

Institutional Innovation for Neglected Diseases: The Case of the Priority Review Voucher

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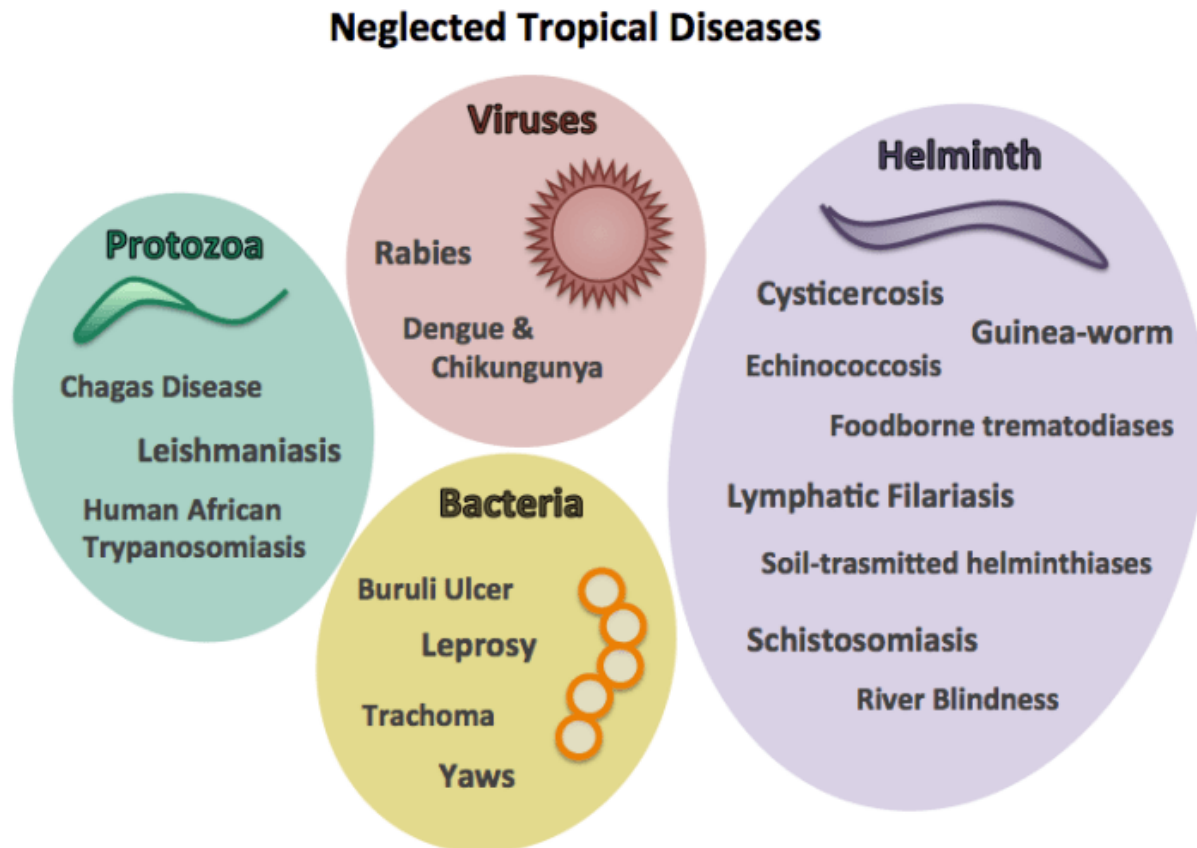
Challenges of Incentivizing Innovation for LMIC

- **Innovation** is critical to economic development, but **R&D capacity** is limited in low- and middle-income countries (LMICs)
 - Limited resources and capacity for R&D, but large disease burdens
- Diseases prevalent in LMICs (e.g., neglected tropical diseases, NTDs) are increasingly relevant to high-income countries (HICs)
- **Push** (can be insufficient) vs. **Pull** (may not be sustainable)
- This paper: focus on a pull policy linking NTDs with US market

Q: How does the U.S. Priority Review Voucher (PRV) affect innovation activities in neglected disease (NTDs) globally?

Disease setting: neglected tropical diseases (NTDs)

- A diverse group of conditions caused by a variety of pathogens
- Complex epidemiology, often related to environmental conditions
- Annual: affect 1+ B people, ~200,000 deaths, 19M DALYS



Policy: the US Priority Review Voucher (PRV)

- Eff. in 2007 (Ridley et al., 2006): a firm that obtains FDA approval for a designated NTD drug receives a **PRV for priority review of another drug**; can **use or auction** the PRV for \$ (\$100-350M)
- 16 PRV-eligible diseases on the 2007 initial list by Congress
 - Blinding trachoma, Buruli ulcer, Cholera, Dengue, Dracunculiasis, Fascioliasis, Human African trypanosomiasis, Leishmaniasis, Leprosy, Lymphatic filariasis, Malaria, Onchocerciasis, Schistosomiasis, Soil transmitted helminthiasis, Tuberculosis, Yaws
- 8 addition in later years (by 2019) by Congress or FDA(*)
 - 2014 Filoviruses/Ebola; 2015 Chagas*, Neurocysticercosis*; 2016 Zika;
 - 2018* Chikungunya virus disease, Cryptococcal meningitis, Lassa fever, Rabies
- Ex ante: unclear whether PRV can effectively spur NTD R&D

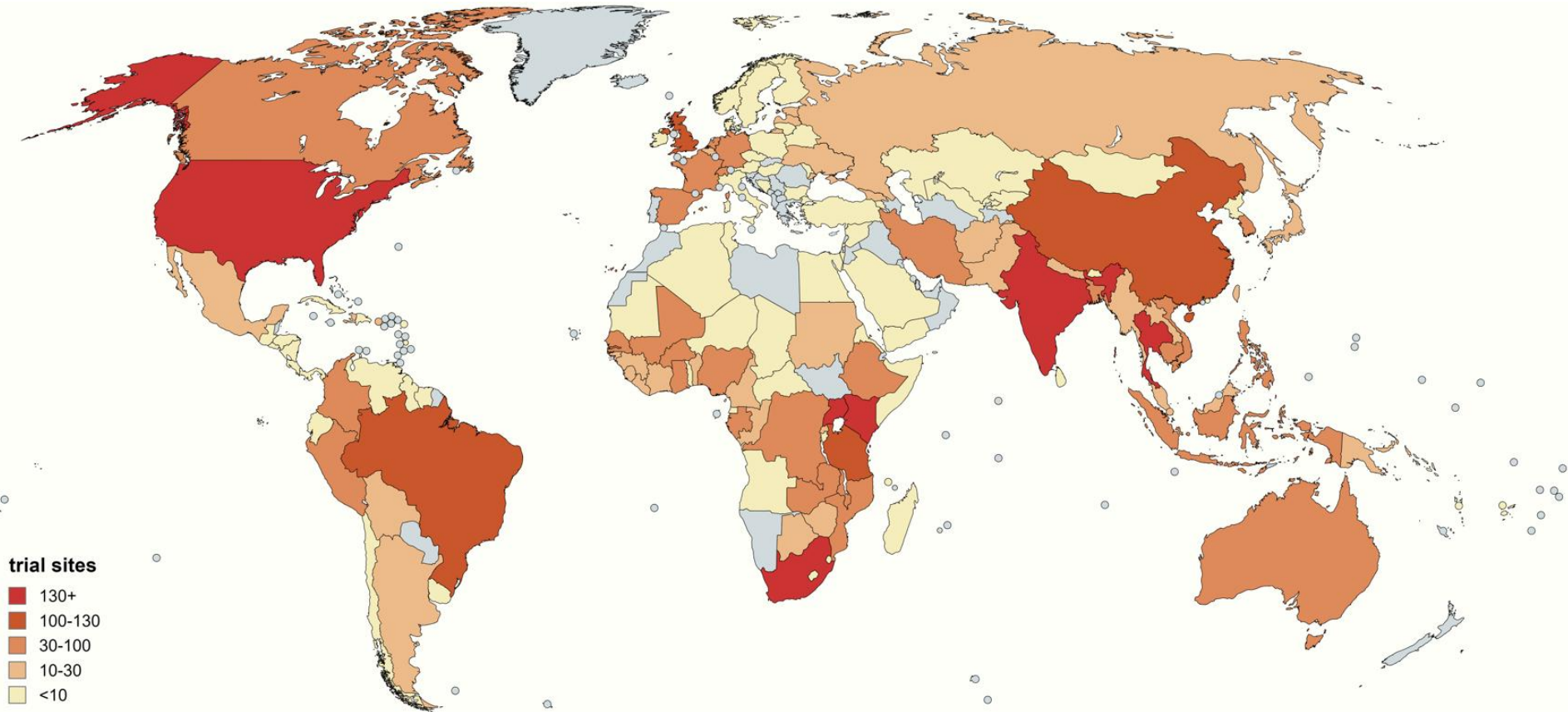
Data Construction

- **PRV eligibility dates:** 2007-2019
 - PRV-eligible diseases and dates added to the list (by Congress or FDA)
 - Source: <https://priorityreviewvoucher.org/eligibility/index.html> & FDA sites
- **G-FINDER survey data:** Policy Cures Research's Global Funding of Innovation for Neglected Diseases (G-FINDER) survey, 2007-2019
 - Annual data on global funding into R&D for NTD from various sources
- **WHO Intl. Clinical Trials Registry Platform (WHO ICTRP), 2000-2019**
 - Sourced from various national clinical trials registries across the globe
 - Searched by each PRV-eligible conditions, then extensive RA check by trial
- **Clarivate Analytics' Cortellis Clinical trials Data:** supplementary data
- **World Development Indicators, etc:** country income levels and controls
- **Sample:** exploratory analysis with G-Finder 2007-2019 and disease-year panel level clinical trials (by income, phase, drugs, \$-value) in 2000-2019



Geographic distribution by clinical trial site locations

If a trial has multiple main clinical sites across countries, each country is counted once.



Sankey plots on NTD clinical trials & funding flows

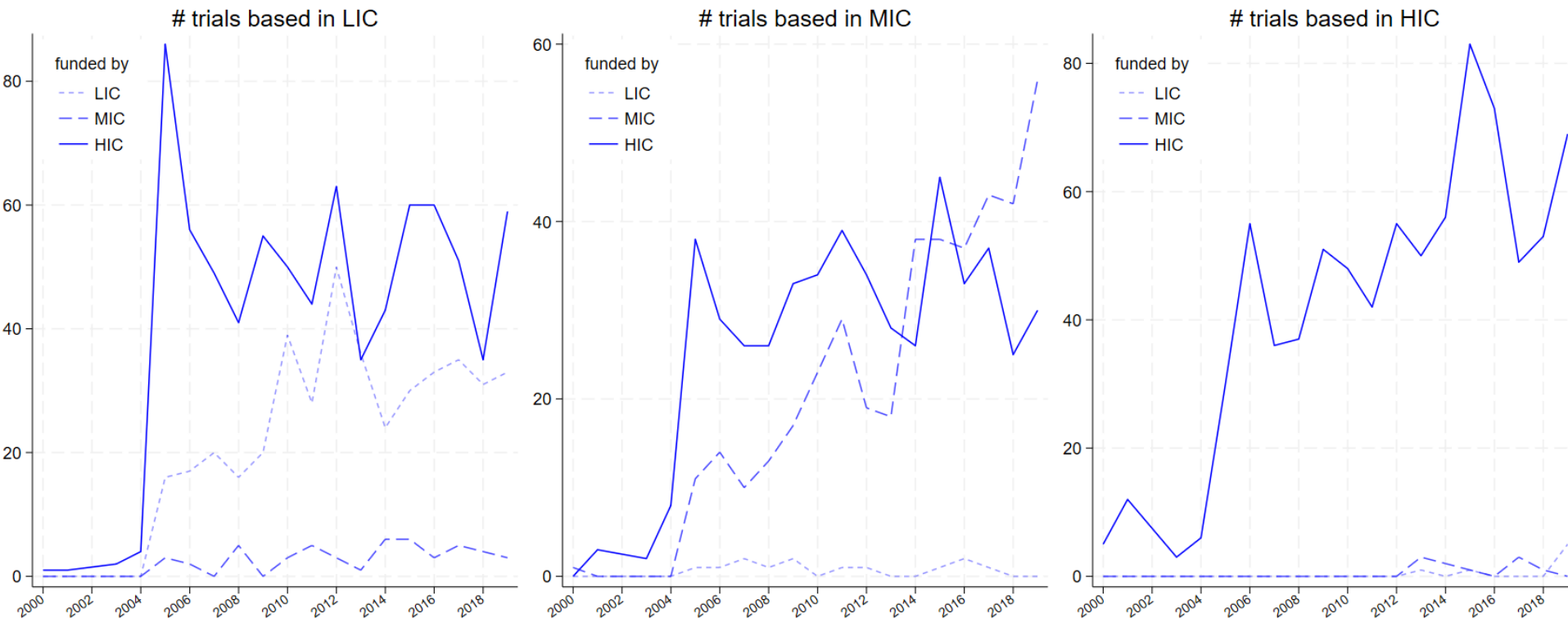
clinical trial site location vs. primary sponsor location



recipient location vs. funder location

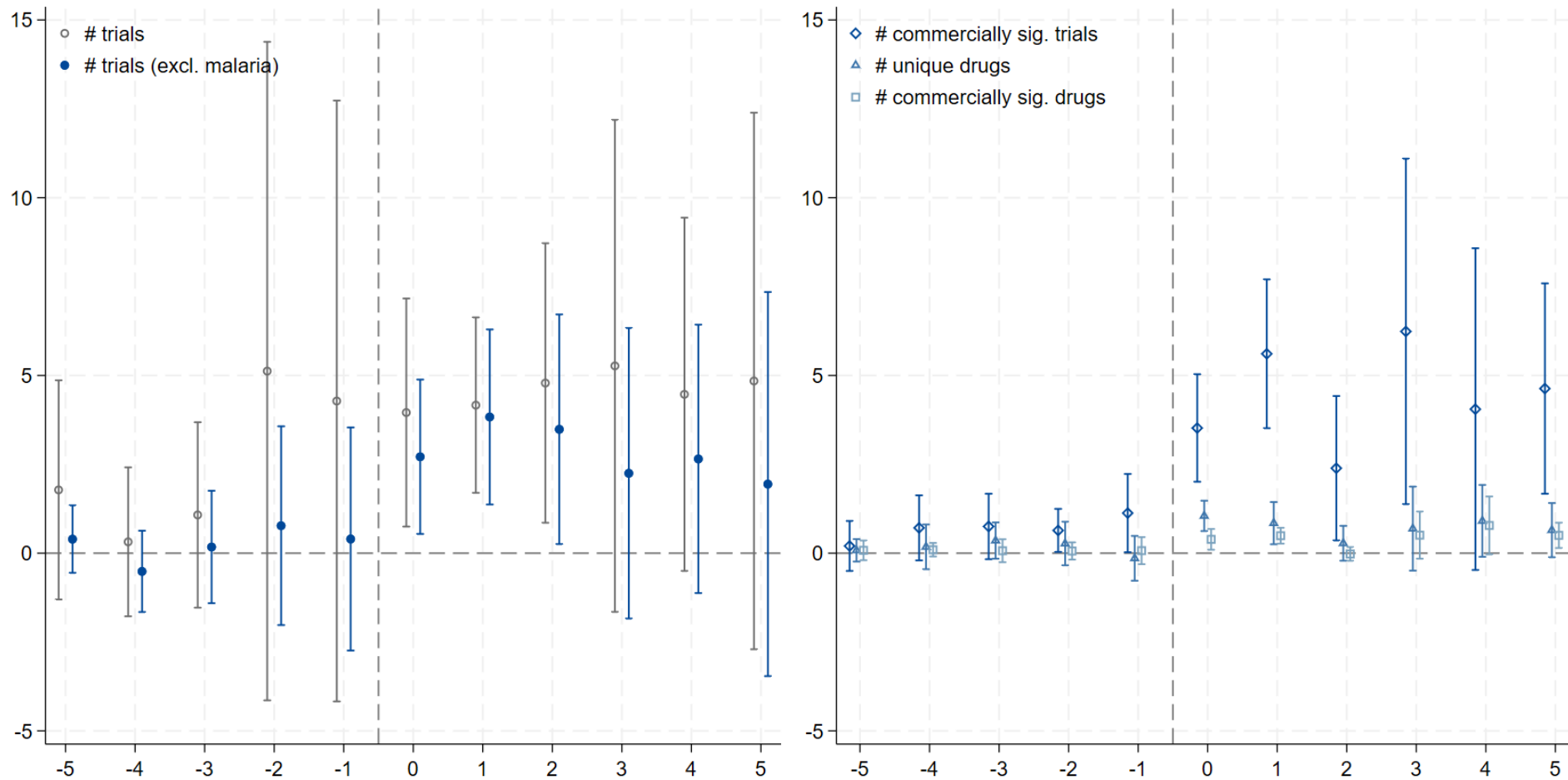


Trends of PRV-relevant trials by site-funder pairs

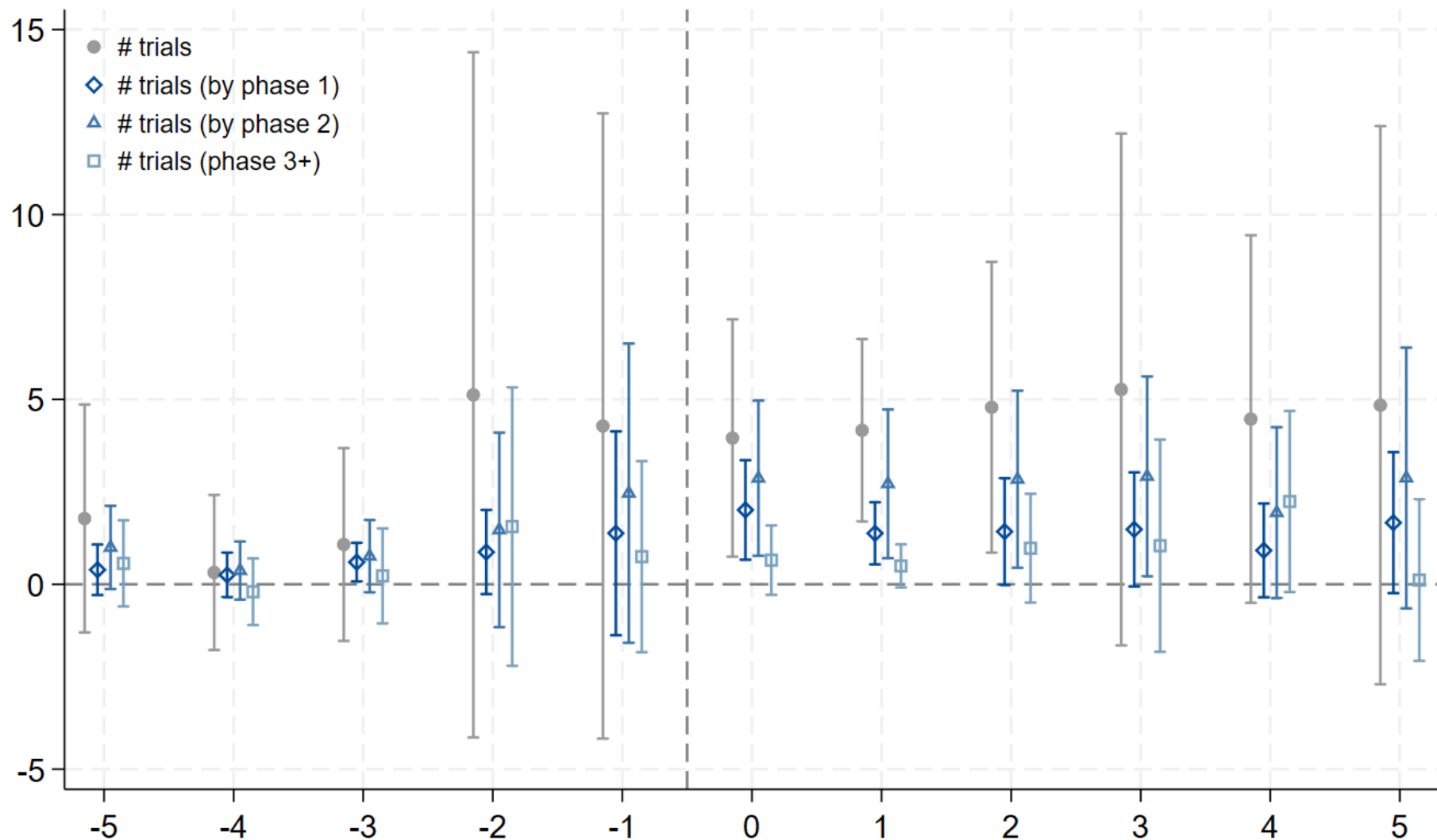


Empirical Methods and Main Results

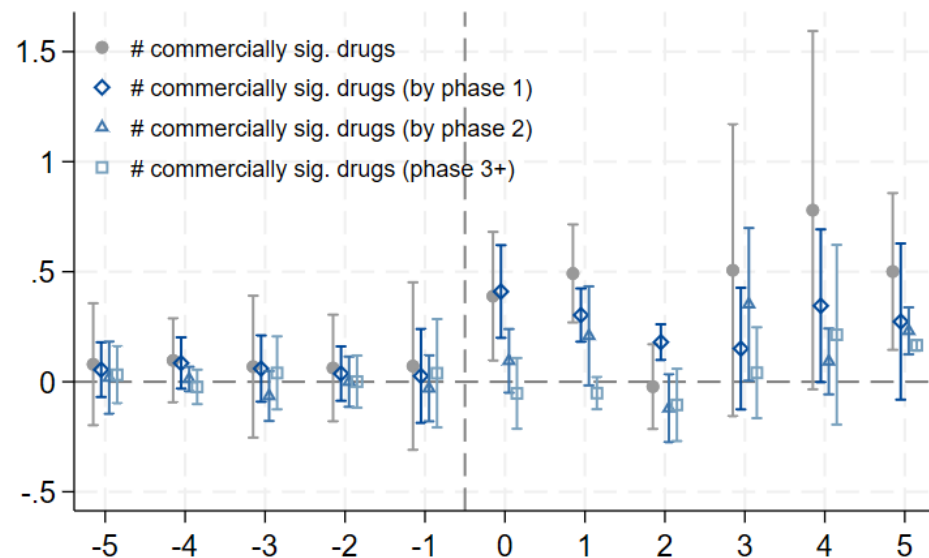
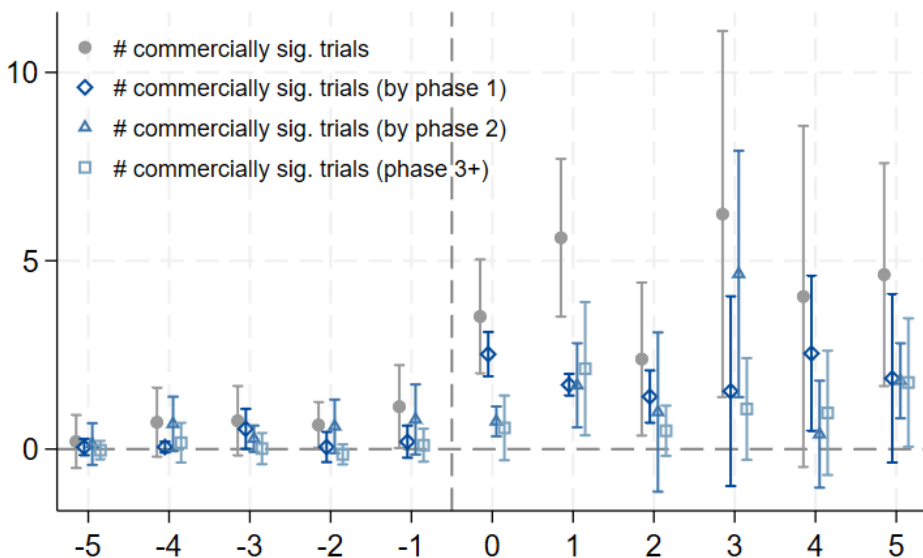
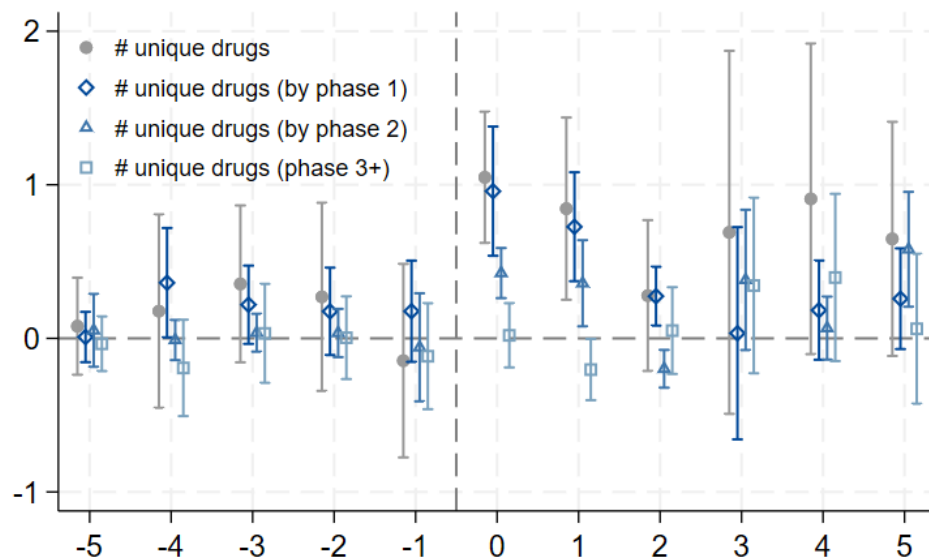
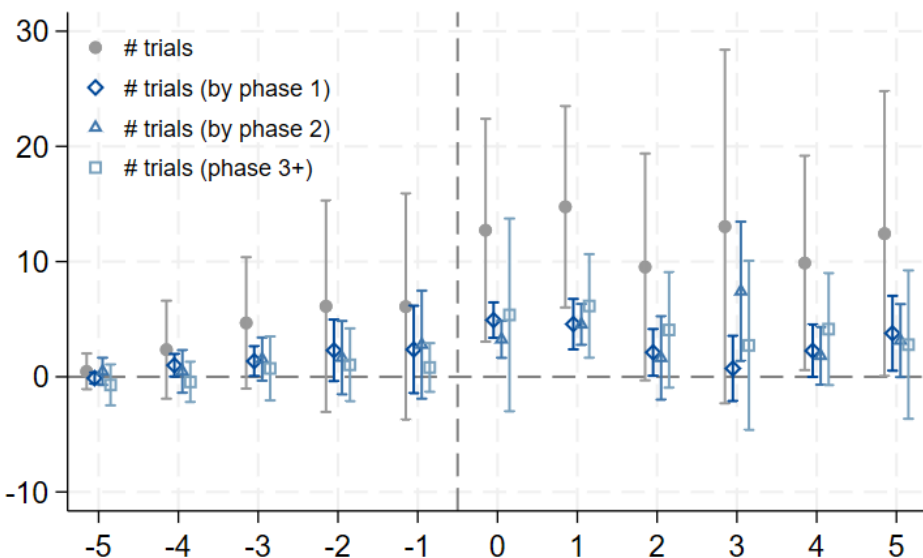
- Exploit the staggered inclusion of PRV-eligible conditions
- Condition-year level panel analysis, # trials and by stratified trials
- Staggered event studies & DiD w/ imputation (à la Borusyak et al., 2024)



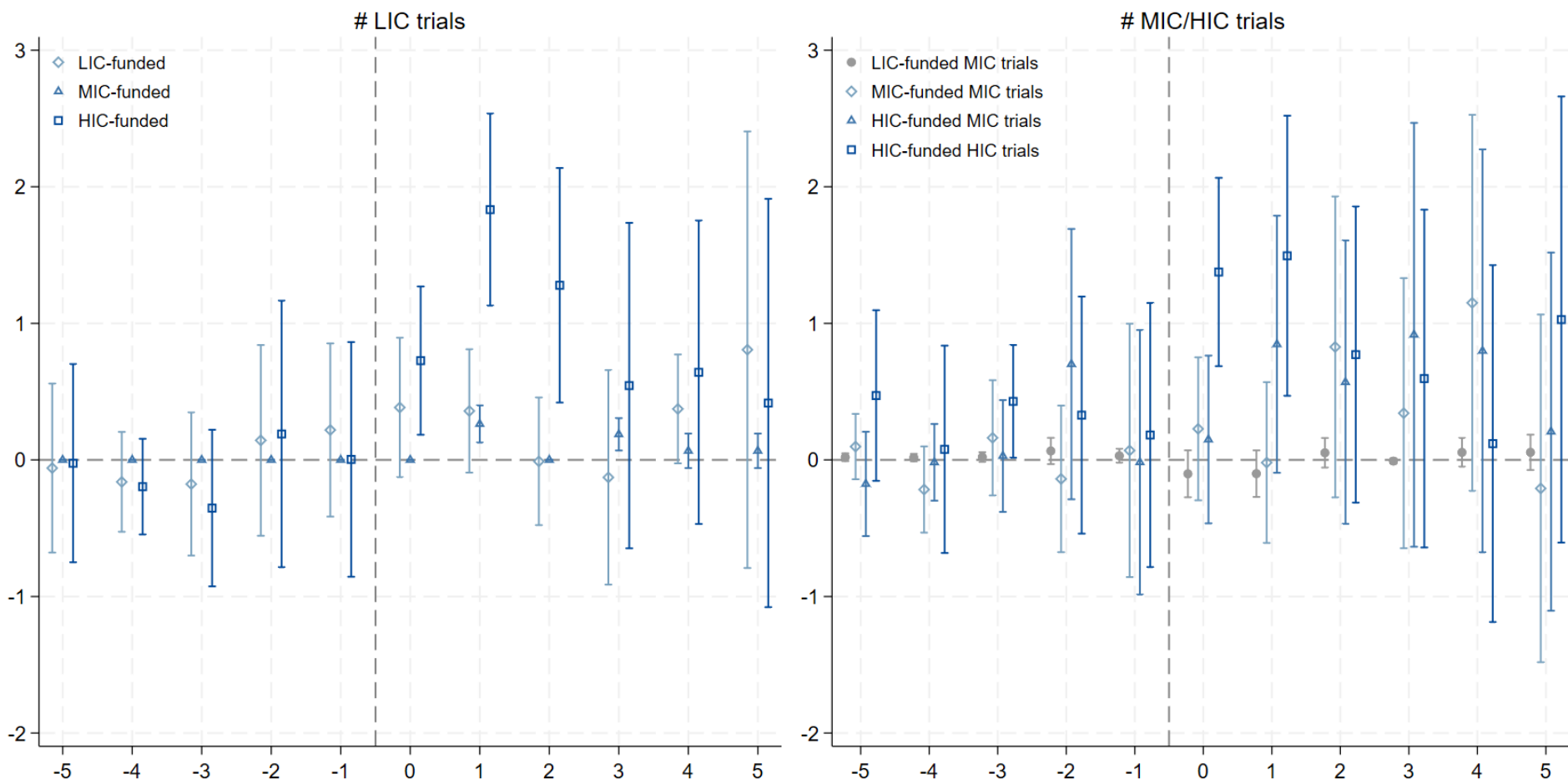
PRV inclusion and new clinical trials by phase



PRV addition on trials & unique drugs (Cortellis)



trials, by site and funder country income group



Conclusion & Discussion

- We find **meaningful but limited increase** in trials after **PRV addition**
 - More trial initiations, esp. commercially significant trials, unique drugs
 - Concentrated among HIC sponsors, in LICs and HICs, and early-stage
 - Late-stage trial increases are increased in limited subsamples
 - Consistent w/ case studies (e.g., bedaquiline) that extra help is needed
- Policy implication: PRV is a novel design w promises & boundary
 - Good impact & address concerns on geo relevant & regulatory gaming
 - But limited in supporting complete therapeutic development
 - Need complementary policy interventions (push+pull, w/ insurance?)

Thank you! (Comments welcome: Emma.C.B.Dean@dartmouth.edu, xiaoluwang@umass.edu)

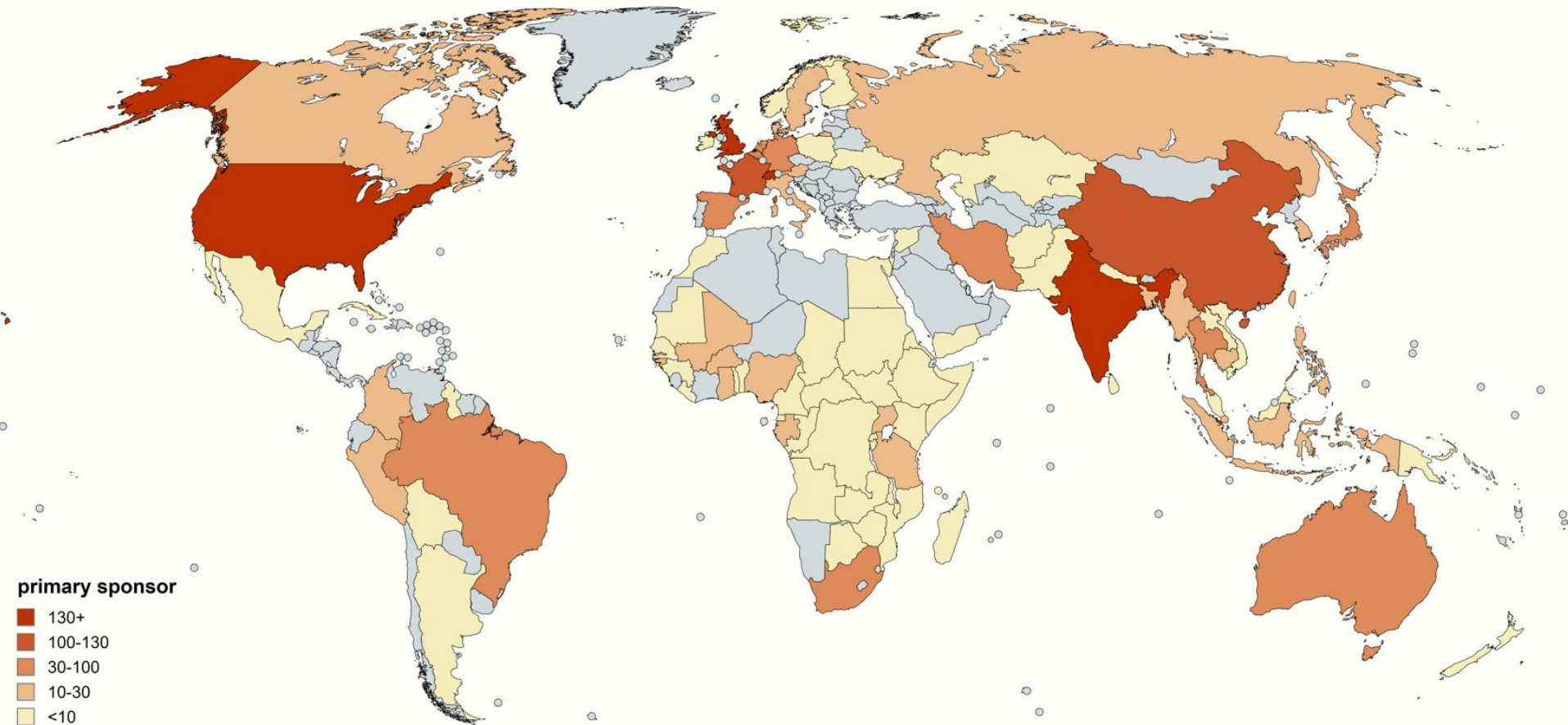
Sankey plot on funding flow by institution types

recipient institution vs. funder institution



Geographic distribution by primary sponsor locations

The primary sponsor location is usually tied with a unique major sponsor, with a few cases where two equally important primary sponsors are designated and counted.



Trend in total grant money (G-Finder data)

