

# Release Notes

## April 2026

Weave Baseline NDA Template Set  
HAQ Manager

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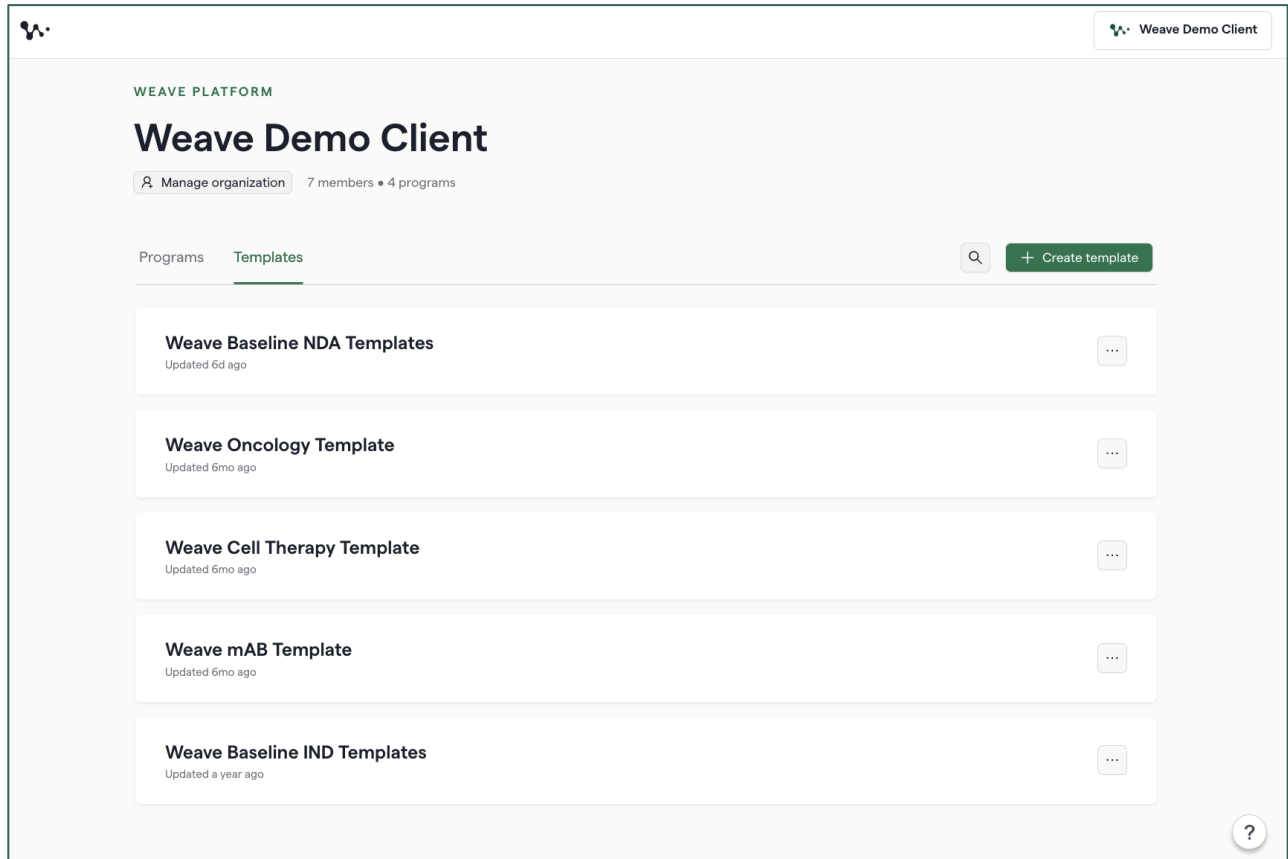
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# Baseline NDA Template Set

The Weave Platform now supports submissions from IND-to-NDA.

Every new Weave platform account is pre-loaded with two baseline template sets:

- Weave Baseline IND Template
- Weave Baseline NDA Template



When creating a new program, users can select the NDA baseline template set to begin building their NDA submission in Weave.

**CREATE PROGRAM** ✕

Let's create your Program

\* Program Name

WEA-123 NDA

\* Program Template

Weave Baseline IND Templates

**Weave Baseline NDA Templates**

Weave Cell Therapy Template

Weave mAB Template

Weave Oncology Template

Veeva Product Family (optional)

WEA-123

Once connected, you can sync all source reports from this product family to your data room. Syncs will run automatically every evening once you have connected a product family.

Cancel Create Program

## NDA-specific AI Template updates

### Module 1

Templates include a full set of Module 1 templates, including Forms, Fast Track designation requests, Draft and Final Labeling.

### Module 2

Templates have been optimized to support the volume and types of studies typically present in NDA submissions, including summaries of clinical efficacy and safety.

### Module 3

Templates include support for commercial manufacturing process & pivotal submission batches, multiple dosage forms & strengths, and their corresponding stability evaluation.

## NDA-specific AI Template updates (continued)

### Module 5

Templates for the ISS and ISE have been updated to support integrated summaries of clinical studies. New templates include the ISI (Integrated Summary of Immunogenicity) and the ISS SAP (Integrated Summary of Safety Statistical Analysis Plan).

## HAQ Manager

### Response files for similar questions

If applicable, similar questions now link to its corresponding response files. This could be both the version drafted in Weave as well as the final submitted response files associated with that similar question in the Data Room.

Similar questions ✨

Responses to these questions may be included in Response source files.

- > File BLA STN 125742/0 Question 1 **85% similarity**
- ▼ File A1 Question 1 **85% similarity**
  - Question**

Please complete the following table to summarize the numbers and percentages of BNT162b2 and placebo recipients, by age group and study period, who reported the indicated categories of unsolicited adverse events during blinded follow-up in study C4591001. Please use denominators of the corresponding population in each column and please do not report percentages in 100/PY.
  - Response document in Weave**
    - View in editor
  - Submitted response files**
    - View in data room 125742\_S74\_M1\_response-20aug2021.pdf
- > File A1 Question 14 **45% similarity**
- > File A1 Question 12 **42% similarity**

This helps to easily find and reuse previous responses to questions that are similar, especially those from other jurisdictions.

# New and Improved Functionality

## New:

- NDA template set
- Added response files for similar questions when applicable

## Improved:

- HAQ Manager Discipline column bug fix