

How Do We Get from Here to the Next Patient-Centered Long COVID Clinical Trials

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RECOVER-TLC Path Forward

Learning from ACTIV and other clinical trial networks - we love to see it

- Should reflect the **urgency and collaboration** of ACTIV and **meaningful patient engagement** of HIV/AIDS Clinical Trials Network

Agent Submission Portal - cool

- Need patient and caregiver **representation on panel**
- Get patient input when choosing **who is on the panel**
- Criteria and scoring/weighting chosen **with patient input**
 - “Safety” can have different thresholds and mean different things between a researcher and a patient
 - Data is biased. Preclinical and clinical efficacy data can have different levels of quality and meaningfulness to patients (e.g. is it testing exercise or a video game? **No thank you!** Already tried!)



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RECOVER-TLC Path Forward

Clear need for **both** larger platform trials and smaller experimental/proof of concept trials

- Need **funding mechanisms** for both and a **coordinator**, esp. for trials that are done outside of network/not chosen from agent submission portal (Office for IACCI Research)
- Network to be used to also validate smaller trials' findings

Trials are great opportunity to do the biologically probing work necessary to characterize, phenotype, etc.



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Choosing interventions

- **Curative** top priority
- **Accessible**
- **Wide** array
- Need **both** new drug development and repurposing
- Consider the **end goal/last mile**



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Design

REMEMBER POST-EXERTIONAL MALAISE - we can't ignore it, neither can you. Design for it, measure it.

Types of trials: Decentralized, combination, adaptive, platform, basket, umbrella

Consider medication interactions, whether run in treatment is needed (e.g. salts/fluids for POTS, H1/H2 blockers for MCAS)

Consider phenotypes and comorbidities (e.g. connective tissue disorders, reproductive health conditions)

Comparator groups of non-COVID infection-associated chronic conditions like POTS and ME/CFS

- Remember those impacted by past and future pathogens

Remember what impacts symptoms and disease severity, and account for that in design: illness duration, seasons, mast cell triggers (*could even be from how the drug is formulated!!*), PEM triggers, menstruation, current medications, reinfections, viral reactivations



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Design

Endpoints: Need to **validate PROs** and **continue study & development of objective biomarkers** in parallel to **working with what we have now** (see: REVERSE-LC, Putrino's Truvada & maraviroc trial, Peluso's outSMART LC) and doing **exploratory analyses** (hormone, immune assays, tissue biopsies)

Design using [disability justice principles](#), design as an experience, return results to patients ASAP, use trauma-informed practices

Offer **expanded access** (esp. important while we figure out right endpoints and phenotypes in order to identify signal!) **and treatment waitlist for control group**



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Populations

Responsibility to **entire** community, and to **meet people where they are**

- People who are severe and very severe
- Transgender and gender diverse people
- Black, Indigenous, and people of color
- People with lower socioeconomic status
- People living in rural areas
- Those without a positive test
- Children
- Older adults
- Pregnant people
- Incarcerated people
- People outside of US
- People with other infection-associated chronic conditions
- People with pre-existing conditions

Consider **safety** (require masking, ventilation), **digital equity**, **compensation**, **gender competent care**, **culturally competent care**, **trust**, **separate pediatric trials**

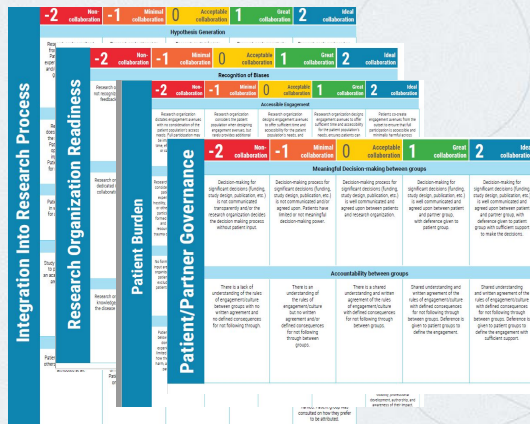
Patient navigators can help

Meaningful engagement of patients throughout

More diverse patient and caregiver representation

Learn from our experiences and other infection-associated chronic conditions

Include us on committees and as reviewers as **real partners** - we want to solve this together



Scorecards available at:

<https://cmss.org/patient-led-research-integration/>



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Designing and optimizing clinical trials for long COVID

Julia Moore Vogel^{a b}  , Beth Pollack^{b c}, Ezra Spier^b, Lisa McCorkell^b,
Toni Wall Jaudon^{b d}, Megan Fitzgerald^b, Hannah Davis^b, Alison K. Cohen^{b e}

Vogel JM, Pollack B, Spier E, McCorkell L, Jaudon TW, Fitzgerald M, Davis H, Cohen AK. Designing and optimizing clinical trials for long COVID. *Life Sci.* 2024 Oct 15;355:122970. doi: 10.1016/j.lfs.2024.122970. Epub 2024 Aug 13. PMID: 39142505.

- + Al-Aly, Z., Davis, H., McCorkell, L. et al. Long COVID science, research and policy. *Nat Med* 30, 2148–2164 (2024). <https://doi.org/10.1038/s41591-024-03173-6>
- + Forthcoming *Cell* article



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**Listen
Learn
Collaborate**
Turn this meeting into action



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