For the Call Today...

- Work Recap
- Site Challenges Survey
  - Share Results
- Virtual Trial Capable Training – Approach post summit
- Group Work layout

Last Meeting

- **Site Challenges Discussion**
  - Survey questions
- **Future work**
- **Training Discussion**

Work To-Date Recap

- Starting with protocol design – understanding at the site level
- How DCTs are operationalizing/Process flows
- Following a Journey – Patient, Site, Data
- Visual Elements - Settled on the idea of a Subway-type map presentation
- Sub Projects
  - Survey of Site Challenges
  - Virtual Trial Capable Training
- Group Work Pending
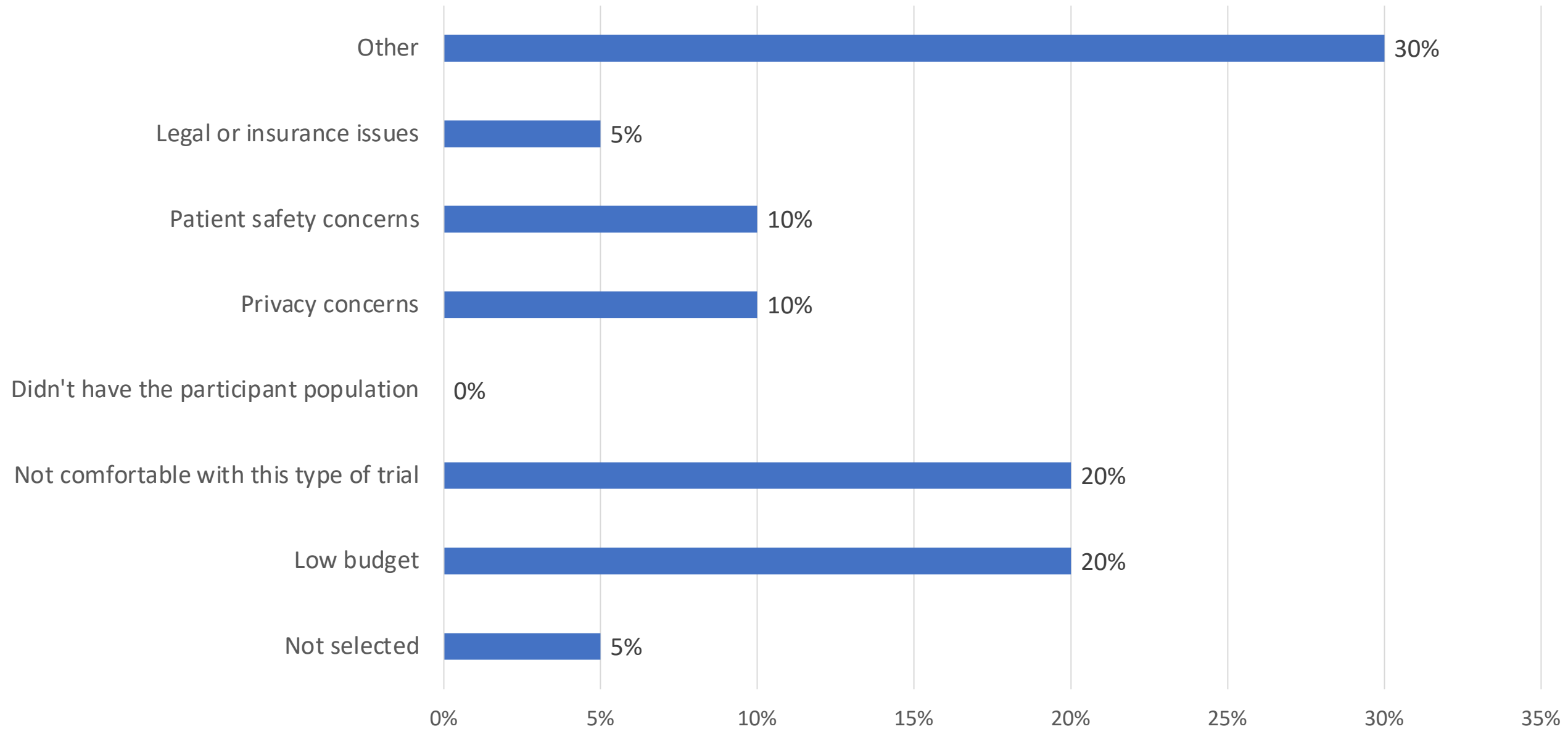- Virtual Trial Capable Training Development

In 2020-2021, were you approached by a sponsor or a CRO to conduct a 100% virtual/decentralized trial (where none of the patient visits would occur at your location)? Please answer based on trials that were planned to be decentralized, rather than changed due to COVID.

Did you Participate?

Unsure 4%
Yes 37%
No 59%

No 24%
Yes 76%
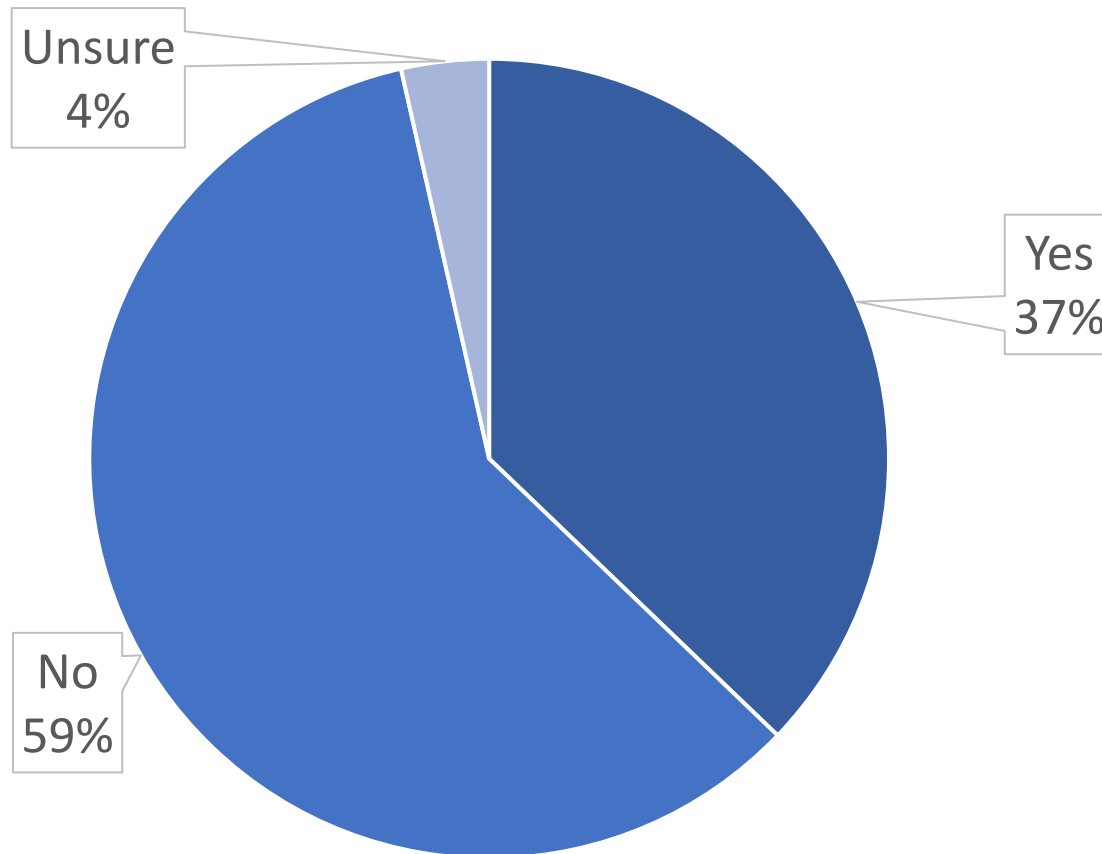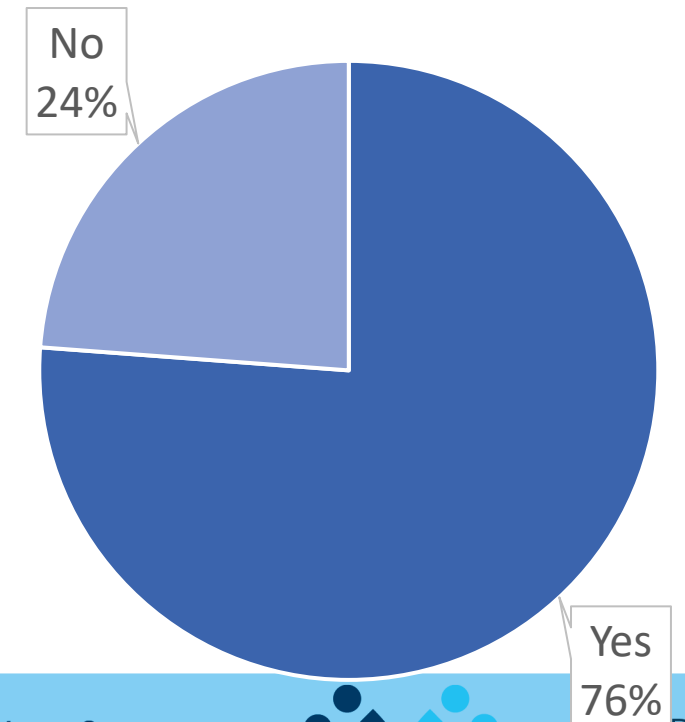
Why didn't you participate

Other Answers

The CRO literally competed and undercut our budget via decentralized process. Lot of trust lost in CRO because we lost a few hundred thousand dollars in the process.
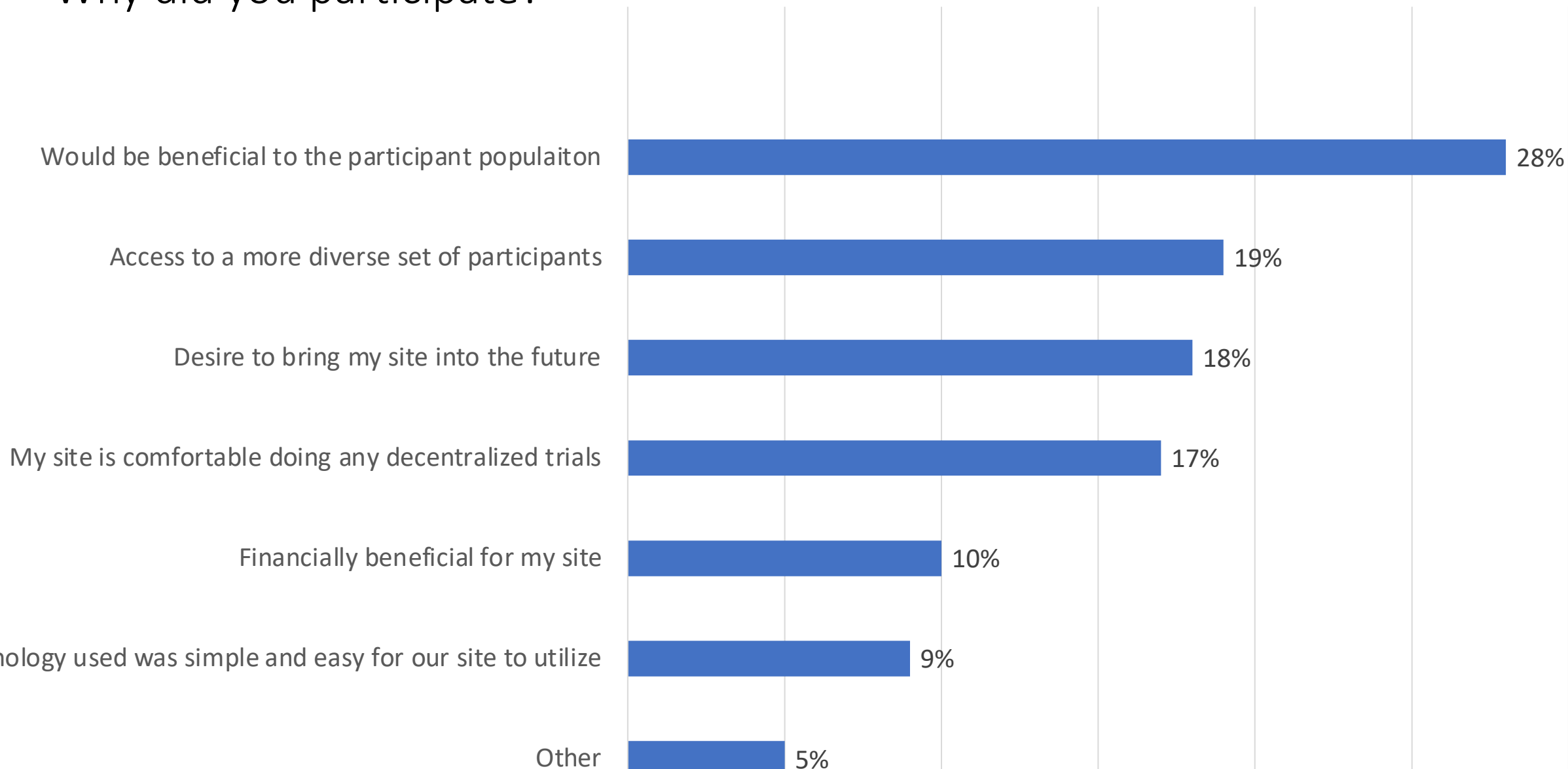
Trial was not planned well, no thought process on site involvement which made it unable to support

sponsor delayed trial

No PI and equipment to participate

Was not able to pivot, workforce challenges.

Why did you participate?

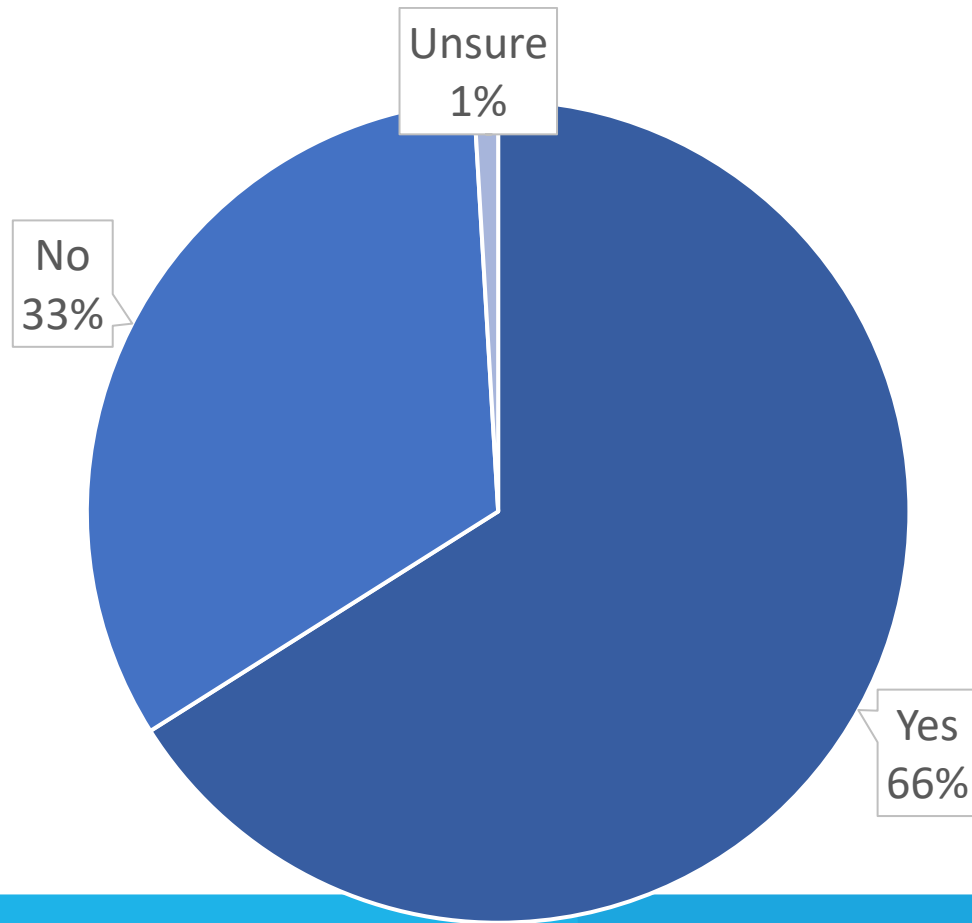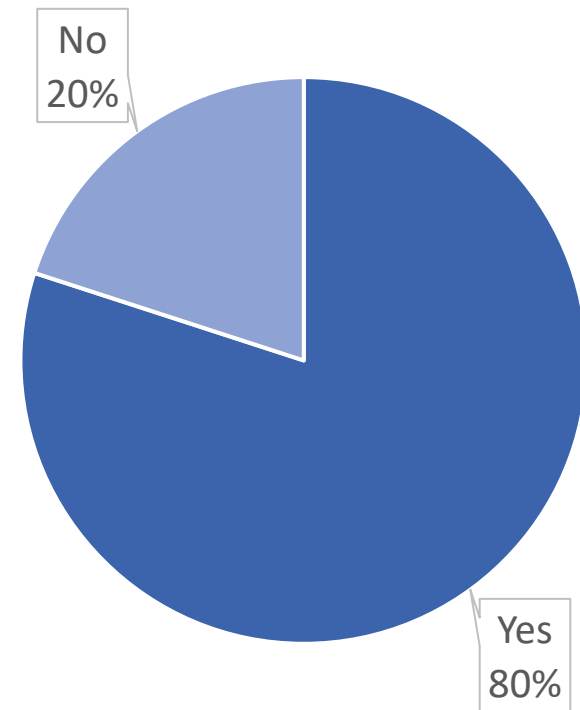| Response	Percentage
Would be beneficial to the participant populaiton	28%
Access to a more diverse set of participants	19%
Desire to bring my site into the future	18%
My site is comfortable doing any decentralized trials	17%
Financially beneficial for my site	10%
Technology used was simple and easy for our site to utilize	9%
Other	5%

In 2020-2021, how many trials at your site converted from a trial with subject site visits to a 100% virtual/decentralized trial (where none of the patient visits would occur at your location)?

Unsure
2%

All
2%

About 75%
5%

About 50%
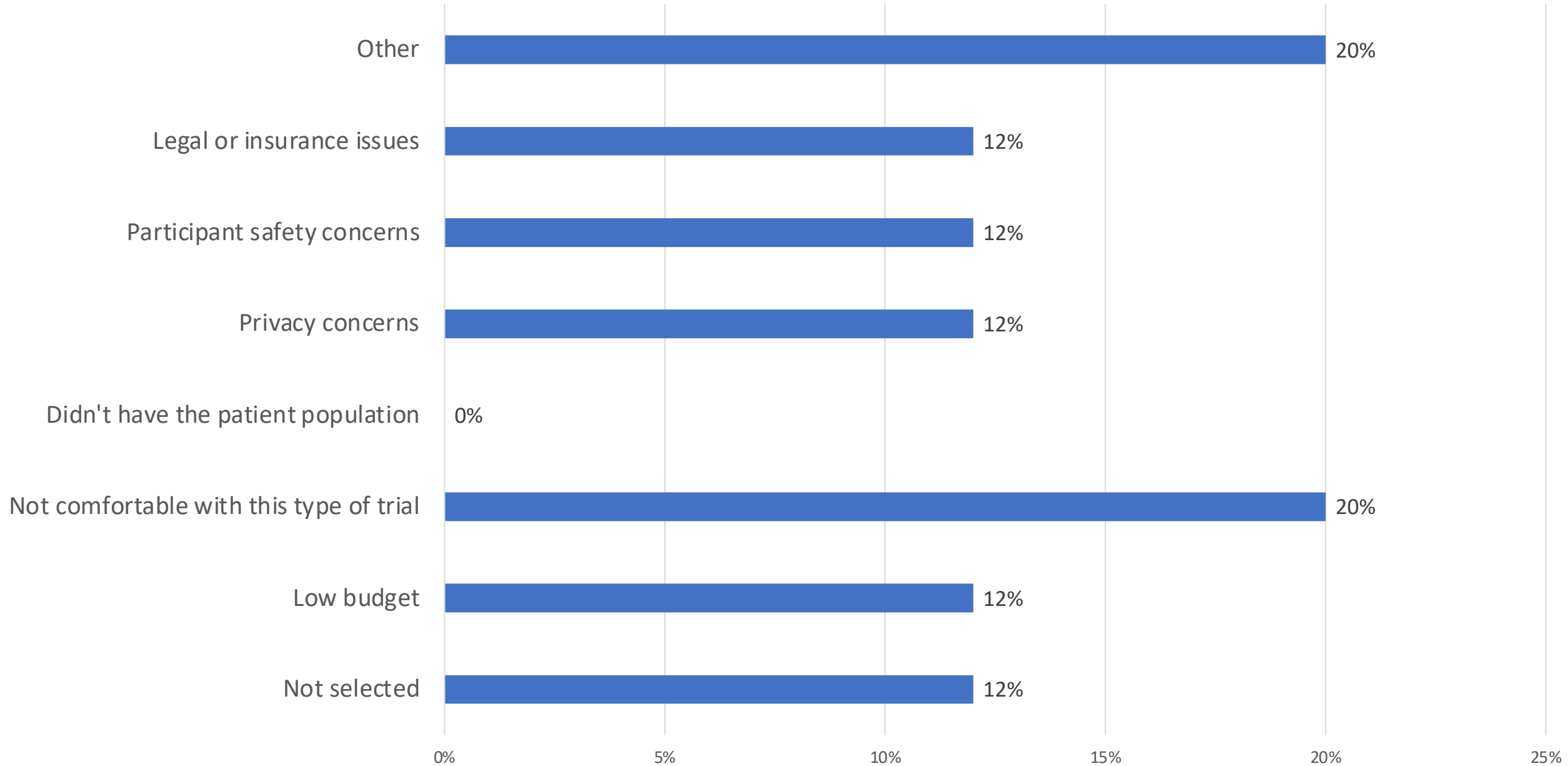8%

About 25%
16%

None
67%
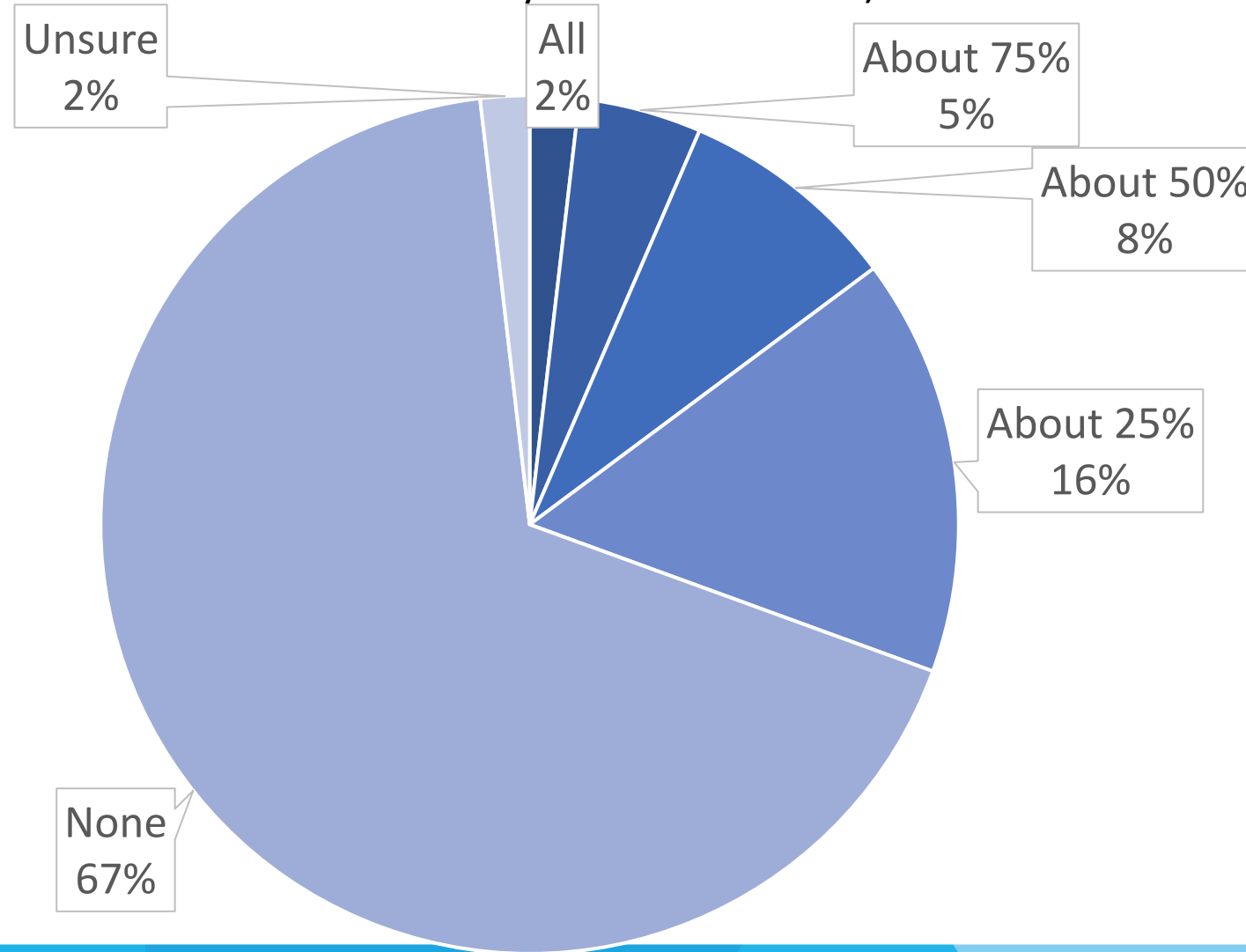
In 2020-2021, were you approached by a sponsor or a CRO to conduct a hybrid-type trial (where some but not all of the patient visits are done virtually)? Please answer based on trials that were planned to be hybrid, rather than changed due to COVID.

Did you Participate?

Why did you participate?

Category	Value
Other	20%
Legal or insurance issues	12%
Participant safety concerns	12%
Privacy concerns	12%
Didn't have the patient population	0%
Not comfortable with this type of trial	20%
Low budget	12%
Not selected	12%

Why did you participate? - Other

If you are not on the ship, then you will be left behind.

We have frequently performed studies where some of the visits occur via the phone. No trials where visits are visual

COVID related concerns made a hybrid option easier
sponsor request

Accepted study participation with more home visits worked in for whatever reason (could have been due to COVID)

Why didn't you participate?
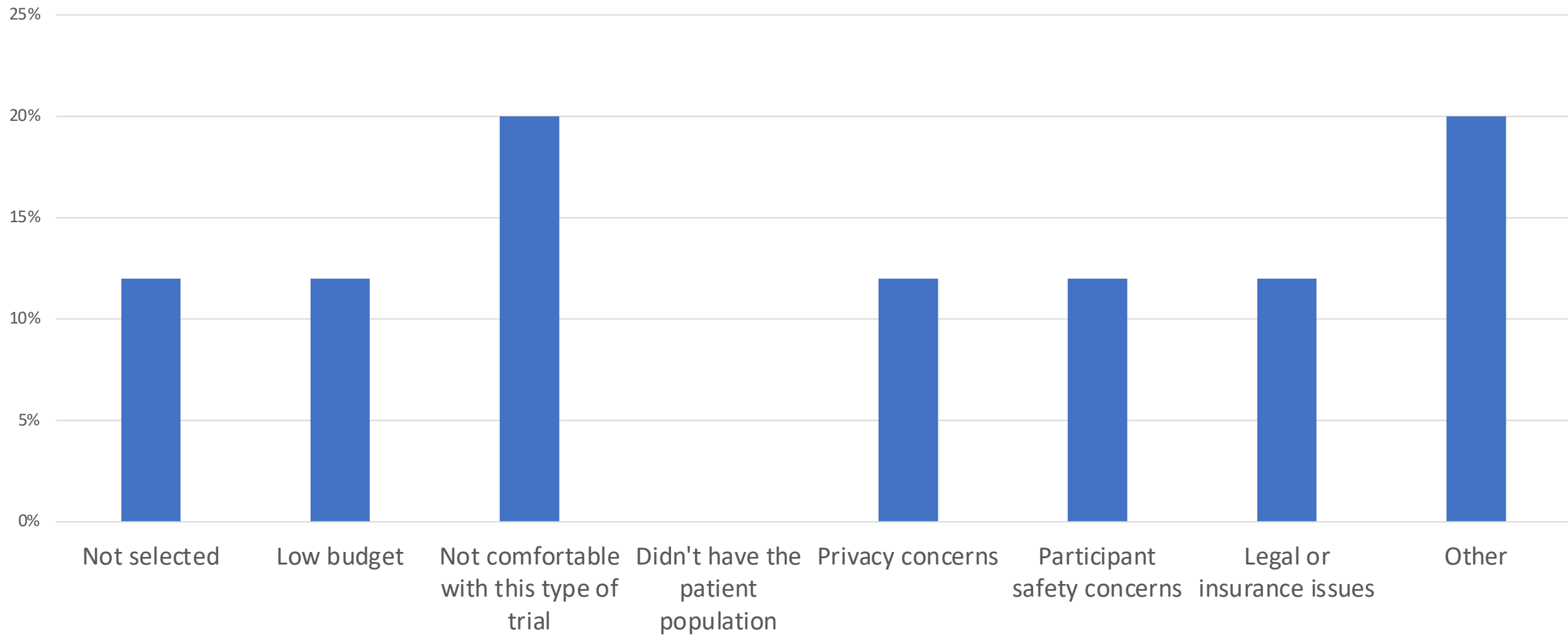
Why didn't you participate? - Other

patients prefer to come to site

PI not comfortable with delegating to a unknown person

No sure how the PI oversight can be guarantee

In 2020-2021, how many of active trials at your site converted from a trial with subject onsite visits to a hybrid-type trial (where some but not all of the patient visits are done virtually) or gave you the option to conduct visits remotely?

Unsure 3%

All 5%

About 75% 9%

None 31%

About 50% 18%

About 25% 34%
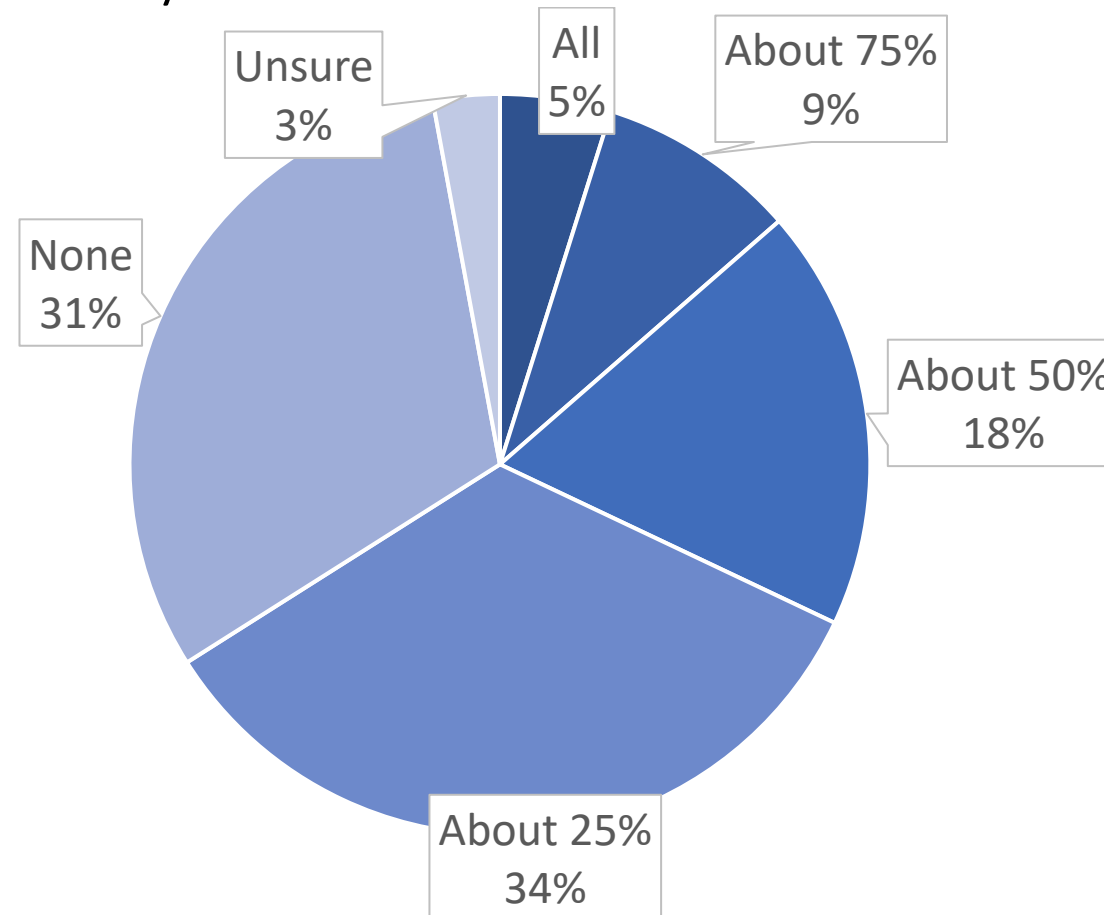
What would you expect to be the biggest challenges for your site in participating in a decentralized / virtual or hybrid trial, if you were to participate? (Rank the top 3)

Top Three – Most Votes in Each Category
- Financial Compensation
- There are no challenges, only benefits
- Legal or Insurance Issues

Challenges of least concern
- The Time it would take to implement
- The Quality of the data
- The Time to educate staff

What have you experienced to be the biggest challenges for your site in participating in a decentralized / virtual or hybrid trial? (Rank the top 3)
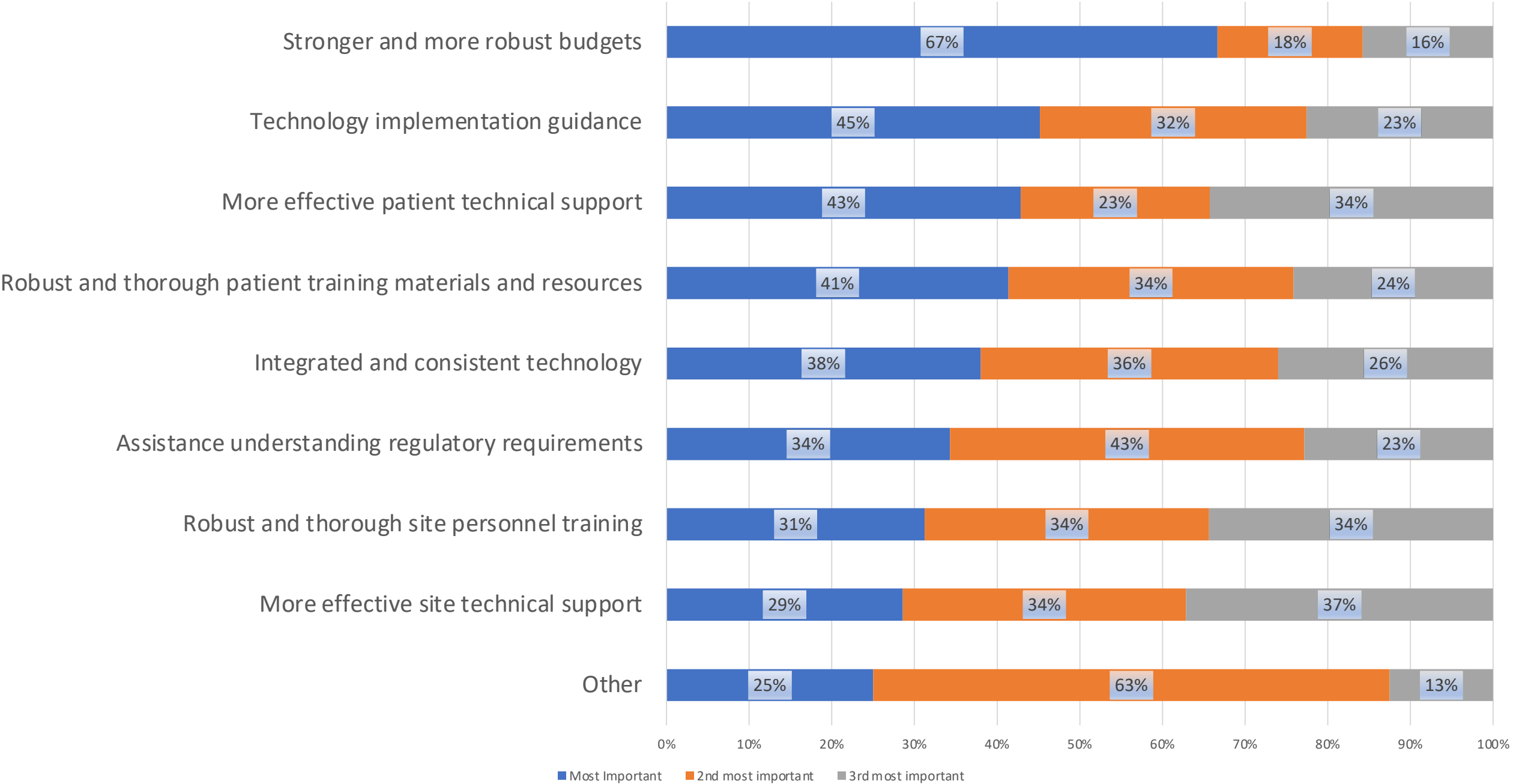
Top Answers – Most Challenging
- Financial Compensation
- Having the Capital to invest in their own tech
- Having the necessary staff to implement
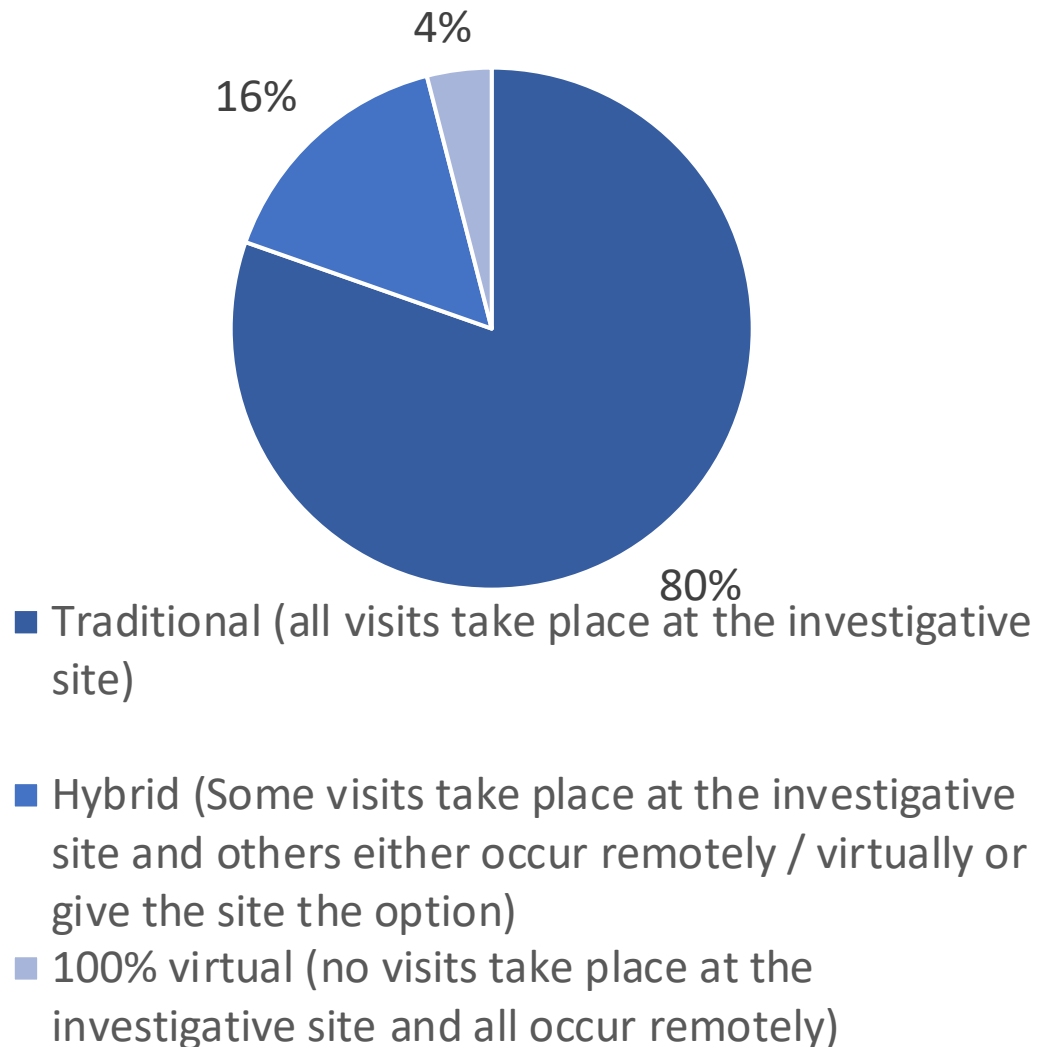
Top Answers – Least Challenging
- The Time to implement
- Difficulty for participants to participate
- Participant safety

What does your site want or need in the form of support from Sponsors and CROs in regards to participation in decentralized and hybrid remote clinical trials? Select all that apply. (Top 3)

Category	Most Important	2nd most important	3rd most important
Stronger and more robust budgets	67%	18%	16%
Technology implementation guidance	45%	32%	23%
More effective patient technical support	43%	23%	34%
Robust and thorough patient training materials and resources	41%	34%	24%
Integrated and consistent technology	38%	36%	26%
Assistance understanding regulatory requirements	34%	43%	23%
Robust and thorough site personnel training	31%	34%	34%
More effective site technical support	29%	34%	37%
Other	25%	63%	13%

■ Most Important   ■ 2nd most important   ■ 3rd most important

From 2020-present, what percentage of type of clinical trials has your site conducted?

4%

16%

80%

- Traditional (all visits take place at the investigative site)

- Hybrid (Some visits take place at the investigative site and others either occur remotely / virtually or give the site the option)
- 100% virtual (no visits take place at the investigative site and all occur remotely)

From the present time through 2022, what percentage of type of clinical trials will your site be conducting, based on current feasibility and selections?

34%

16%

81%

- Traditional (all visits take place at the investigative site)

- Hybrid (Some visits take place at the investigative site and others either occur remotely / virtually or give the site the option)
- 100% virtual (no visits take place at the investigative site and all occur remotely)
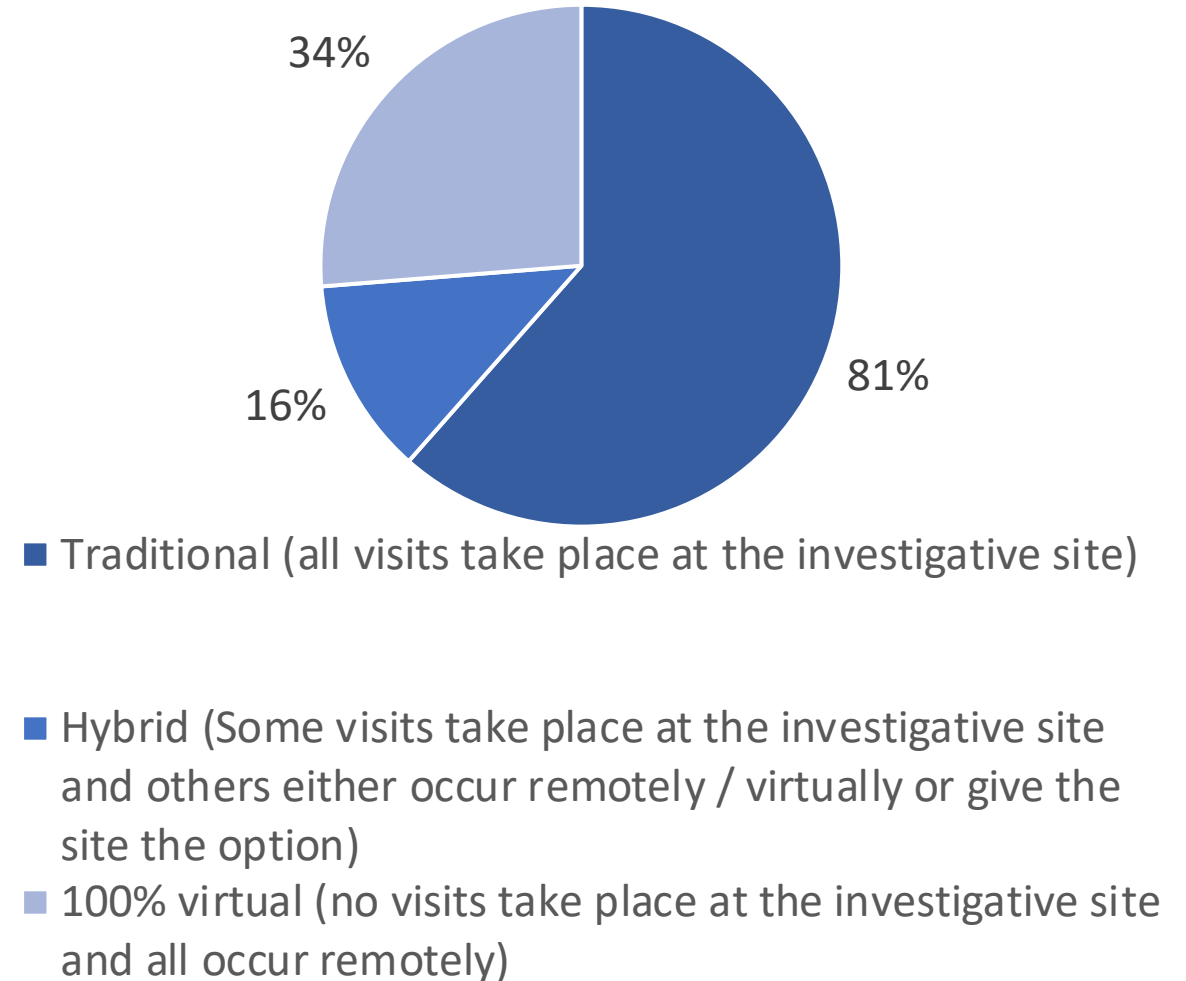
When it comes to technology use preferences in 100% decentralized and hybrid decentralized trials, which of the following applies most directly to your site?


13%

32%

55%

- We prefer to use all of our own technology

- We prefer to use a mix of our technology and technology made available by the sponsor/CRO

- We prefer to use technology made available by the sponsor/CRO
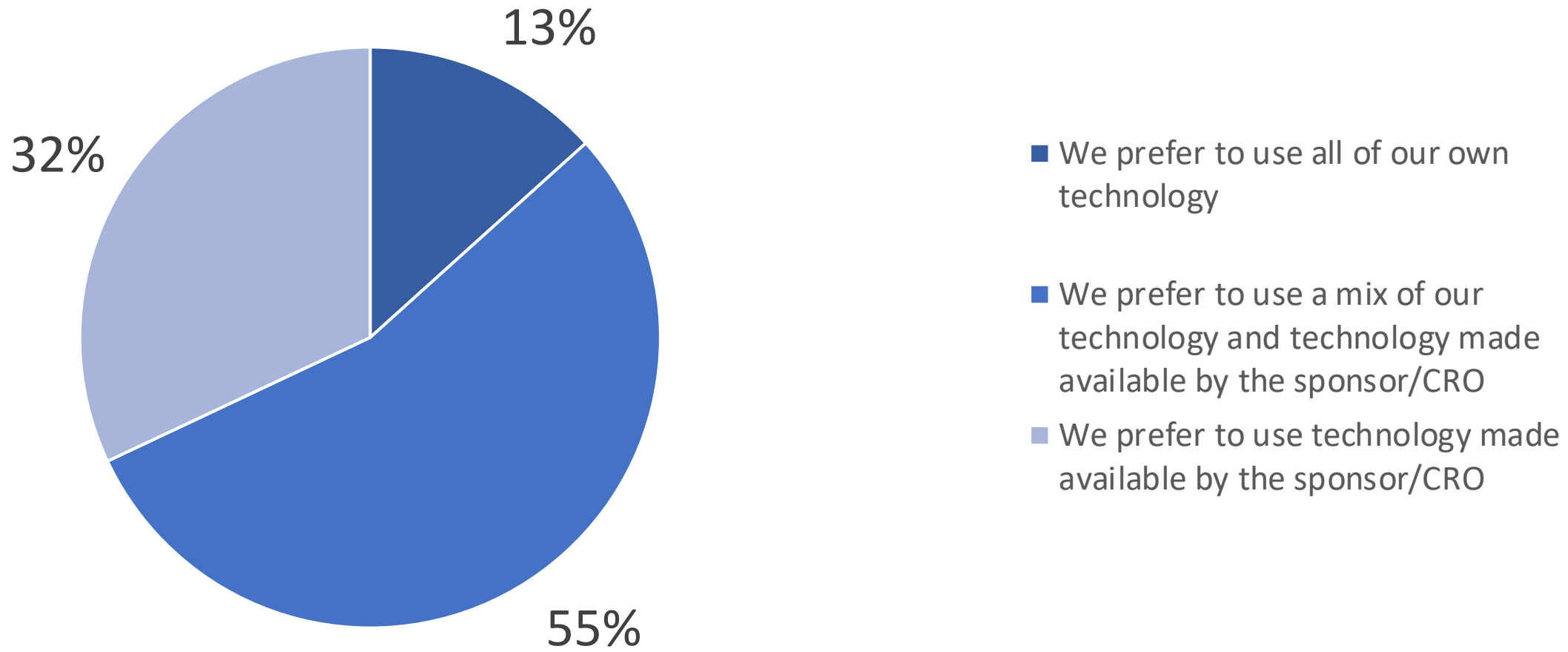
What are you doing now, or planning to do, to prepare for 100% decentralized or hybrid decentralized trials? Select all that apply.
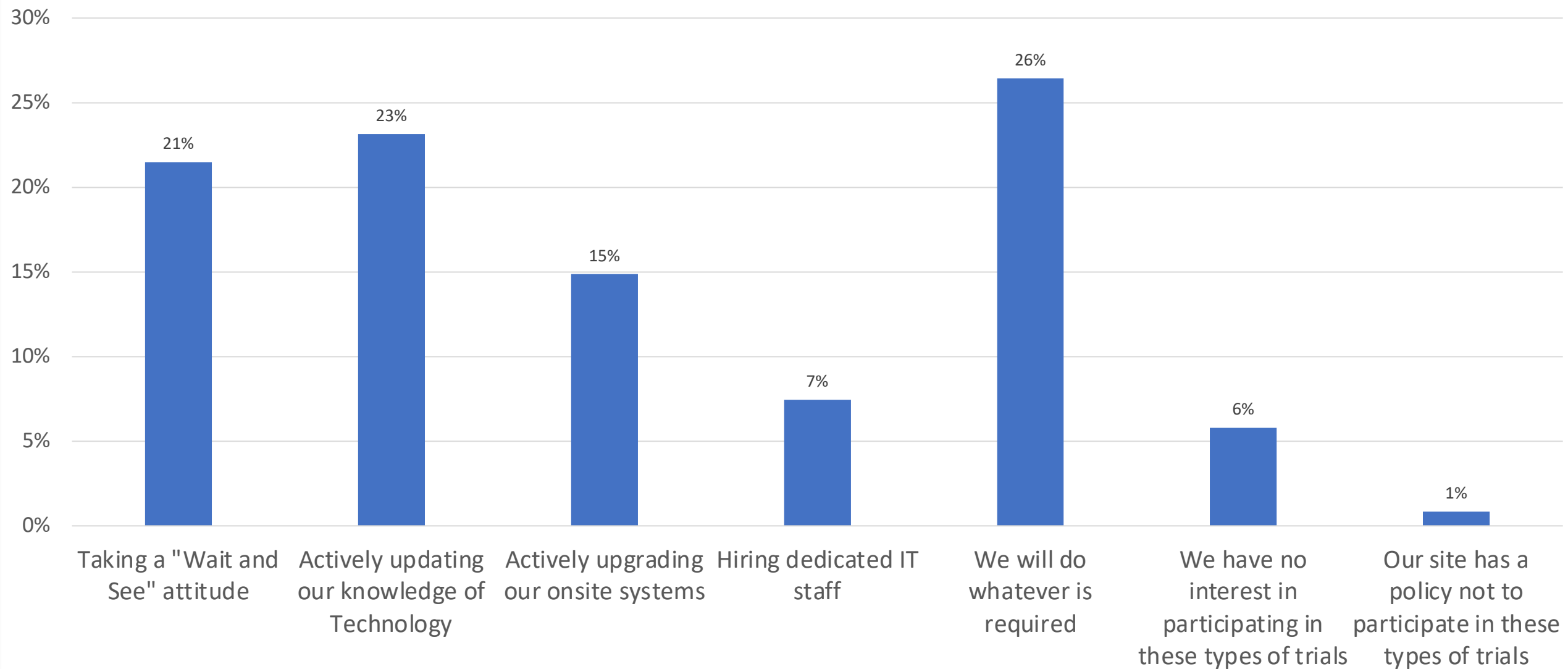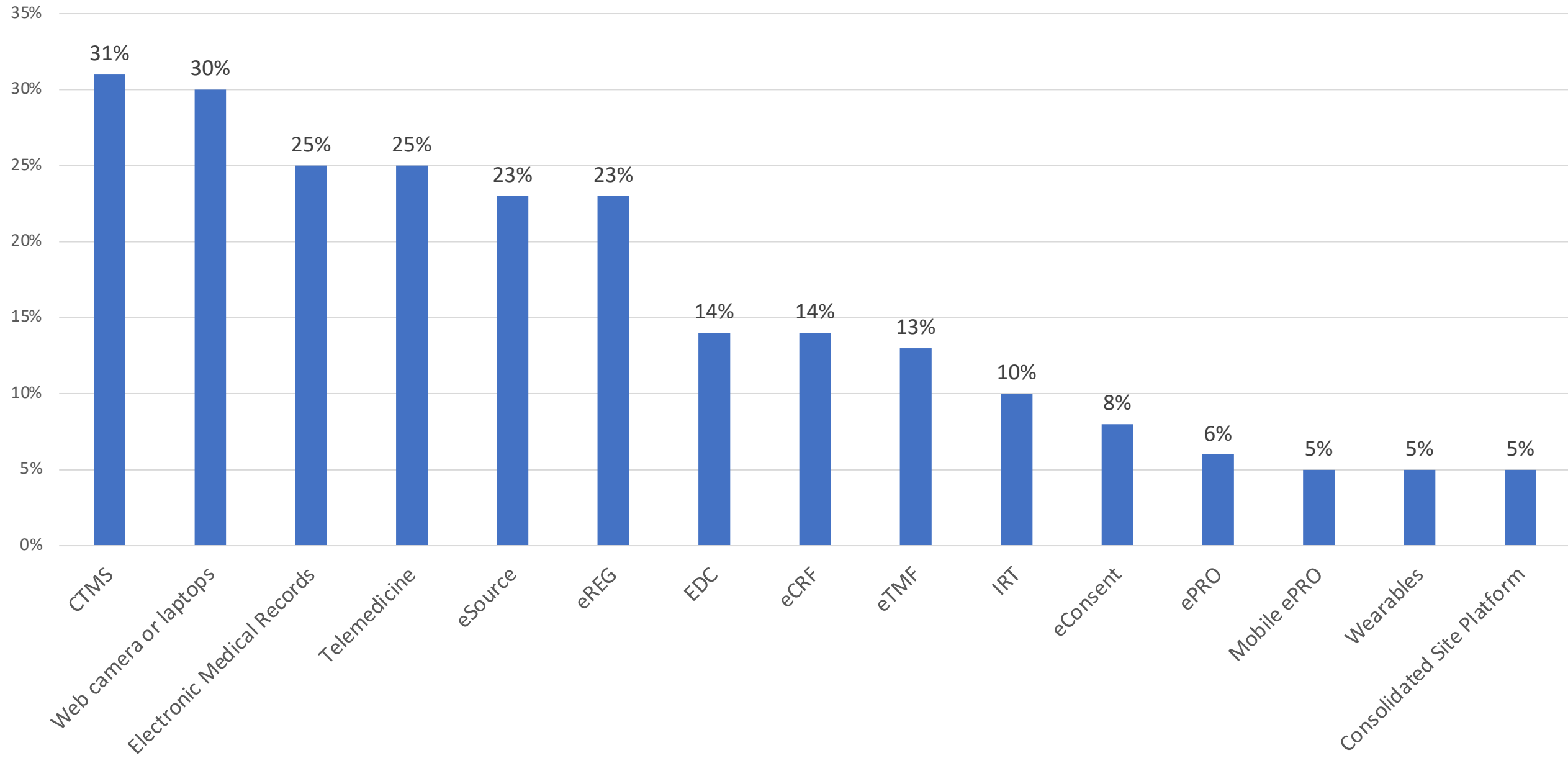
Which of the following technologies are you currently using, or have used, at your site? Select all that apply.
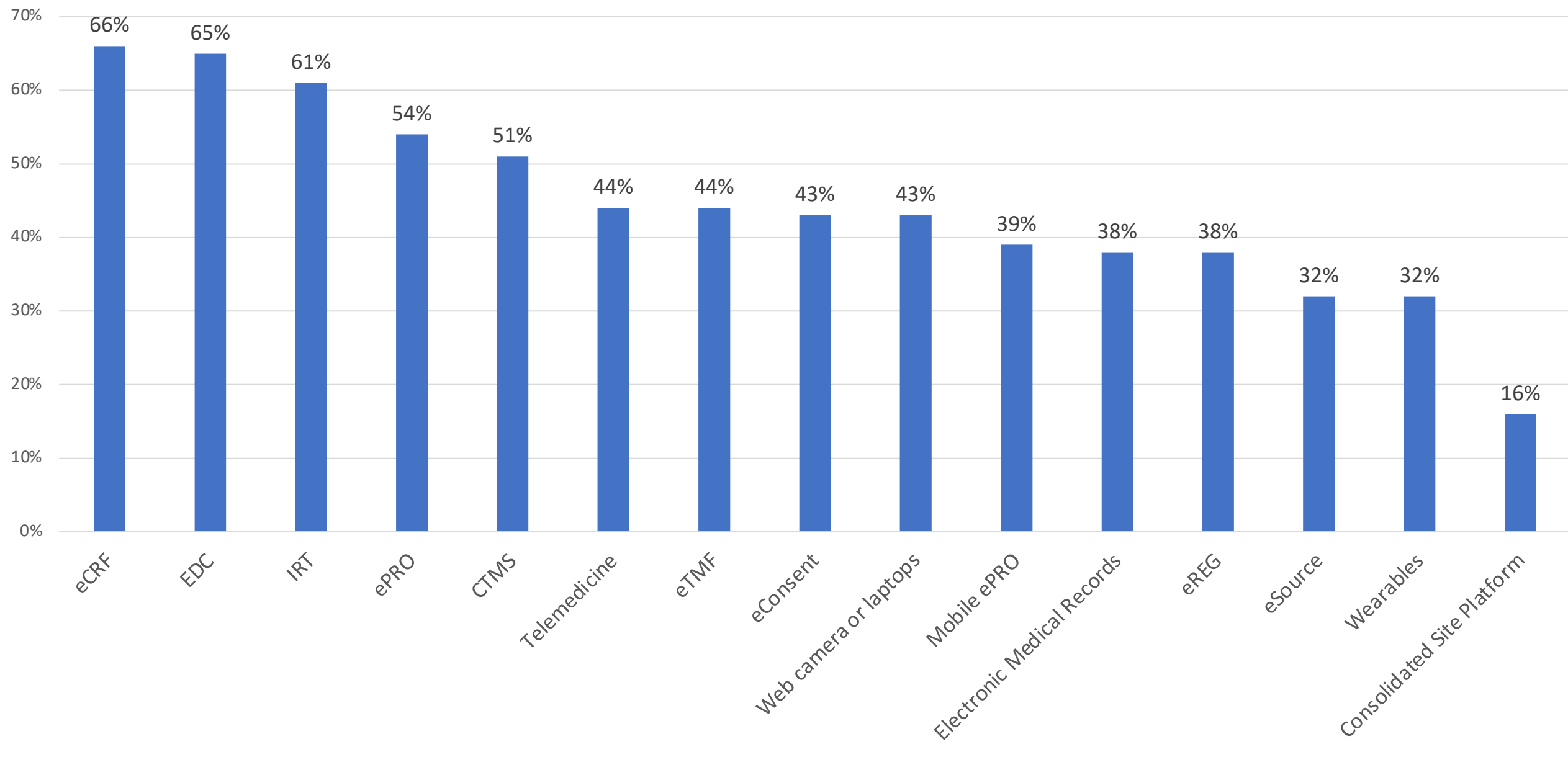
Which of the following technologies are you NOT using, that you intend to implement at your site? Select all that apply.
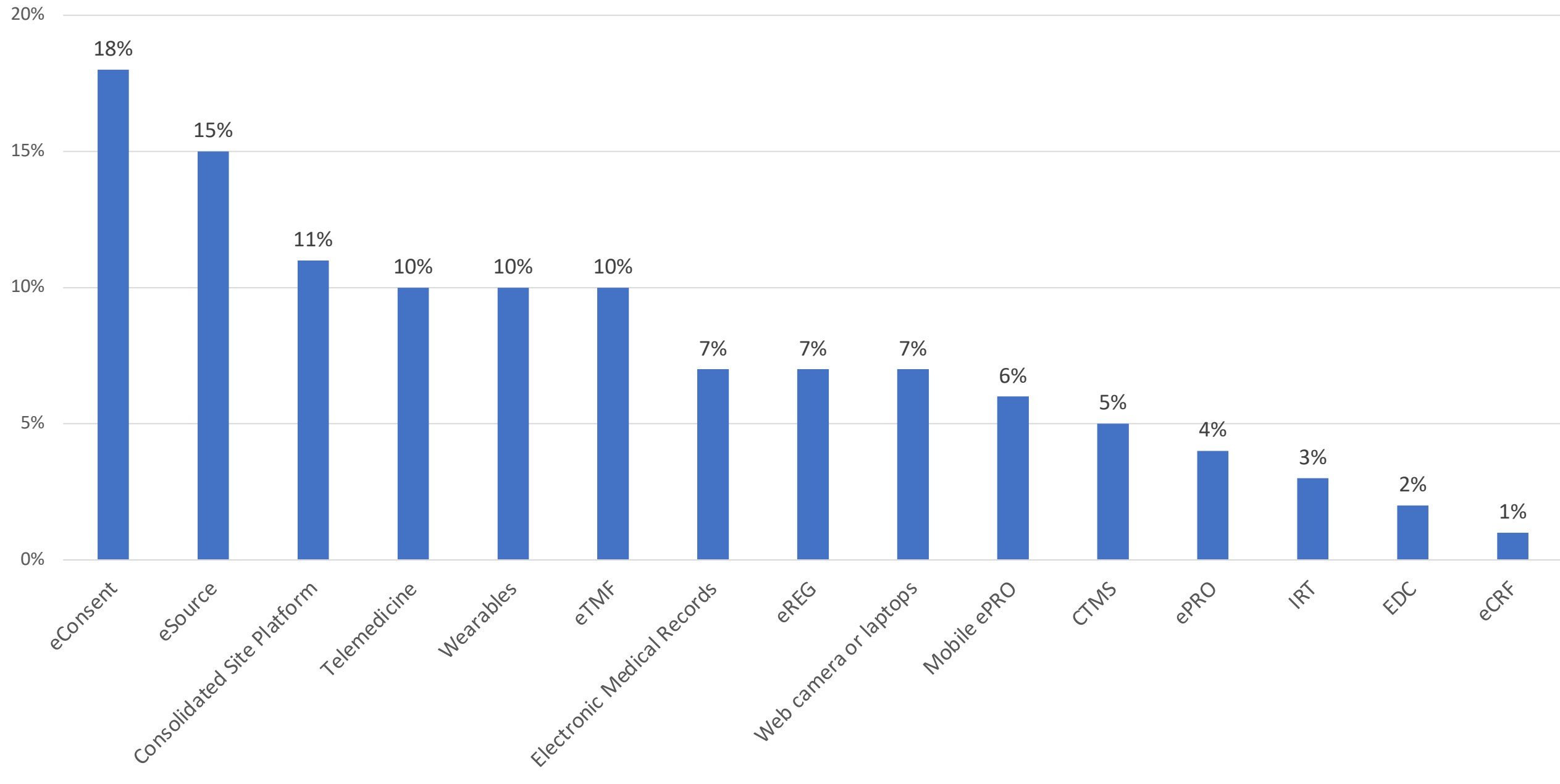
Which of the following technologies has your site invested in or adopted organizationally? This would be opposed to using just what a Sponsor or CRO requires. Select all that apply.

Which of the following elements or components of a decentralized trial are you willing or planning to utilize at your site? Select all that apply
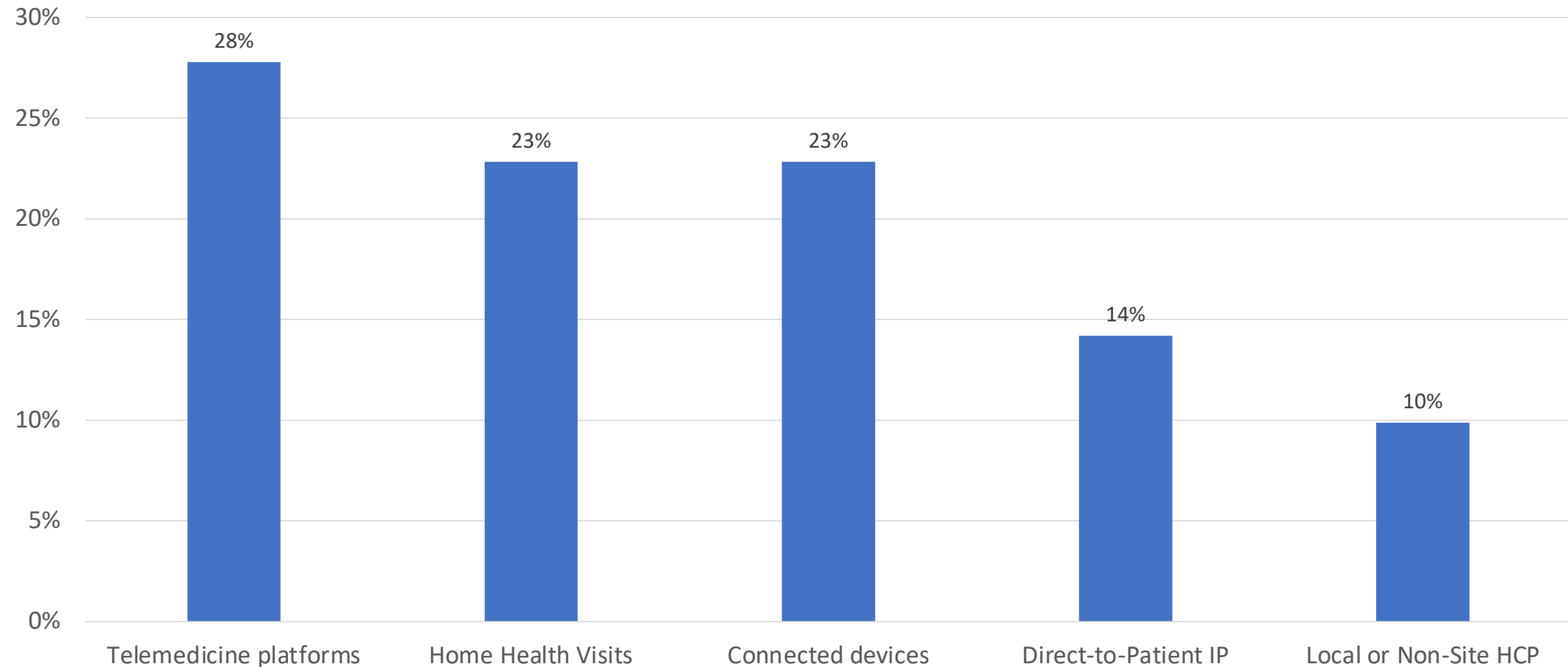
Which of the following elements or components of a decentralized trial are you currently able to or have utilized at your site? Select all that apply
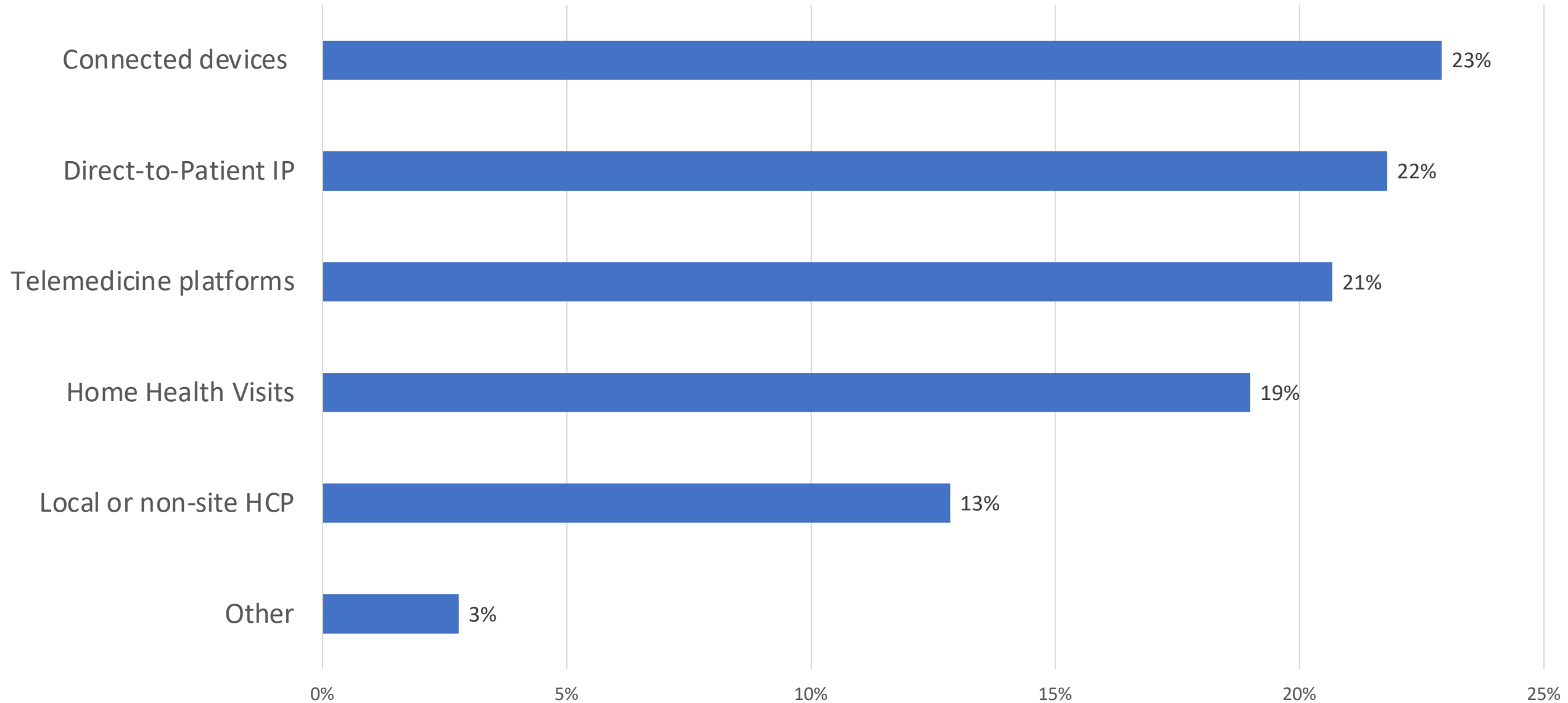
Do you feel that training for trials with decentralized elements take more time than those without decentralized elements?

Unsure 20%

No 18%

Yes 62%
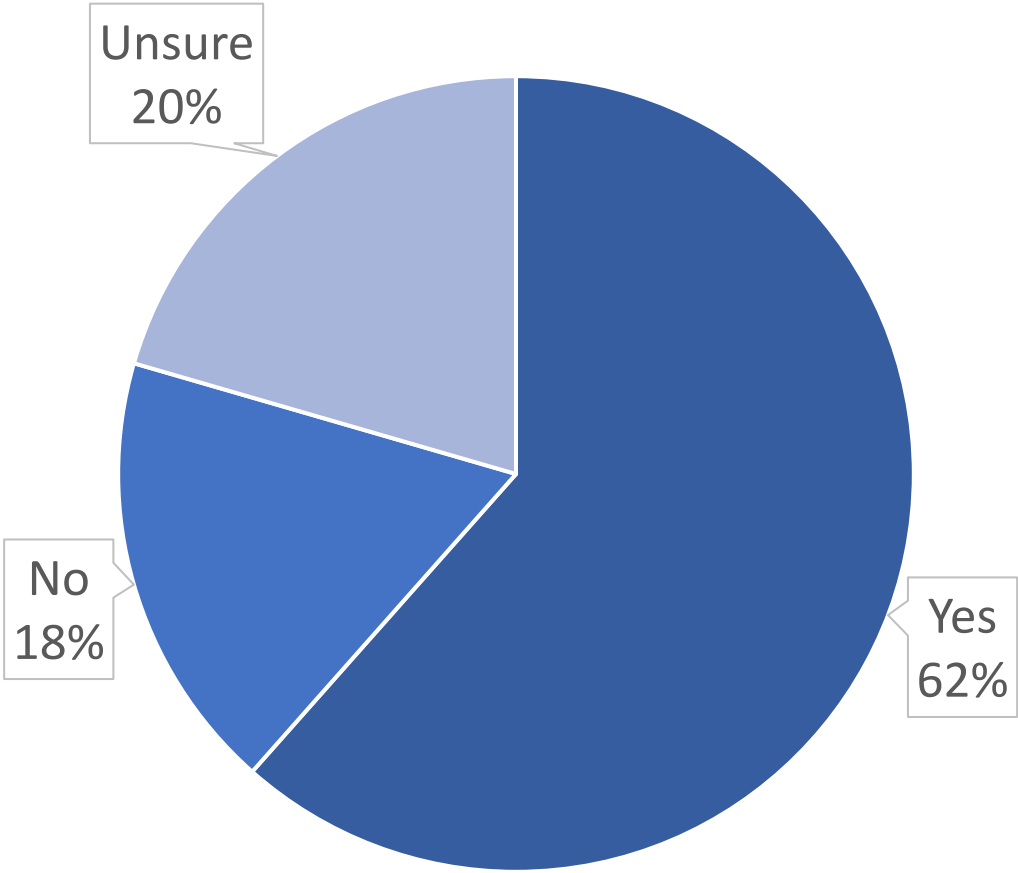
How much estimated time in number of hours does your site spend, per month per trial on average, on training for trials with decentralized elements as compared to a trial without decentralized elements?

Minimum	Maximum	Mean
0	90	17.52

Do you predict that 100% decentralized / virtual trials, in which participants will not be seen at the study site, will have a negative effect on site sustainability?

Probably will not
11%

Definitely will not
1%

Definitely will
39%

Might or might not
19%

Probably will
30%
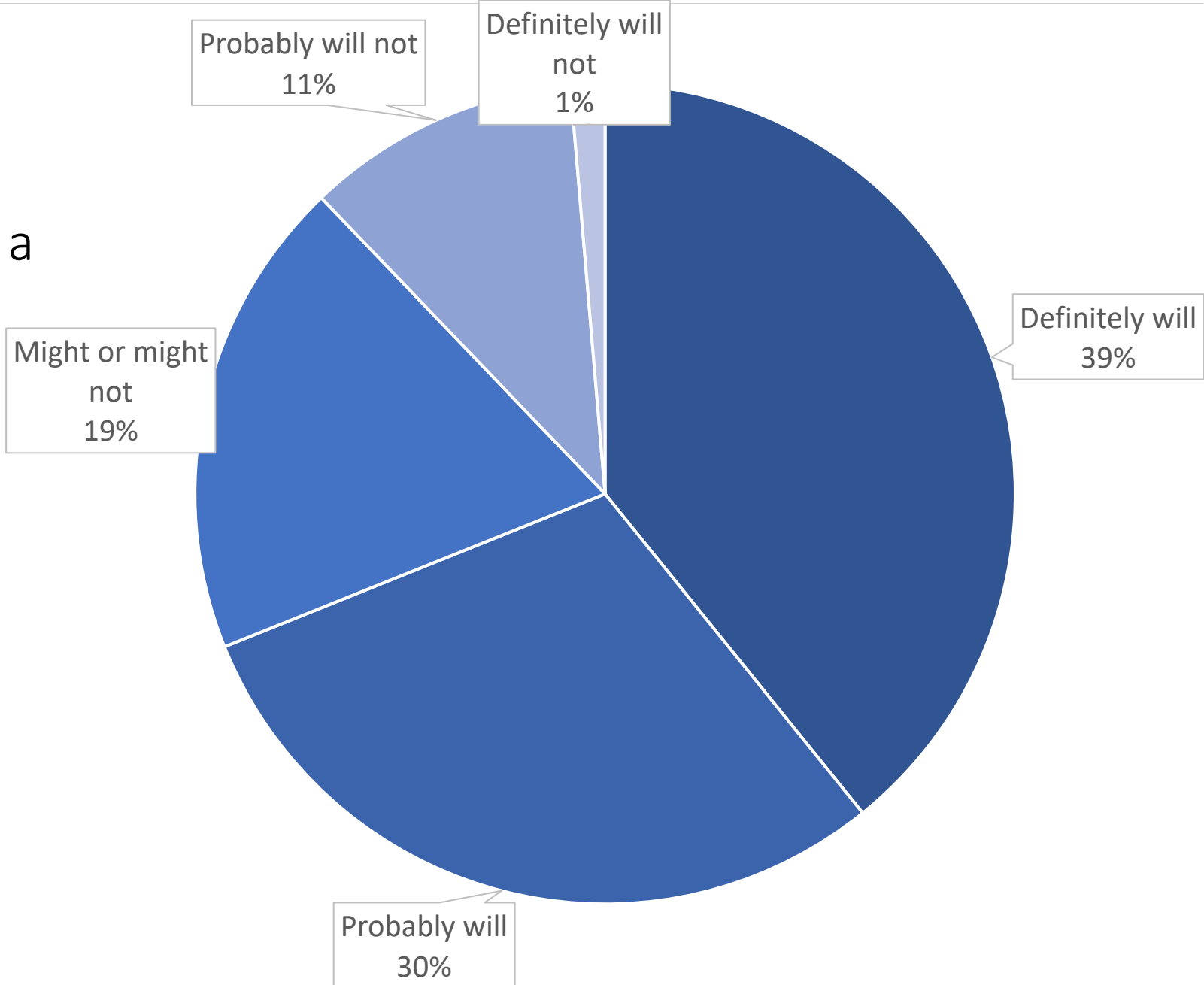
Do you feel that your site is being fairly compensated for the work and effort involved in DCT's

Unsure / N/A
10%

Yes, in all instances
7%

Yes, in some instances
35%

No
48%
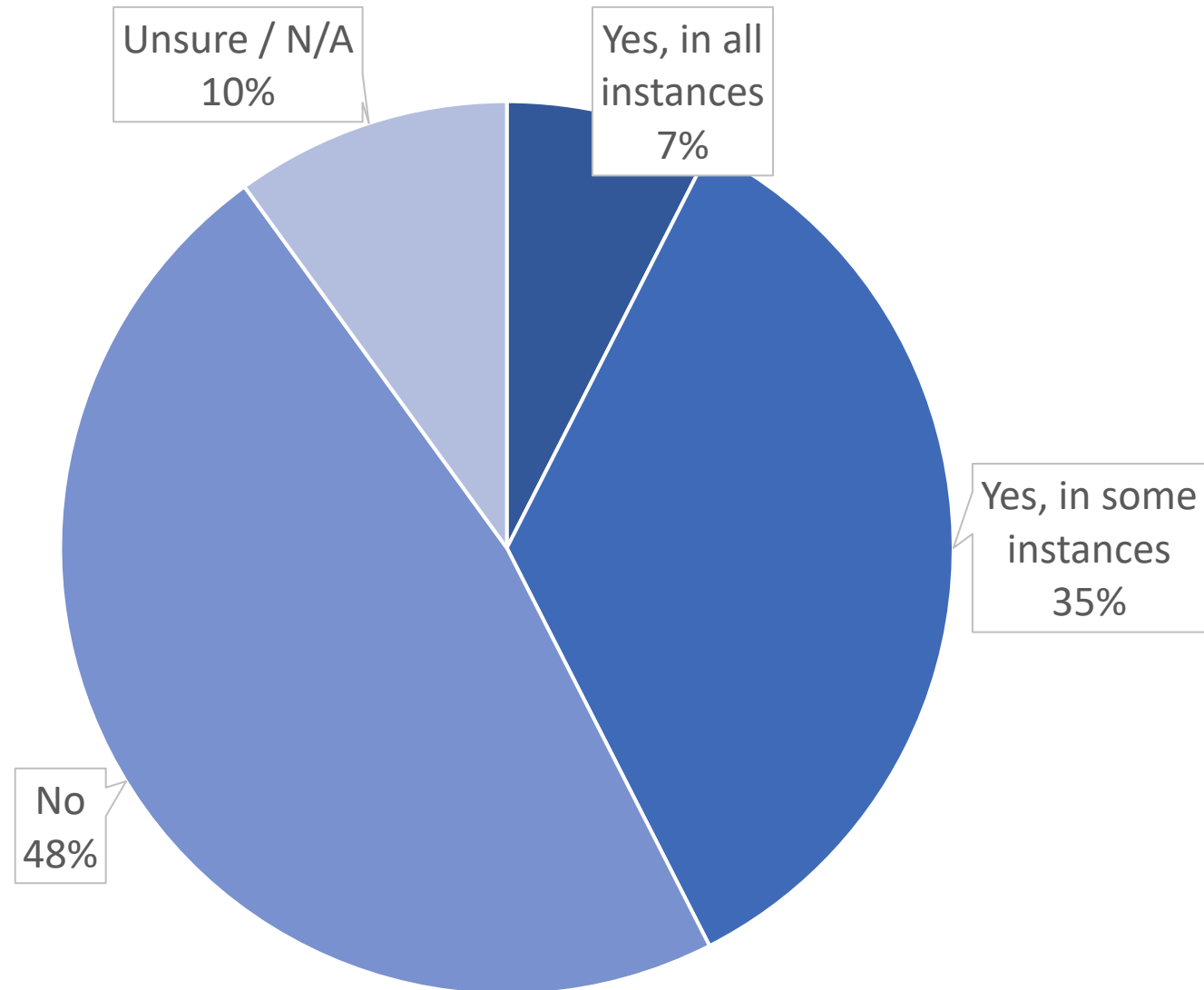
What role could SCRS play with regards to virtual / decentralized and hybrid trials that would have the greatest impact for your company? (Rank the top 3)

Legend: ■ Most important role ■ 2nd most important role ■ 3rd most important role

Categories (top to bottom):
- Other
- Develop feasibility tools for these types of trials
- Actively advocate for the site voice to be considered
- Develop best practices for sites pertaining to virtual and hybrid trials
- Educate sites on new virtual/hybrid technologies
- Develop a training process for sites focused on virtual and hybrid trials
- Be a resource for sponsors looking for PI's to oversee/participate in virtual and hybrid trials
- Provide education to industry on how to include sites in virtual and hybrid trials
- Provide education on virtual and hybrid trials to sites

X-axis: 0%, 10%, 20%, 30%, 40%, 50%, 60%

Future Work –

- What does this mean?

- What do we do with this data?

- Do any data points stand out for us to incorporate?

- How does that affect our training program?

Future Work – Breakout Groups

- Breakouts – 45 minutes

- Establish the Starting and Ending point for this Journey
  - On or around Protocol design

- Assure focus – The site. This is for them and it needs to be focused on information they need

- What are the key positions of this journey? Elements, considerations, points of mention
  - What do the sites need to know along the way
  - What are the "stops" along the journey?

- After that, build out each of these "stops"
  - What does each one need to explain or portray?
  - What is the important information here?

Virtual Trial Capable Training

- ~30-minute series of video modules

- Check for Understanding

- Previous Training had
    - Introductory Video on DCTs
    - Tele-health best practices
    - Initiating Patient Contact
    - Capturing and Entering Patient Data

- What else do we want to have?

- Are these the right things?

- Issue a Certificate and badge post-completion

- Sponsor/CRO recognized

Project Work Progress

- **Phase 1 – Definitions and Scope**
  - ✔ Settle on terms to define, where to find definitions
  - ✔ Establish Scope and purpose of publication
- ➡ Phase 2 – Recommendations
  - Establish what sites need to be prepare for DCTs
    - Staffing, Finance, Operations, Technology, Regulatory
- Phase 3 – Recommendations Tool
  - Checklist/reference guide
- Phase 4 – Resources Available

Recap and Next Steps

- Finalize Survey collection
- Continue to develop content for the Training
- Groups at next meeting