

What could regulatory agencies do to facilitate increased adoption of appropriate DCT solutions in clinical trials?

Publish clear guidances on the implementation of DCTs (long overdue!)

provide clear and consistent guidance

Publish clear guidelines to adapt DCT

Importance of Health Authorities issuing guidance

Provide guidance on implementation of DCTs

guidelines

Publish guidance

be positive & see the opportunities. But also make clear, what is acceptable and what not.

Guidance - clear and concise



What could regulatory agencies do to facilitate increased adoption of appropriate DCT solutions in clinical trials?

Reduce barriers of cross state, cross country regulatory differences e.g. licensure, differences in eConsent regs, etc.

Issue draft guidance and facilitate deep discussion of feedback with stakeholders.

clear guidance on what is needed

Sponsor development of best practices/toolkits

Be realistic! DCTs are not "stoppable" anymore. Europe seems to be a little behind with DCTs, therefore more progress in Europe would be good. CTs are global projects!

Provide framework for agreements between sites/HHCP/sponsor

Ensure that the regulatory approach is consistent across different departments and agencies

flexibility beyond COVID

Provide guidelines

What could regulatory agencies do to facilitate increased adoption of appropriate DCT solutions in clinical trials?

Provide real time lists of accepted data collection devices and procedures

ICH E6 is going to be key to the data aspects. The timelines for that are pretty long and that will hold up implication of DCTs today. How do we move forward?

harmonize

Road show? Continuous participation in these types of virtual conferences and sharing the messages of adoption, learning and doing.

Tackle eSource direct-data-capture head on

Provide encouragement, guidelines, and alleviate regulatory barriers.

Clear guidance

global alignment - given the global nature of clinical trials, sponsors are only as innovative as the lowest common denominator country

Clarification on what health authorities will and will not inspect when DCT features are employed



What could regulatory agencies do to facilitate increased adoption of appropriate DCT solutions in clinical trials?

Provide guidance on verification/validation requirements for digital tools and the right balance between remote vs. onsite monitoring

remove barriers (US) from State/local laws (e.g. Medical practicing across state lines, IMP prescriptions, etc..)

clarification on variability and what it means for analyses - i.e., are DCT features adding "more" selection bias or "different" selection bias?

emphasizing Diversity and Inclusion for clinical trial participation

update public health educational material on clinical trials to say they may/may not include DCT features depending

What can Industry and other stakeholders do to help build on the benefits of DCTs that we have seen during the pandemic?

Besides publishing DCT guidance, putting together globally harmonized guidance will be hugely beneficial.

We (industry) should remember that we also have a responsibility to openly share our experiences and learnings regarding DCT implementation.

Share their experiences with each other and regulatory agencies.

Sharing lesson's learned in this kind of forum is very helpful

plan and prepare and involve stakeholders at the beginning of the trial prior to implementation

Sharing of case studies/lessons learned for others to learn from

DKMA's dialogue forum is providing a great opportunities to informally share DCT experiences - Other authorities could consider this kind of informal knowledge-sharing workshop.

Share lessons learned... what works and doesn't...

Improve DCT tools

What can Industry and other stakeholders do to help build on the benefits of DCTs that we have seen during the pandemic?

paradigm shift to more of a sponsor/vendor partnership - Vendors working across sponsors will have more experience than any one sponsor. They need to be more than just a vendor, but a strong partner.

Sharing lessons learned and key decisions made to mitigate any issues.

Expand recruitment and education to ensure diverse participants.

share experience, successes and failures to improve DCT practices

IMI Trials@Home pilot trial (RADIAL) will generate large data volumes and will compare conventional, hybrid and virtual trial delivery.

Sponsors should harmonize what they expect from sites --> use TransCelerate!

Participate in CTTI, DIA and other working groups to propose feasible solutions

Keep the education and public awareness of CTI ongoing to healthcare and patients alike

Leverage technology to reach more diverse participants.

What can Industry and other stakeholders do to help build on the benefits of DCTs that we have seen during the pandemic?

Share best practices

vendors have a lot of good tech capabilities. They have an opportunity to become stronger in the regulatory requirements and in project management capabilities

stakeholders can work on developing the value proposition
- are we at the point where actual benefits can be calculated?

Propose and publish reasonable methods for maintaining data integrity, how to analyze data from trials that incorporate optionality

Industry members to find forums to share information (e.g. Clubhouse, virtual conferences, etc)

Strong senior leadership and middle leadership within companies to support project teams doing DCT approaches is essential

Advocate for keeping regs established during emergency as permanent.

EDUCATE / Learning / Training on DCTs for the industry.

would like to hear more from patients, do they like DCT features? Is there a way stakeholders can survey patients? Are we at that point where we can get this information?

What can Industry and other stakeholders do to help build on the benefits of DCTs that we have seen during the pandemic?

DCT studies are global. Share how to handle the protocol where there will be disparity between countries on which elements will be used. How do we avoid having country-specific protocols?

Be mindful of costs to conduct DCTs -- don't increase exponentially, unnecessarily.

What are the greatest challenges or unresolved questions about PI oversight in decentralized trials?

Data integrity

data quality and consistency of care / touchpoint with the participants

Data quality

Comfort with not seeing patient in person

Loss of communication

Which responsibilities fall to local PI vs centralized PI?

Data quality and bias

How to handle delegation of responsibilities and 1572 requirements

How can PI provide oversight of home health vendors, if they have not trained and met individual care providers



What are the greatest challenges or unresolved questions about PI oversight in decentralized trials?

Making sure that actions are standardized

How to oversee the data collection and standardization.

data integrity and completeness

Data quality. Patient reported data.

Lack of in-person contact

Involving the patient's PCP - what responsibilities can they take

ensure that the patient completes the task as requested, at the time requested and done correctly.

Determining when individuals are on 1572 and Delegation of Authority Log (eg. what is considered clinical care)

I think the "business model" doesn't currently support optimal oversight.

What are the greatest challenges or unresolved questions about PI oversight in decentralized trials?

Who will be responsible for adverse event attribution?

timely data capture and reporting

Cross state and country differences when overseeing multiple remote sites

how would our PI actually provide true oversight of care provided by outside providers he has never met this is a huge challenge when he perceives oversight as his responsibility on the 1572

an SAE that occurs, how is PI involved, managing the event

Data privacy regulations and ability to implement digital tools (eConsent, eSource, remote monitoring) globally

PIs do not feel comfortable putting mobile healthcare provider on DOA which means they have direct oversight for them. Sites have told us that some sponsors don't require site to list mobile healthcare on DOA - is that possible?

In a fully virtual trial, how to ensure the required oversight? If the PI "never" sees the patient in person, can we really say that the oversight is given?

IMP accountability and compliance by patient with no technology to track



What are the greatest challenges or unresolved questions about PI oversight in decentralized trials?

If a DCT includes a mobile phlebotomist drawing blood at a participant's home, what level of oversight does the PI need have on the mobile phlebotomist, and what does that look like in terms of training, availability, safety events, etc.?

missed visits that impact data collection or Patient Safety. What is the PI's responsibility from an oversight perspective.

How to bring in local labs or imaging (if), etc., to ensure PI oversight on the patient continuous participation in the CT is appropriate.

How can we demonstrate this aspect has been fully considered in the protocol when it's the PI's responsibility to demonstrate it during a clinical trial

Does this question infer a fully DCT trial or does this question propose that received comments would apply to both full and partial (hybrid) DCT

Publish clear guidance documents on DCTs (long overdue!)

What oversight, if any, is expected if PI collects data from local HCP if data collection does not require protocol training

How can you consistently document PI oversight of external vendors that PI has not met and confidently provide oversight for a patient care where the PI doesn't meet the patient



What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

Listen

Transparency & education for patients! Patients need to understand

flexibility based on patient need

Earlier interactions with Patients and Sites to obtain their input into CTPs

more investment of time and planning with all stakeholders

solicit more feedback earlier on in the drug development plan

greater degree of collaboration between all the players

engage with stakeholders in protocol development early on

should be a partnership , not a transactional relationship. Input from all stakeholders



What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

clearly defined operational plans--at a level of detail not seen or required for traditional clinical trials

what are the benefits for a patient compared to a conventional trial?

paradigm shift to more of a sponsor/vendor partnership - Vendors working across sponsors will have more experience than any one sponsor. They need to be more than just a vendor, but a strong partner.

Solid protocol design

Providing options to patients without adding too much logistical burden to the study team

open and honest discussions and appropriate training/education

Involvement in trial design and planning

include them in the development of the protocol

Standardization within and between sponsors - requirements, communications, etc.

What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

Less complexity and more streamlined ways of working and interactions

clear evidence for a decreased burden!

Patient AND caregiver education

More transparency from Vendors regarding what their systems current do and don't do and what their actual experience is in this space

Embed DCT in protocol design and proactively engage sites in the process during site selection to ensure alignment on remote visits

Trial design and planning.

More thorough interaction during protocol design of the different parties

Centralization to facilitate exchange of information/communication

EDUCATE

What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

Thinking - having all stakeholders think a bit more creatively as to how to get the essential aspects of a trial completed.

active partnerships with sites

There needs to be more holistic collaboration involving ALL stakeholders with stakeholders not only coming to the table with their ideas in hand but with open ears and minds to consider the feedback of others.

we as the sponsor need to implement well defined process and procedures for DCT solutions so we can have consistency and control. DCT is so new and we don't have established processes.

More sharing of Lesson's Learned from all parties involved in DCTs

vendors have a lot of good tech capabilities. They have an opportunity to be stronger in knowledge of regulatory requirements and in project management

Easy administration

FLEXIBILITY!

Practice/Testing of protocols with sites and sample patients

What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

Improved communications with patients, especially the underserved.

Investigators need to separate their own discomfort with DCTs from valid reasons to oppose DCT features

More oversight of CROs to ensure they are not adding undue burden sites and patients.

HCPs learn how to reach and explain clinical trials and encourage their patients to enroll.

Education / training needed so sites, patients, etc aren't left to figure DCT aspects on their own

more fit for purpose designs based on specific patient population

sponsor brings investigators and patients to the table in the design phase

SURVEY engines that are targeting stakeholders (site, patients, etc) for Protocol development in accommodating DCT elements

More willingness to try and be open to failure (before reassessing and trying again). We won't get it right first time and if we have, then we're probably kidding ourselves

What needs to change in sponsor interactions with investigative sites, patients, and vendors to successfully implement DCT solutions?

would like to hear more from patients, do they like DCT features? Is there a way to survey patients? Are we at that point where we can get this information?

Perhaps getting all the previous information out of what works and doesn't work. Keep constant feedback in the planning and intervention.

Value proposition -Are we at the point where actual benefits of DCT approaches can be calculated?