

Clinical Cancer Research During COVID-19: *Challenges & Potential for Patients*

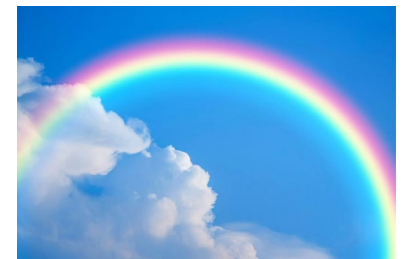
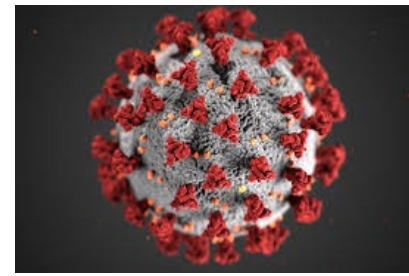
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Who Am I and Why Am I Here



- ▶ Jane Perlmutter (janep@gemini-grp.com)
- ▶ Long-term cancer survivor and active research advocate
- ▶ Especially interested in:
 - Innovations that can accelerate the development of better treatments for the patients who need them
 - Clinical trials that are patient friendly and will therefore rapidly accrue and meet patient needs
- ▶ Steering Committee member for I-SPY and TAPUR trials
- ▶ Advocate member of NCTN Alliance and ASCO's "Road to Recovery" Project



	Pre-COVID	During COVID	Post COVID
Public Awareness/Interest in Clinical Trials	Limited	Increasing	Continuing Interest
Health Disparities	Limited awareness	Increased Awareness	Increased action to ameliorate
Where Clinical Trials Take Place	Heavily reliant on academic hospitals	Sometimes suspended	More distributed
Focus of Clinical Trials	Heavily research focused	Reduction in non-critical components	More focused on impacting treatment
Accrual in Cancer Clinical Trials	Limited--~5% of adults	Initially slow; currently similar to pre-COVID	Increasing as trials become more patient friendly

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KNOWLEDGE CONQUERS CANCER

Road to Recovery: Learning from the COVID-19 Experience to Improve Clinical Research

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Road to Recovery: Research Goals

Goal 1: Ensure that clinical trials are accessible, affordable, and equitable for patients

Goal 2: Design more pragmatic and efficient clinical trials that are better integrated into routine clinical care

Goal 3: Simplify, streamline, and standardize protocol requirements and trial operations to minimize administrative and regulatory burdens on research sites

Goal 4: Recruit, retain, and support a well-trained clinical trial workforce that is committed to providing patients with access to high-quality research

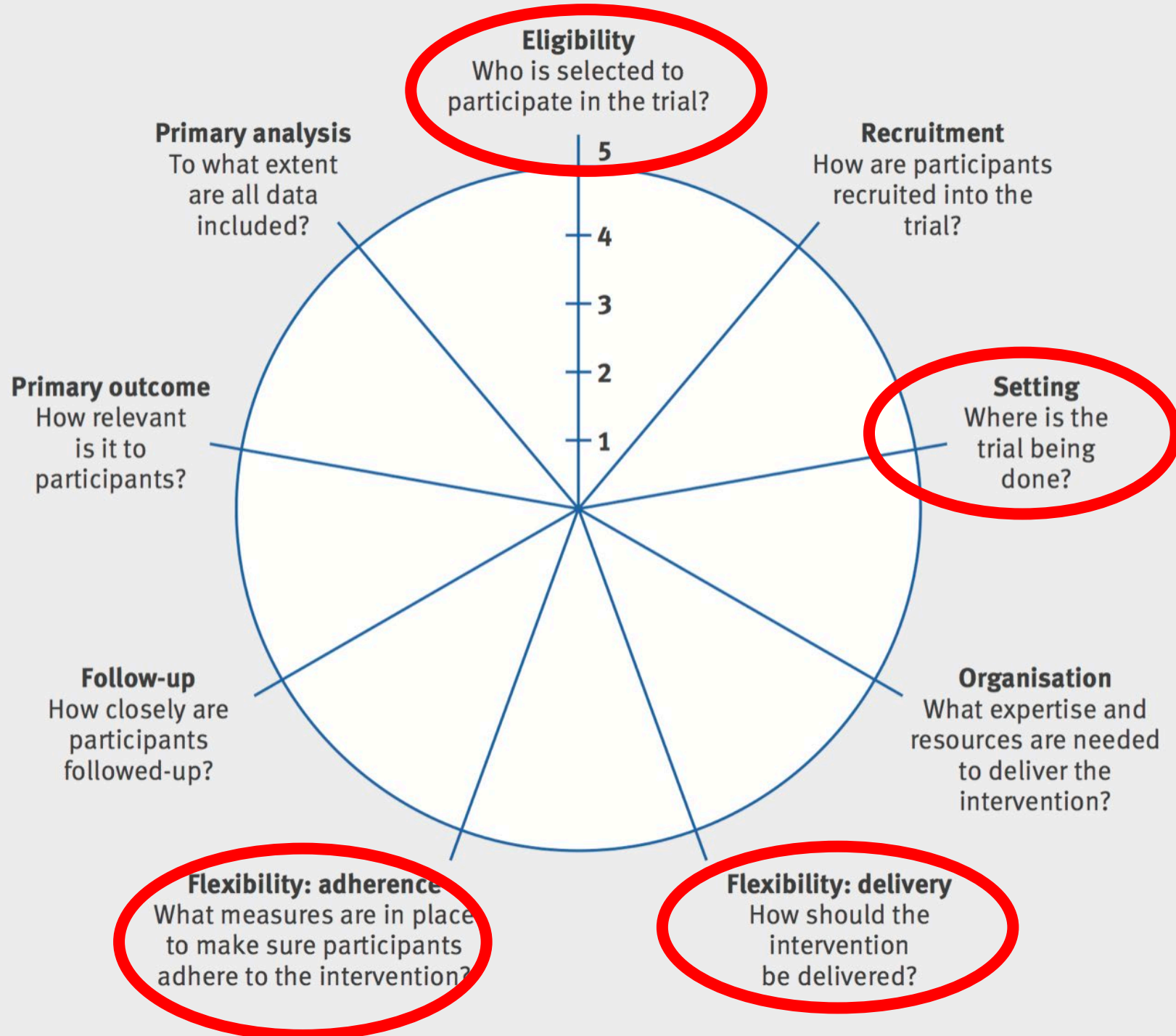
Goal 5: Promote appropriate oversight and review of clinical trial conduct and results

Make CTs More Accessible, Affordable & Equitable

Aspect of Trial	Attributes	Benefits	Challenges
Eligibility Criteria	Limit to protecting patients	- More diverse patients - More generalizable results	Focus on patient safety
Recruitment	Expand into diverse communities	More diverse patients	Developing awareness & trust
Consent	eConsent	- Patient convenience³ - Family involvement	Technology
Health & Symptom Assessment	- Telemedicine - Mobile devices & wearables - Flexible scheduling	Patient convenience³ & financial burden	- Insurance coverage - Technology
Administering Treatment	- Use oral drugs with home delivery when feasible - Allow local and/or home administration for IV drugs	Patient convenience³	- Logistics - Financial transfers
Collecting Biospecimens	- Use local sites - Reduce collections	- Patient convenience - Reduced cost	May jeopardize exploratory research
Imaging Assessment	- Use local sites - Reduce assessments - Flexible scheduling	- Patient convenience - Reduced cost	May require central review

PRECIS-2
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9 Dimensions of Pragmatism



Pragmatic Trials

- Are not all-or none; there are many dimensions on which trials may be more or less pragmatic
- Are not biased; they generally include randomization
- Are likely to increase error variance and thus require more participants
- Are generally more patient-friendly and thus likely to accrue more rapidly
- Are especially well-suited to establishing effectiveness; may be less relevant for registration trials

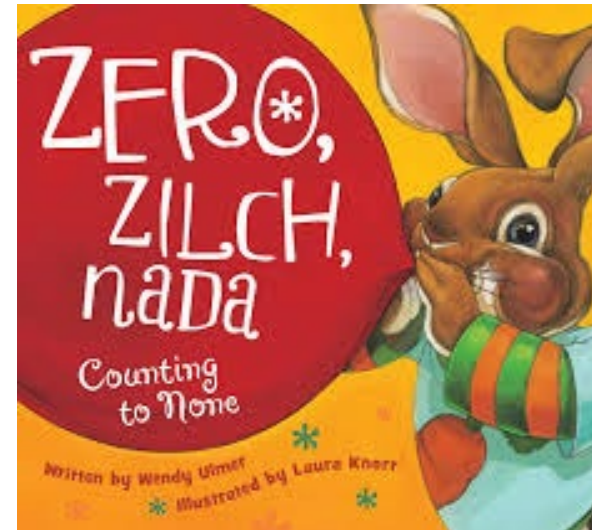
What is the Value of a Treatment that is Efficacious but NOT Effective?

***Efficacy trials** determine whether an intervention produces the expected result under ideal circumstances. **Effectiveness trials** measure the degree of beneficial effect under “real world” **clinical** settings.*

For Drug Companies



For Patients



- Be Flexible
- Be Innovative
- Be Thoughtful
- Don't Jeopardize Patient Safety or Scientific Integrity

THE POST-COVID RECOVERY

an agenda for resilience,
development and equality

DON'T GO BACK



Build
Back
Better