



# Comparing Outcomes in Trial-Eligible vs Real-World COVID-19 Patients

## The Case of Invasive Mechanical Ventilation

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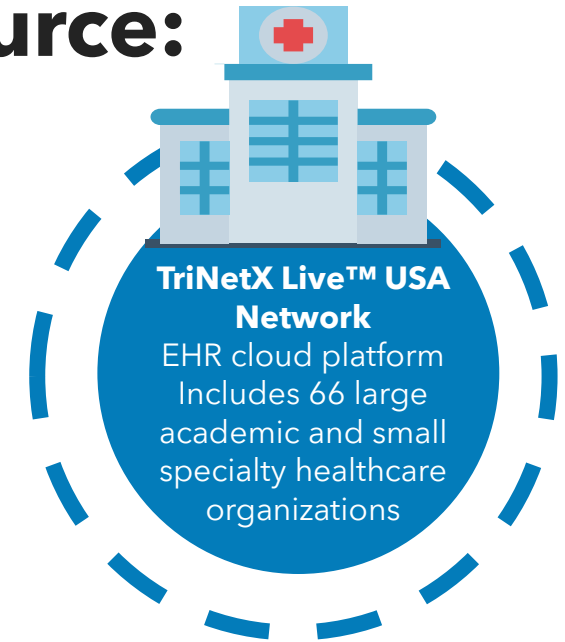
# Disclosures

- The views expressed in this presentation represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.
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- The authors have no conflicts of interest to disclose.

# Background

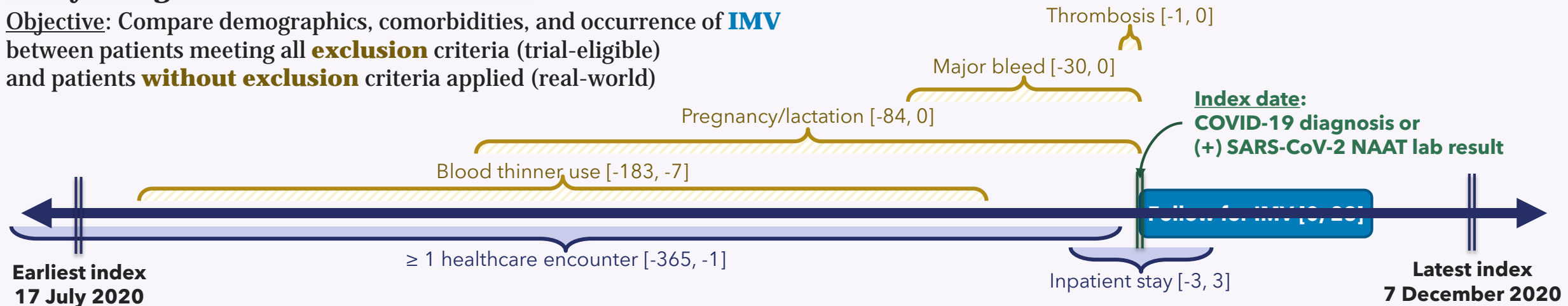
- Patients with severe or critical **COVID-19** may require invasive mechanical ventilation (**IMV**)
- Randomized controlled trials (RCTs) that investigate occurrence of **IMV** recruit highly selected populations with different clinical profiles than “real-world” patients
- **Are results from trial-eligible patients comparable to outcomes among real-world, more complex patients?**

# Data Source:

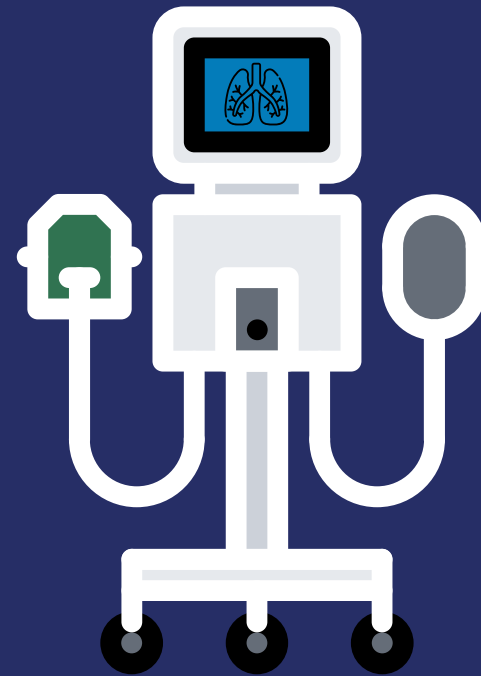


## Study Design Based on ACTIV-4a RCT

**Objective:** Compare demographics, comorbidities, and occurrence of **IMV** between patients meeting all **exclusion** criteria (trial-eligible) and patients **without exclusion** criteria applied (real-world)

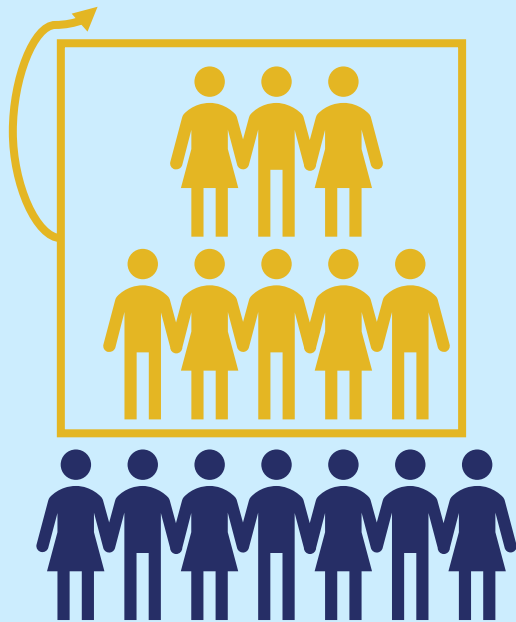


**“Real-world” patients with COVID-19 are statistically and clinically different from “trial-eligible” patients**



**Twice as many invasive mechanical ventilations among real-world patients  
10.7 vs 5.5%**

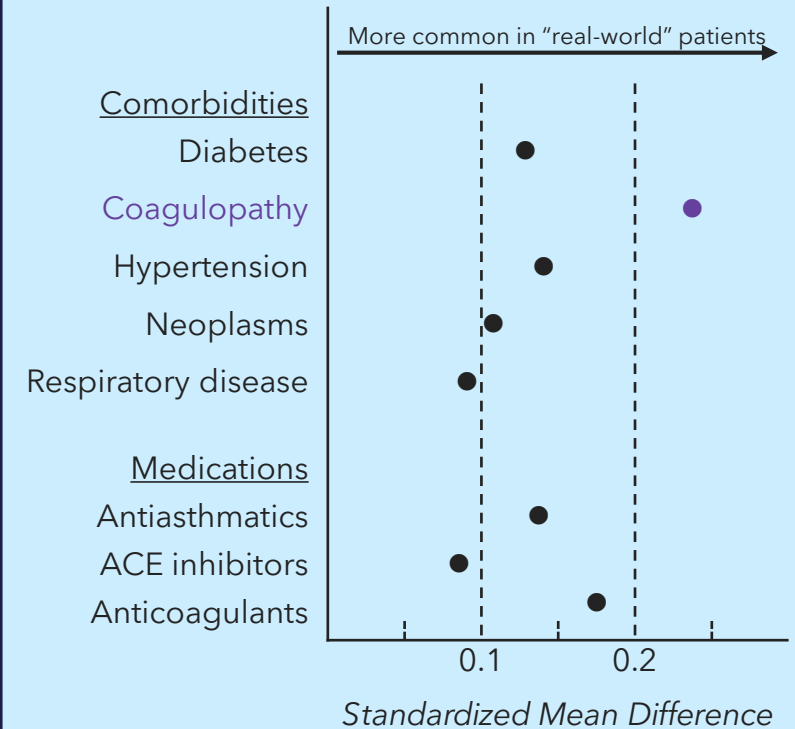
53.7% trial-eligible



**28,280 hospitalized patients w/COVID-19**

All patients were on average 60 years old; ~50.5% were female

**Characteristics assessed in the year prior to hospitalized COVID-19**



At baseline, “real-world” patients were at a higher risk for IMV and other COVID-19 complications