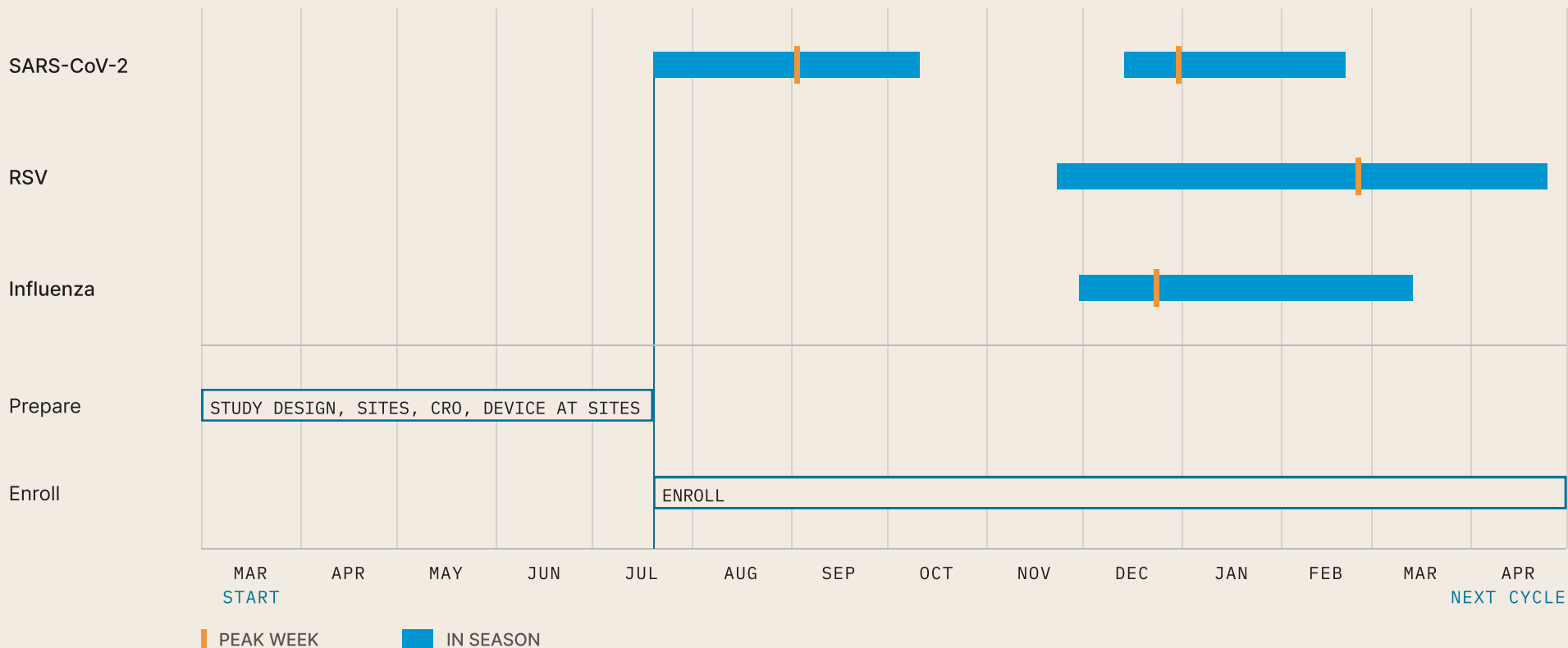


Respiratory Program Planning Timeline

What has to happen before the season opens, and why it starts earlier than most programs plan for.

A test for SARS-CoV-2 has to be ready by late July, so prep begins in March.

In 2025 to 2026, SARS-CoV-2 hospitalizations ran high from late July into mid-October and again from mid-December into late February. RSV was in epidemic season for 22 weeks. Influenza held above the CDC national baseline for 15 weeks. [1][2][3]



Bars: RSV on the CDC epidemic definition, 3 percent of PCR tests positive for two consecutive weeks; influenza on the CDC national ILI baseline of 3.0 percent. CDC publishes no season threshold for SARS-CoV-2, so it is shown as weeks at or above half the annual COVID-NET hospitalization peak, a DCN Dx reading of CDC data. Those weeks move every year. Provisional data, past seasons, timing only.

[1] [CDC COVID-NET, 2025-26](#). [2] [CDC NREVSS, 2025-26](#). [3] [CDC FluView, 2025-26](#).

General planning considerations from DCN Dx. Not regulatory, legal, or clinical advice, and not a substitute for your own protocol design, regulatory strategy, or consultation with FDA or qualified counsel.

What has to happen, and when

Most of this takes longer than sponsors expect, and it has to be done before the season starts.

BEFORE YOU ENGAGE A CRO

WINTER

- Draft the clinical plan.
- Set the analyte mix and a positive target for each analyte.

CONTRACTING

WINTER INTO SPRING

- Select and contract the CRO.
- Identify sites with a demonstrated enrollment record, not just the right clinic type.
- Decide specimen handling early: fresh at site, refrigerated inside validated stability, or frozen. Confirm which your assay and your claim support.

READYING THE SITES

SPRING, BEFORE ONSET

- Get product into site hands.
- Agree how and when each site switches on.
- Qualify each site before the first specimen: positive and negative controls, operator competency, and a training run on characterized material.

ONCE YOU ARE ENROLLING

IN SEASON

- Plan the low-yield stretch instead of stopping cold: reduced enrollment, or a scheduled pause with sites kept warm.
- Report a drop in weekly counts the same week it appears.
- Record what limited the season before the next one opens.

“I would say by the spring, I’d love to see your study design, even if it’s in a draft clinical plan. And then you should have your CRO selected by the summer.”

Emily Friedland, VP of Clinical Research, DCN Dx
On the winter enrollment window.

“One of the most expensive things that can happen in a respiratory program is running out of season before you’ve enrolled, and having to come back for another year.”

Emily Friedland, VP of Clinical Research, DCN Dx

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