while 30.5% expressed uncertainty.
Further analysis by organizational type reveals that within research institutions, 56.7% will initiate DCT after regulatory improvements, with only 10.5% selecting 'No,' and 32.8% expressing uncertainty. Among sponsors, 52.0% will begin DCT after regulatory improvements, 23.6% selected 'No,' and 24.3% expressed uncertainty. For CROs, 39.3% will start DCT after regulatory improvements, 33.3% selected 'No,' and 27.4% expressed uncertainty.

The survey results indicate that participants recognize the importance of regulatory improvements for commencing DCT, with 51.9% stating they will do so only after such improvements. Further analysis by organizational type reveals similar trends, with 56.7% of research institutions, 52.0% of sponsors, and 39.3% of CROs planning to initiate DCT post-regulatory improvements. However, uncertainty persists among 30.5% of respondents. This underscores the need for stakeholders to closely monitor regulatory changes and ensure alignment with the latest requirements.

While recent guidelines from the China National Medical Products Administration (NMPA) on few topics: **"Technical Guidelines for Patient-Centric Drug Clinical Trial Design (Trial)", "Technical Guidelines for Patient-Centric Drug Clinical Trial Implementation (Trial)", "Technical Guidelines for Patient-Centric Drug Benefit-Risk Assessment (Trial)"** offer promising regulatory frameworks, their impact remains to be seen and requires active promotion for widespread adoption.

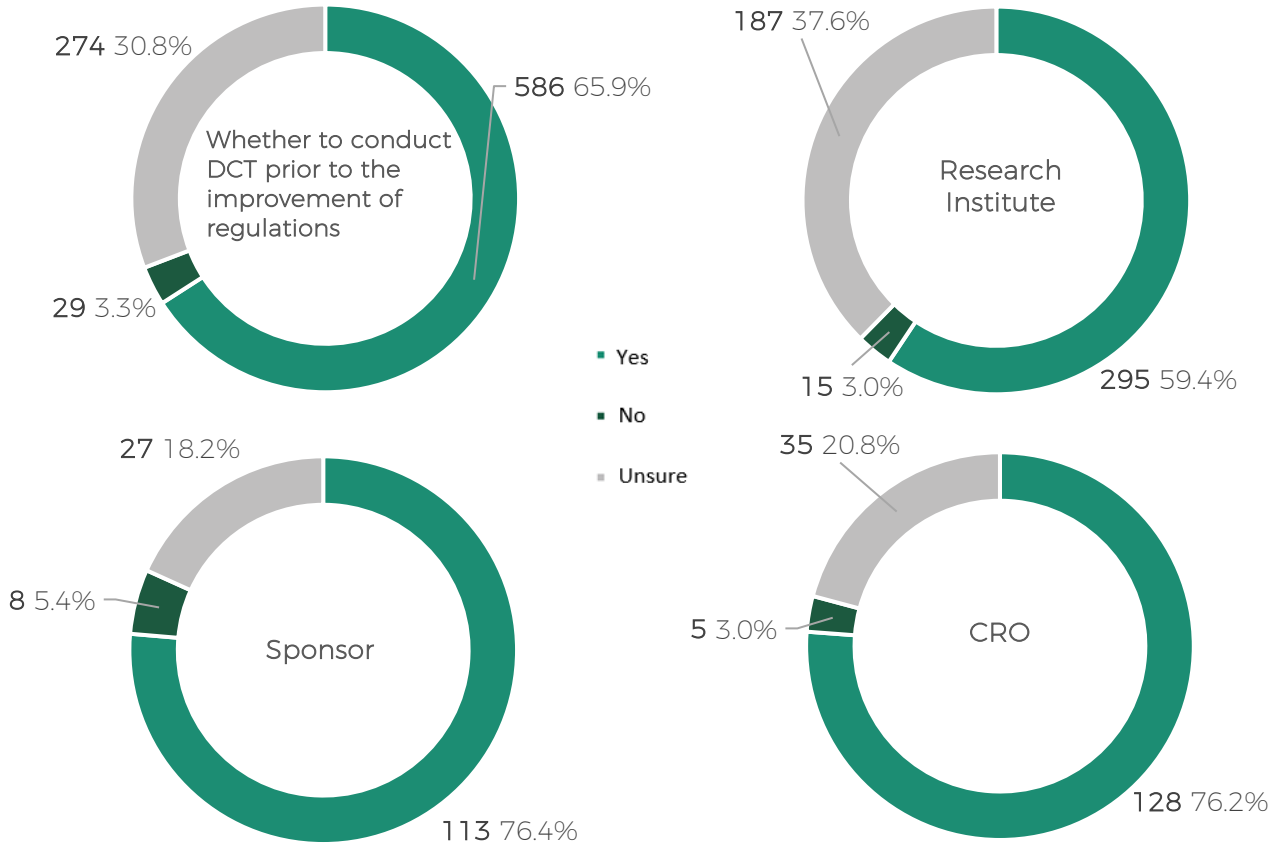
Question:

Do you believe that exploring and experimenting with DCT in the industrial sector, continuously accumulating experience, can drive the construction and improvement of regulations and guidelines?

According to the survey results, 65.9% of the participants have adopted the sequence of conducting DCT first and then refining regulations. Only 3.3% chose "No," while 30.8% expressed uncertainty. Further analysis shows that within research institutions, 59.4% have followed the sequence of initiating DCT first and then refining regulations, with only 3.0% choosing "No," and 37.6% expressing uncertainty. Among sponsors, 76.4% have adopted the sequence of conducting DCT first and then refining regulations, while 5.4% chose "No," and 18.2% expressed uncertainty. In CROs, 76.2% have followed the sequence of conducting DCT first and then refining regulations, with only 3.0% choosing "No," and 20.8% expressing uncertainty.

The survey results indicate that, in the process of implementing DCT, the majority of participants opted to embracing DCT methodologies, to continuously accumulating experience while waiting for regulatory enhancements. This inclination towards initiating DCT before refining regulations highlights the industry's readiness to innovate and adapt to evolving clinical trial methodologies. Regulatory agencies and governments should continue to support the implementation of DCT and strive to collaborate with the industry to better understand business requirements during the regulatory development process.

Only a very small number of participants chose to conduct DCT after regulatory improvements, which may be due to regulations imposing restrictions on their business. Additionally, survey participants should actively engage in the formulation and improvement of regulations to ensure they meet practical needs and create a better environment for the development of DCT.



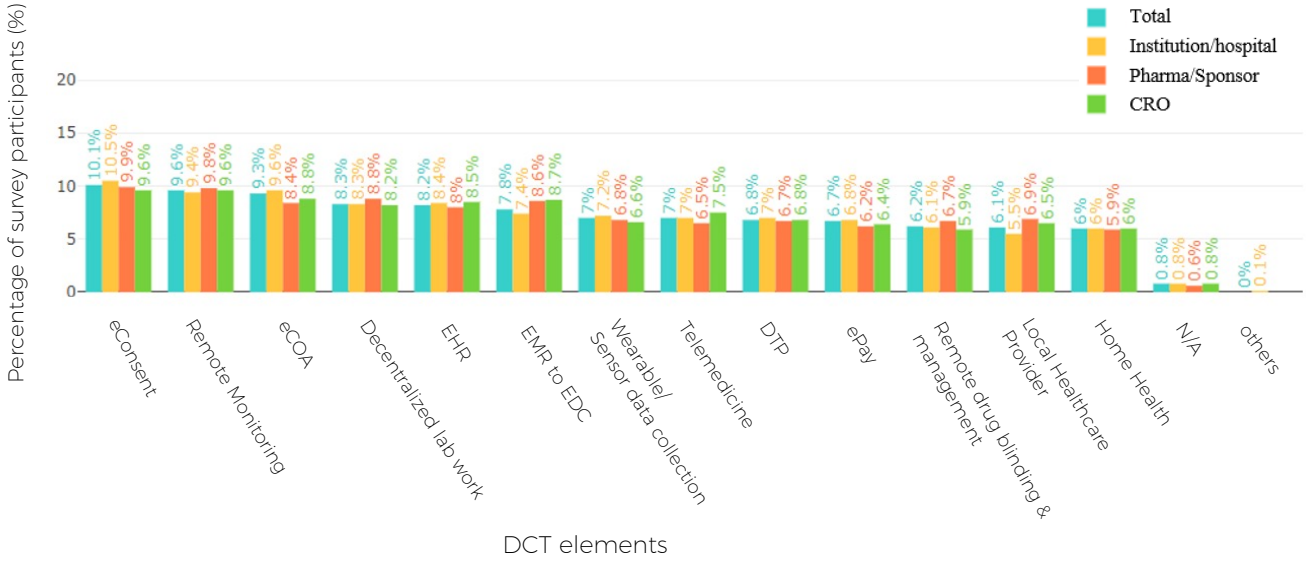
Question:

As the regulatory environment for DCTs varies significantly from country to country and is constantly changing, what aspects of regulations, guidelines, and implementation details do you hope regulatory agencies will formulate for DCT in the future?

For future regulatory guidelines and implementation details, the respondents express the highest expectation for the segment of eConsent, accounting for 69.1%. Following that are eCOA / electronic patient-reported outcomes (ePro) / electronic diaries (eDiary) and remote monitoring, with percentages of 63.9% and 65.2%, respectively.

In comparison, demand for other segments such as electronic payments, local visits, and mobile healthcare is relatively lower. The demand for the "other" and "not applicable" segments is very low, at only 0.2% and 5.3%, respectively.

Future distribution of regulatory agencies in formulating DCT processes.



Regulatory agencies should prioritize the development of guidelines and implementation details for eConsent, eCOA, ePro, electronic diaries (eDiary), and remote monitoring, as the demand in these areas is most pressing. Additionally, regulatory agencies need to closely monitor changes in the regulatory environment to ensure that their regulations remain in sync with technological advancements and industry needs.

05

Industry Outlook

Decentralized clinical trials: Decoding Industry Dynamics

Industry Attractiveness

The field of digitalized/decentralized clinical trials (DCT) demonstrates strong appeal in China, particularly among the younger, highly educated demographic. Participants with higher education levels constitute a substantial portion, offering robust talent support for the industry's future growth, innovation, and policy research and development. The acknowledgment and embrace of DCT within the clinical trial sector, with research institutions playing a pivotal role, pharmaceutical companies/sponsors serving as primary decision-makers, and clinical research organizations (CROs) displaying notable dynamism and innovative drive, are paramount. Although Tertiary-A hospitals are prominent participants in DCT, others may require additional support and broader promotion to ensure balanced advancement. The active engagement of ethics committees furnishes invaluable insights into ethical considerations in this domain, ensuring trial adherence and ethical viability.

Practices and trends

Key elements of Decentralized Clinical Trials (DCT), such as eCOA, remote monitoring, electronic payments, and electronic informed consent (eConsent), have seen widespread adoption. For the Chinese DCT industry landscape, DCT is expected to continue driving innovation and efficiency improvement in clinical research, becoming an ongoing important trend in the field. This trend is anticipated to have a profound impact on trial design, implementation, and regulation. Industry stakeholders need to collaboratively explore ways to integrate DCT elements into future projects and seize opportunities amid uncertainties. Establishing industry standards and sharing best practices will promote the collective development of the industry and lower the barriers to adopting DCT. With concerted efforts from various stakeholders, DCT is poised to become the mainstream model for future clinical trials, offering more opportunities and achievements in drug development and clinical practices.

Regulatory System improvement

As the trends of digitalization and decentralization become increasingly apparent in the Chinese clinical trial landscape, the enhancement of the regulatory system will be a crucial driving force for the industry's healthy development. Regulatory agencies are actively responding to the industry's demands and have already released three technical guidelines on "patient-centered" approaches, along with a draft soliciting opinions for a rare disease Decentralized Clinical Trials (DCT) technical guideline. These guidelines establish clearer standards for clinical trial participants, reducing uncertainties in practical operations and playing a significant role in advancing the development of digitalized and decentralized clinical trials.

Subject’s voice

The development of Decentralized Clinical Trials (DCT) will bring profound changes and innovations to the clinical trial landscape in the future. Its core value lies in providing more choices and possibilities for the conduct of clinical trials through diverse technologies and innovative models. The ultimate goal is to center around the patient, aiming to alleviate their burden of participating in trials, enhance convenience, and create opportunities for a broader range of patient groups to engage in clinical trials, especially rare disease patient populations. The voice of patients is crucial in clinical trials, and it is essential for all stakeholders to fully listen to and respect their input. Integrating patient perspectives into trial design and implementation is vital to offering more personalized and convenient trial environments, making it easier for patients to participate and enhancing their overall medical experience.

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