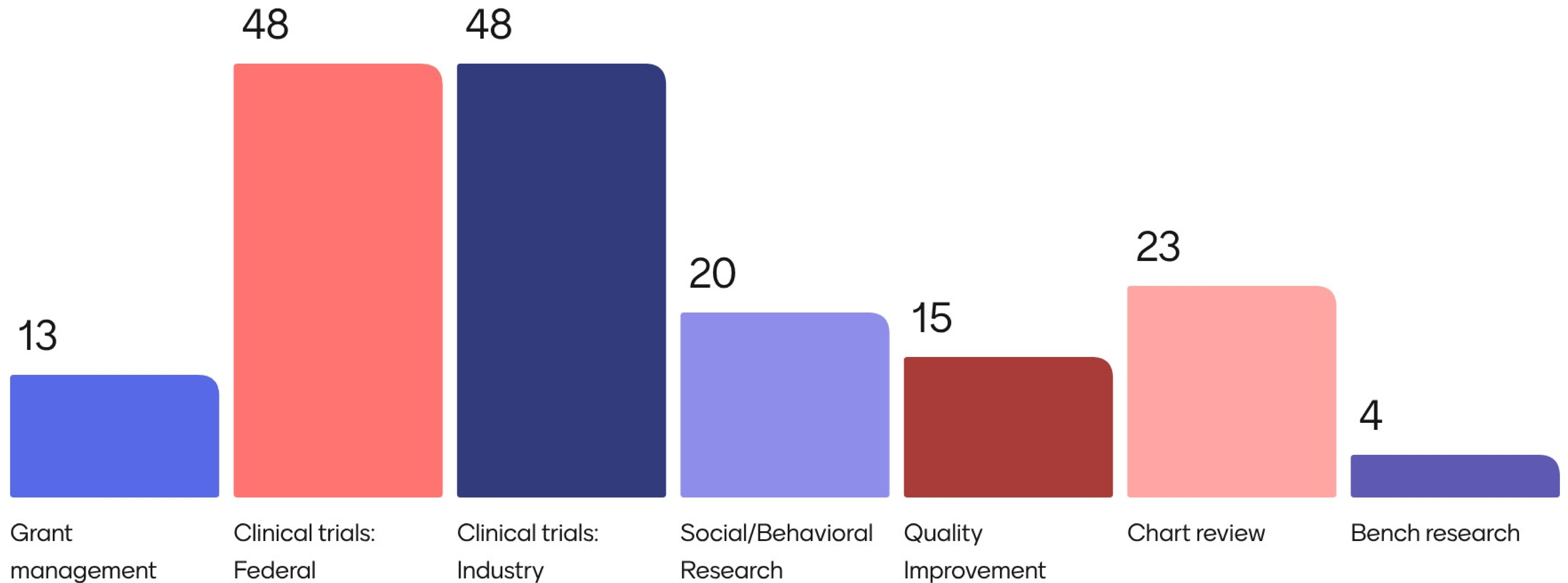


What is your current role?



What research projects are you currently working on?



What are your biggest organization challenges?



SMART Goal - Example 2 - Specific

focus on screening /
enrollment tracking

Barriers to enrollment

Increase recruitment

Increase recruitment by
15%

Recruit X patients at
each site.

We want to recruit X or
% goal amount of
participants

Prescreen clinic
schedule on Monday at
10:00AM

Who is involved

SMART Goal - Example 2 - Specific

Flyers

Increase recruitment by 20% in the next 2 months.

Have a target number

Increase number subjects

Increase recruitment

hang posters advertise

Increase recruitment from X to Y

Media advertising

SMART Goal - Example 2 - Specific

Increase recruitment goal by 10% in 3 months

create a survey on what is not going as planned

Enroll 3 participants in the next month

Specific: talk to X amount of patients after their clinic visits each week

Recruit # of patients per week/per month

Enrollment will increase from the three month baseline by "X" over the next 6 months; and then re-evaluate

Screening the clinic visit for upcoming week for eligibility

Identify why. Target the problem. Determine how much can be gained. Make a target of % increase over how much time

SMART Goal - Example 2 - Specific

Target number of screening per day

Recruit at least 10 participants at each site in the next 2 months.

Recruit additional X amount of participants by end of year

Increase recruitment at all study sites

Prescreen surveyd

Review current practice and consider new strategies.

focus on tracking

Set realistic enrollment goals based on specific patient population information

SMART Goal - Example 2 - Specific

Implement new tools
post snslydis

prescreen clinics weekly

Overdue data in the
database - Coordinate with
the CRCs to let them know
data that is due via tasks
teams tiles

Keep track on a screening
enrollment log and color
code recruitment statuses
"passed, screen failed, etc"

X amount of annual
accruals

SMART Goal - Example 2 - Measurable

review weekly
information

30 posters hung on X
week

Goal of X amount per
month

Meeting weekly for
updates

How many ppl are being
reached, how many eligible,
how many consent, etc

software survey
responses

Identify 5 patients to
prescreen for the study

Put a due date on the task
and track when it is
complete by days that it
takes to complete and enter
data

SMART Goal - Example 2 - Measurable

X number screened
per/week or day
compared to past

X amount of clinic
patients per week

Determine what a realistic
increase of recruitment
would be. Define what the
increase goal should be and
where it stands each week

XX \$ worth of
recruitment adds posted
to social media

Numbers in enrollment
logs each week

20% increase in 2
months.

how many patients have
been consented or
contacted since
prescreening clinics

X amount of annual
accruals

SMART Goal - Example 2 - Achievable

set a certain goal each week

plan to contact 3-5 patients weekly

NOT "I will enroll everyone by next week"

Have check ins with recruitment staff in weekly touch points

Assess current enrollment to see if it is realistic in relation to it

Make timelines within reason and requirements

goal is within the time you already have available on your calendar

Review x amount of clinic patient charts for prescreenin

SMART Goal - Example 2 - Achievable

What goal would be realistic and how could it be obtained within reason. Is it actually helping the goal overall

set a time period to have a team meeting to encourage communication

Set a goal within a timeline

Do you have the tools you need to reach the goal?

Increasing recruitment can ensure success of study.

SMART Goal - Example 2 - Relevant

To not make the sponsor mad

Need to have patients on the study

Everyone loves to keep their funding

hit target numbers!

Meet study data needs

Meet sponsors and facility goals and also possible author lines

Relates to keeping the study ongoing and funded

increase enrollment = better quality data for study outcomes

SMART Goal - Example 2 - Relevant

Yes - to meet study timelines

Meet study goals

Meeting site specific recruitment goals is important for the sponsor and to stay as a competitive site.

To obtain NCI designation/qualify for grants

Can have an effect on payment milestones

Keep positive relationship with sponsors

Helps the study continue overall and achieve their goals as well as ours

meet study timelines and goals

SMART Goal - Example 2 - Relevant

Strive to meet enrollment numbers especially early enrollments

To have sufficient data to support the aims of the project.

Consider a reasonable time for each specific study

Assess factors that affect the time within which the increased recruitment target can be met.

SMART Goal - Example 2 - Time-bound

making sure you have time set aside for these tasks.

Weekly goals come together for overall timeline: 1-2 months

Perhaps 3-6 months

3 months

First 6 months

be realistic and plan accordingly

Timelines may be dependent on overall recruitment. Are there issues with study I/E. May need to re-evaluate the study at the site for finances vs. increasing recruitment and changing strategies

Wanting to achieve recruitment goal but how can it be done in a reasonable time and is it otherwise taking away from what would have been time already spent

SMART Goal - Example 2 - Time-bound

you could assess progress month to month to see if you could increase enrollment, decrease time spent, etc

Could set aside 30 minutes every other week to debrief with study staff and reassess.

Strive to enroll early

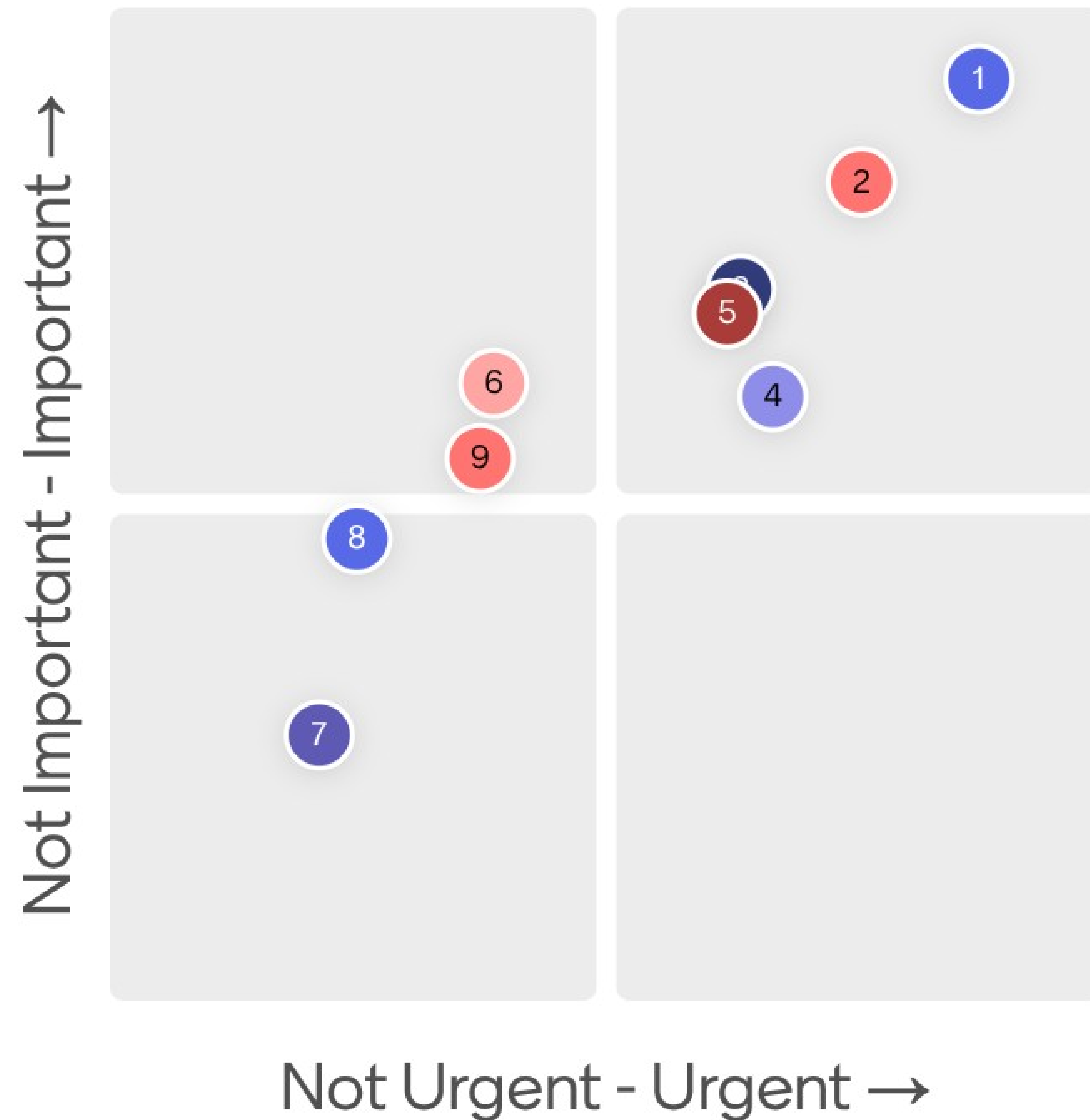
3-6months; or based on patient population seen

Be realistic based on current workload

Understand that when new sites are added enrollment should pick up

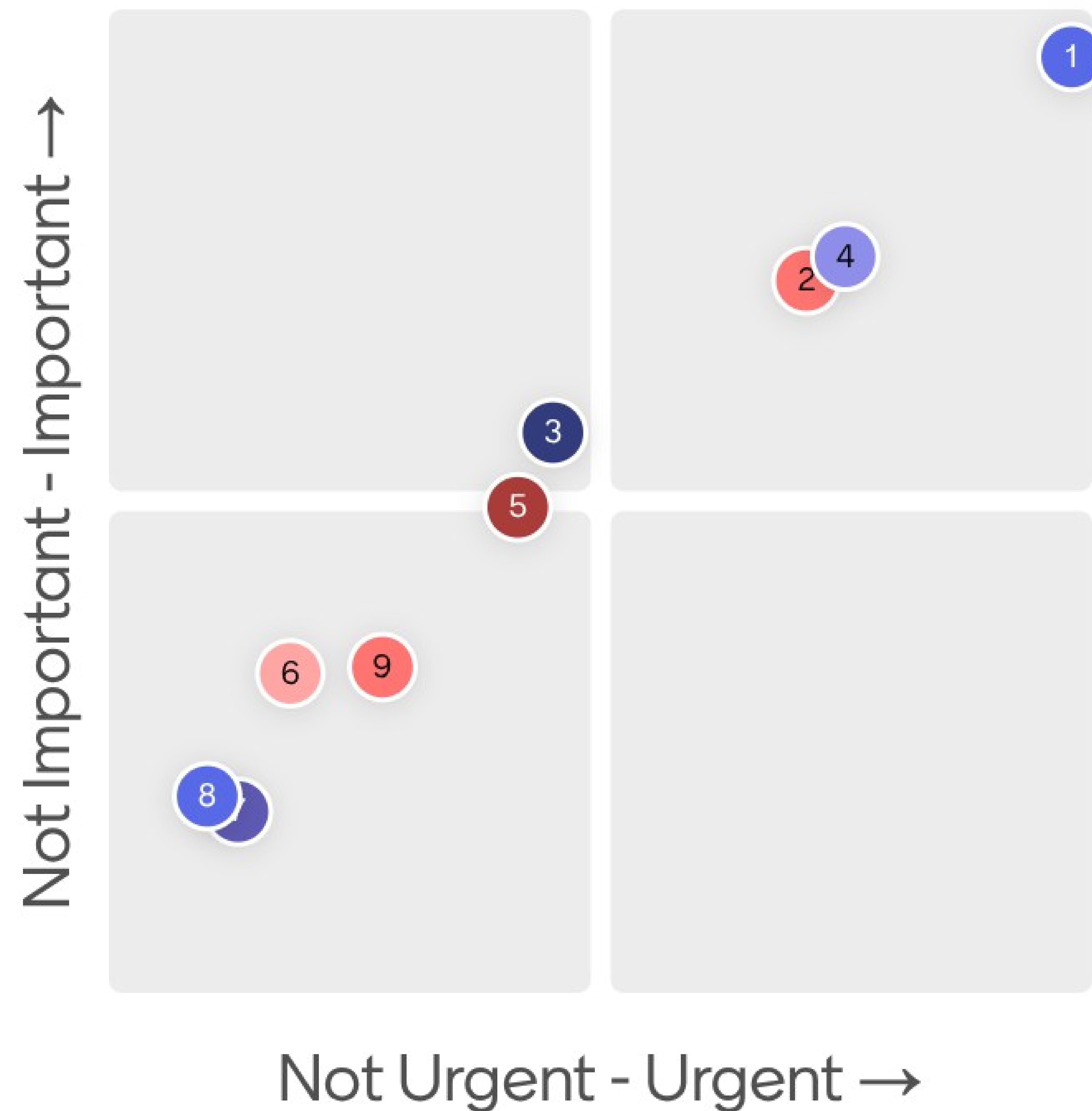
follow it for 3 months , then change the strategy if you don't succeed

Scenario 1 - Baseline



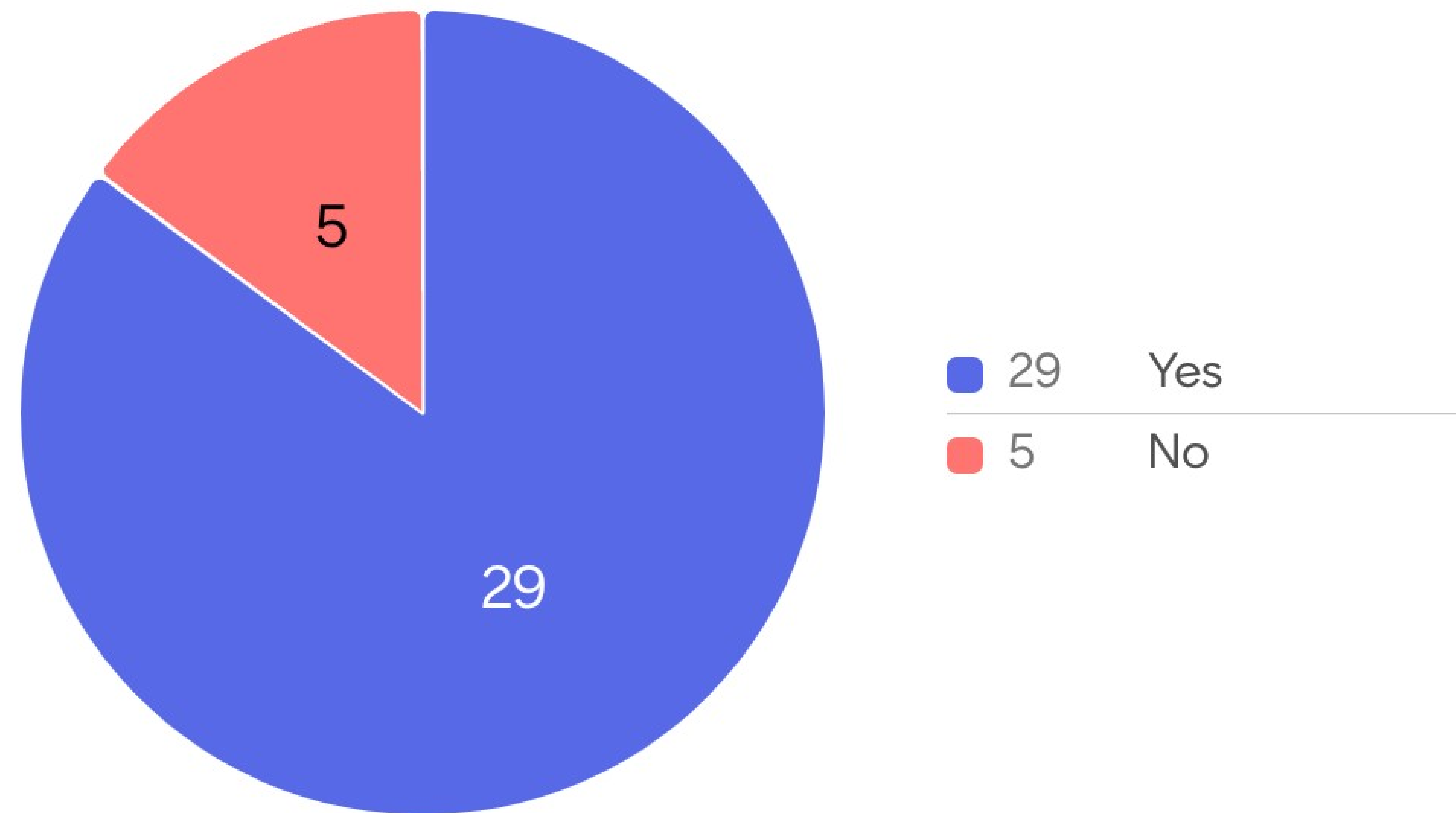
- 1 A patient is scheduled for a screening visit at 9 AM. You need to confirm the lab kit and eligibility checklist.
- 2 Monitor arrives at 10 AM – prepare binder/source documents for Study A
- 3 PI available at 11:30 to sign lab reports and SAE forms
- 4 Sponsor sent urgent query blocking data lock
- 5 Pharmacy needs confirmation for tomorrow's IMP shipment
- 6 Regulatory binder for Study C missing current IRB approval – audit next week
- 7 2 PM team meeting for general site updates
- 8 File last week's signed ICFs
- 9 Schedule two patient follow-ups by end of day

Scenario 1 - Time Constraints

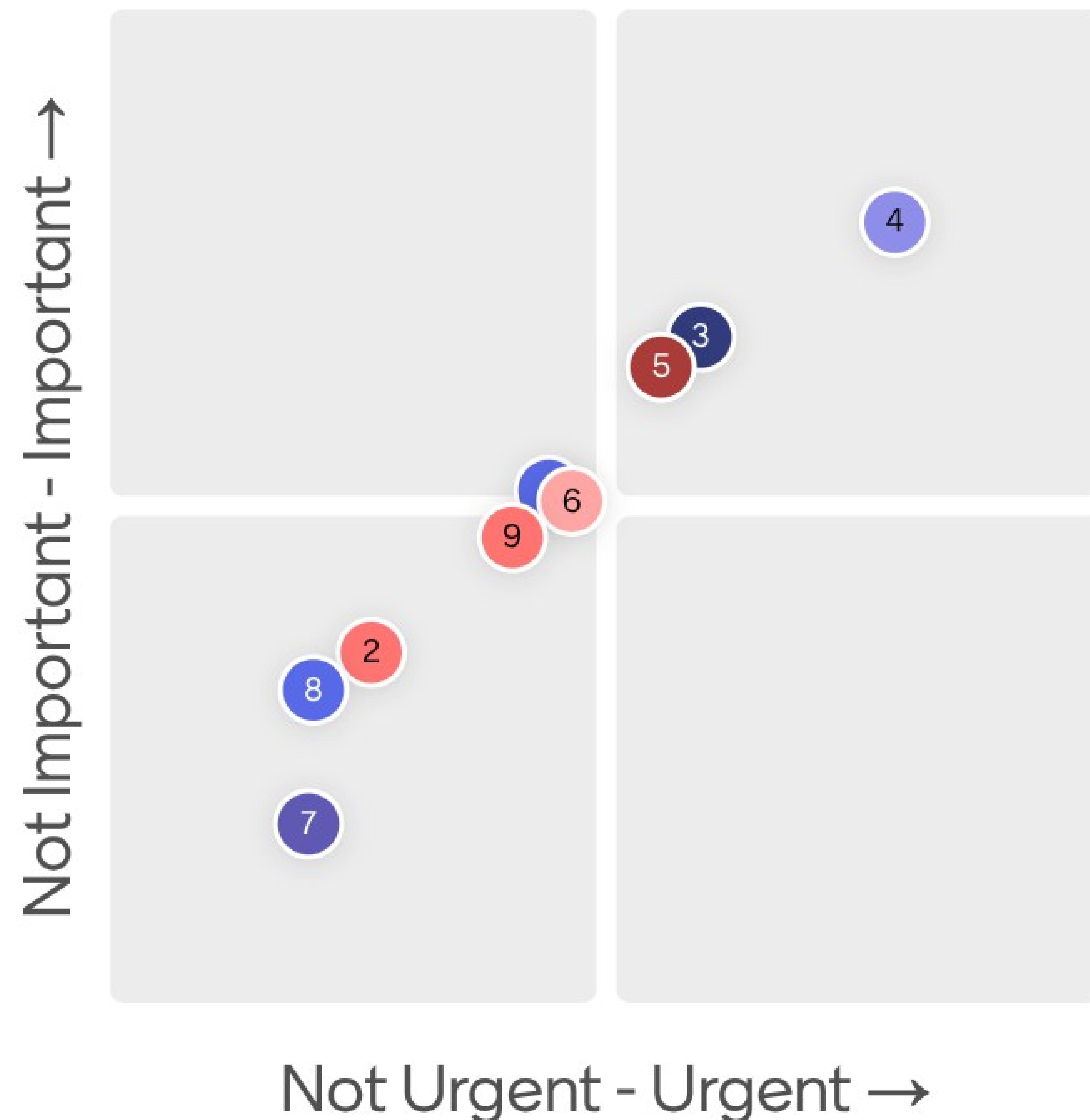


- 1 A patient is scheduled for a screening visit at 9 AM. You need to confirm the lab kit and eligibility checklist.
- 2 Monitor arrives at 10 AM – prepare binder/source documents for Study A
- 3 PI available at 11:30 to sign lab reports and SAE forms
- 4 Sponsor sent urgent query blocking data lock
- 5 Pharmacy needs confirmation for tomorrow's IMP shipment
- 6 Regulatory binder for Study C missing current IRB approval – audit next week
- 7 2 PM team meeting for general site updates
- 8 File last week's signed ICFs
- 9 Schedule two patient follow-ups by end of day

Did your answers change?

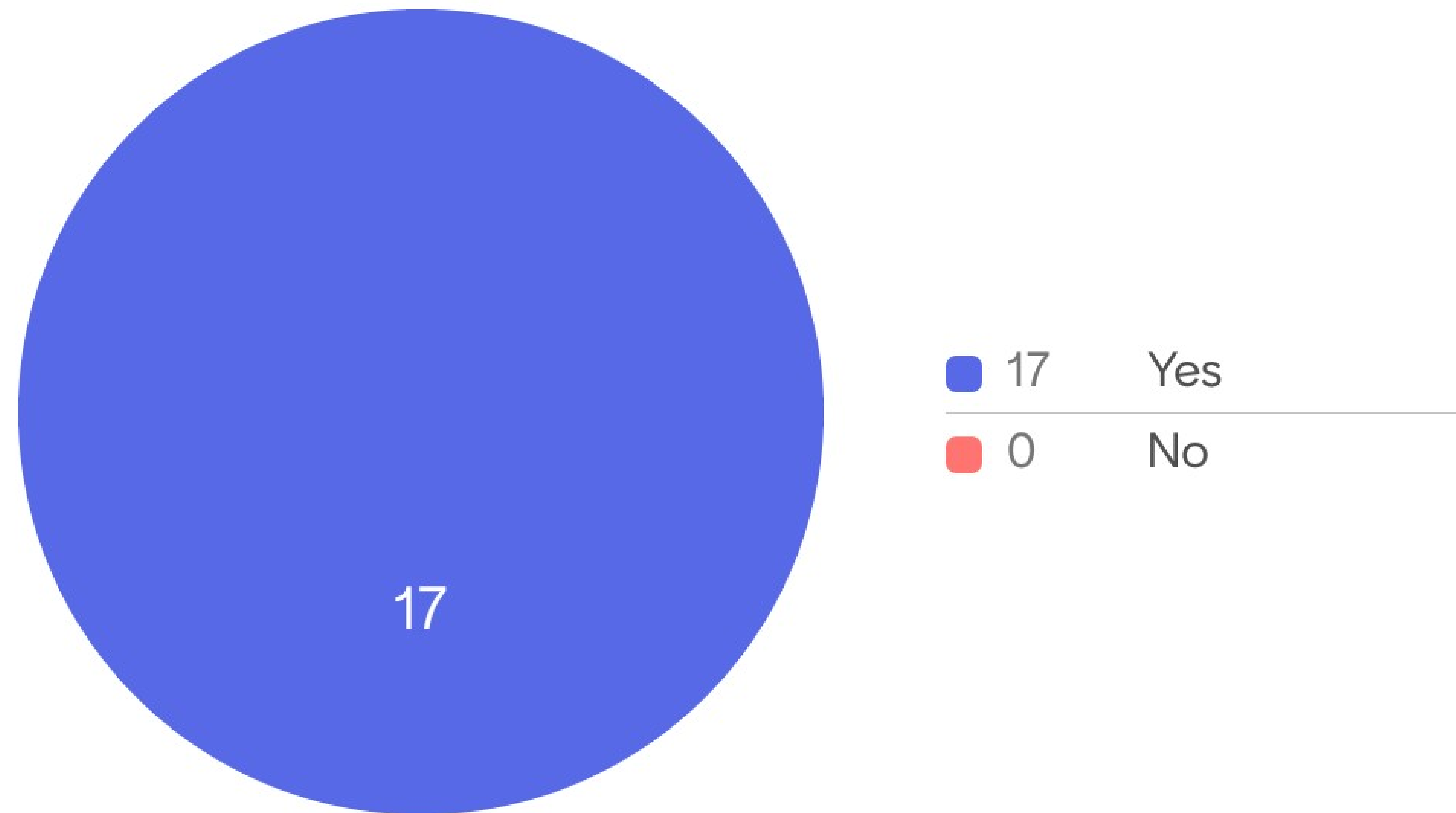


Scenario 1 - Staff Disruption



- 1 A patient is scheduled for a screening visit at 9 AM. You need to confirm the lab kit and eligibility checklist.
- 2 Monitor arrives at 10 AM – prepare binder/source documents for Study A
- 3 PI available at 11:30 to sign lab reports and SAE forms
- 4 Sponsor sent urgent query blocking data lock
- 5 Pharmacy needs confirmation for tomorrow's IMP shipment
- 6 Regulatory binder for Study C missing current IRB approval – audit next week
- 7 2 PM team meeting for general site updates
- 8 File last week's signed ICFs
- 9 Schedule two patient follow-ups by end of day

Did your answers change?



What factors did you consider when making decisions?

Participants come first!

patient safety

Participants are
prioritized

Safety of pt

Participants are priority

Whether the task not being
done would negatively
affect the pt or study

Safety and participants
prioritize

Subject priority

What factors did you consider when making decisions?

Patient safety

patient care first

Patient safety

Regulatory compliance
(AE reporting)

Preparedness for next
task

Safety

Time

What I could delegate, what
I can comfortdo in my time
allowed and patient safety
and therapy

What factors did you consider when making decisions?

Participants are key.

reg compliance

Research participants are priority as they are the timepoints that matter

patient/ participants first!

protocol deviations

subject safety

How our tasks affect participants, as far as when we complete them and how we complete them

Regulatory compliance

What factors did you consider when making decisions?

Can the task still be accomplished at another time without negative impact?

Patient safety, protocol compliance

Time it takes to complete task

Patients are priority first and foremost. Those timepoints must be collected and the patient's time is just as valuable. The other stuff can be done later since things have already been collected

Hard to say in a hypothetical situation, not knowing details of the setting, available resources, capabilities of individual staff, etc.