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Electronic Health Record Build Guide – Epic®

Sample Clinical SmartSet Content

The content provided should be regarded as suggested material and should undergo thorough validation and review by clinical subject matter experts. It is important to acknowledge that all clinical decisions ultimately rest with the health care professionals (HCPs), and the examples furnished in this guide are not intended as definitive guidance for medical treatment.

General

- **Nursing assessments/interventions/communications**
- **Vital signs (temperature, pulse, and respiration with blood pressure)**
- **Oxygen saturation, continuous**
  - Electrocardiogram monitoring
- **Age**
- **Neurologist with any issues or concerns**
- **Anaphylaxis**
  - For anaphylaxis, page Neurology

For single-dose intrathecal injection only.

- **Prior to ITVISMA injection:**
  - Due to the increased risk of serious systemic immune response, administer ITVISMA to patients who are clinically stable in their overall baseline health status (eg, hydration and nutritional status, absence of infection, respiratory status) prior to administration. Postpone ITVISMA in patients with active or recent infections until the infection has resolved and the patient is clinically stable. Clinical signs or symptoms of infection should not be evident at the time of ITVISMA injection.
  - Assess vaccination status. Vaccination status should be up-to-date prior to ITVISMA administration. Prophylaxis against influenza and respiratory syncytial virus (RSV) is recommended and vaccination status should be up-to date prior to ITVISMA administration.
  - Assess liver function (clinical examination and laboratory testing including aspartate aminotransferase [AST], alanine aminotransferase [ALT], albumin, prothrombin time, partial thromboplastin time [PTT], international normalized ratio [INR], and total bilirubin).
  - Obtain creatinine and complete blood count (including hemoglobin and platelet count).
  - Perform baseline testing for the presence of anti–adeno-associated virus serotype 9 antibodies.
- Starting one day prior to ITVISMA injection, administer systemic corticosteroids equivalent to oral prednisolone at 1 mg/kg of body weight per day for a total of 30 days. At the end of the 30-day period, check liver function by clinical examination and by laboratory testing. For patients with unremarkable findings, taper the corticosteroid dose gradually over the next 28 days. If liver function abnormalities persist, continue systemic corticosteroids (equivalent to oral prednisolone at 1 mg/kg/day) until findings become unremarkable, and then taper the corticosteroid dose gradually over the next 28 days or longer, if needed. Do not stop systemic corticosteroids abruptly.

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Sample Clinical SmartSet Content (continued)

- **Following ITVISMA Injection:**
  - Monitor liver function (AST, ALT, total bilirubin) weekly for the month after ITVISMA injection (or longer based on outcomes) and during the corticosteroid taper period (over the next 28 days or longer if needed). If the patient is clinically stable with unremarkable findings (normal, clinical exam, total bilirubin, and ALT and AST levels below 2 × upper limit of normal) at the end of the corticosteroid taper period, continue to monitor liver function every other week for another month.
  - Monitor platelet counts weekly for the first month and as clinically indicated until platelet counts return to baseline.

Procedural Preparation Instructions

- Consider sedation if indicated by the patient's clinical status.
- Consider imaging techniques to guide intrathecal injection of ITVISMA.
- Evaluate patient prior to and after intrathecal injection for the presence of potential conditions that may contraindicate lumbar puncture or increase risk to prevent serious procedural complications.

Intrathecal Injection Instructions

- Prior to administration, remove 3 mL of cerebrospinal fluid using a lumbar puncture needle to create space for injection volume.
- Administer ITVISMA as an intrathecal bolus injection over approximately 1 to 2 minutes through the lumbar puncture needle.
- Place patient in Trendelenburg position (head down at 30 degrees for 15 minutes). Adjust patient positioning and duration based on the patient's clinical status to enhance distribution.
- Follow standard post-lumbar puncture care protocol.

Transfer/Discharge

- **Discharge**
  - Discharge
- **Release Instructions Order**
  - Instructions for when to release order - **required**
    - Release {Date/Week} in {Unit}
- **Prep technician - document in comments section of dispense prep:**
  - Lot and expiry of individual vial
  - Container (Vial) National Drug Code number

Required supplies and materials (not supplied)

- Needle for withdrawal
- Syringe
- Syringe cap
- Spinal needle

Vial Preparation

- ITVISMA should be prepared aseptically.
- Thaw ITVISMA in the refrigerator for approximately 4 hours, or at room temperature for approximately 1 hour. If thawed in the refrigerator, remove ITVISMA from refrigerator on day of dosing.
- Do not use ITVISMA unless thawed.
- Prior to intrathecal injection, ITVISMA should be brought to room temperature.
- When thawed, ITVISMA is a clear to slightly opaque, colorless to faint white liquid, free of particles. After withdrawal of ITVISMA from the vial, a visual inspection is required. DO NOT use if particulates, cloudiness, or discoloration are visible.
- DO NOT SHAKE.
- Immediately prior to dosing, draw the content from the vial into the syringe, remove air from syringe, confirm the dose volume of 3 mL in the syringe, cap syringe, and deliver to patient injection location.
- Once dose is drawn into the syringe, it may be held in the refrigerator at 2 °C to 8 °C (36 °F to 46 °F) for up to 24 hours, including a 5-hour maximum time out-of-refrigeration allowance within the 24-hour period.
- Discard the vector-containing syringe if not injected within this time period.
- DO NOT REFREEZE.

Patient Instructions & Post-Care Notes

PLAN FOR PATIENT NAME

- For the first 2 months (or longer), the doctor will need to monitor the patient's liver function with weekly blood tests and clinical exams.
- After that, when the patient stops taking the corticosteroid, the doctor will continue to monitor the patient every other week for at least 1 month.
- The doctor will also run blood tests to keep an eye on platelet counts. They might also consider a cardiac evaluation and suggest consulting a cardiologist as needed.
- Monitoring beyond 12 weeks may be required.

Managing your care recipient at home post-gene therapy

- Infections before or after ITVISMA injection can lead to more serious complications. Patients, caregivers, and close contacts of the patient should follow infection prevention procedures. Patients and caregivers should contact the patient's doctor immediately if the patient experiences any signs of a possible infection such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.
- Decreased platelet counts could occur following injection with ITVISMA. Seek immediate medical attention if the patient experiences unexpected bleeding or bruising.
- Peripheral sensory neuropathy has occurred with ITVISMA administration. Patients and caregivers should contact the patient's doctor right away if the patient experiences numbness, tingling, prickling, or pain in the arms, hands, legs, and/or feet.
- Decreased blood platelet and red blood cell counts, sudden kidney change, and increased bruising or bleeding, which could be signs of thrombotic microangiopathy (TMA), can occur. Patients and caregivers should seek immediate medical attention if the patient experiences unexpected bruising or bleeding, seizures, or decreased urine output.
- There is a theoretical risk of tumor development with gene therapies such as ITVISMA. Patients and caregivers should contact the patient's doctor and Novartis Gene Therapies, Inc. at 1-833-828-3947 if a tumor develops.

Epic's SmartSets play a role in supporting the management of complex treatments and therapies. These SmartSets may also be utilized in outpatient settings, facilitating processes for orders, prescriptions, laboratory tests, patient information, follow-up care notes, and subsequent visits.

The purpose of this overview is to provide guidance to information technology (IT) support staff. It serves as an example of how to create new SmartSets or request updates to existing ones by modifying the medication and order groups within the SmartGroup(s) or OrderGroup(s) utilized.

In instances where an existing SmartSet is not available, you can initiate a request to create a new SmartSet that incorporates appropriate orders, necessary medications, and relevant laboratory tests. The responsibility for creating and maintaining SmartSets containing SmartGroups lies with the health system's electronic health record (EHR) IT team.

When requesting updates for an existing SmartSet, the process is usually managed by the health system's IT support team, adhering with an established protocol for requesting, approving, and implementing changes. When making an IT request to set up or modify a SmartSet, it is advisable to include the following details to ensure accurate configuration:

- **Specify the name of the existing SmartSet to be modified or the desired name for the new SmartSet to be created**
- **Identify the specific SmartGroup(s) where the modifications should take place. For example, a SmartSet can incorporate SmartGroups for medications, patient information, and follow-up visit time frames**
- **Include appropriate orders or laboratory tests, providing necessary order details**

To create a SmartGroup, complete the following tasks:

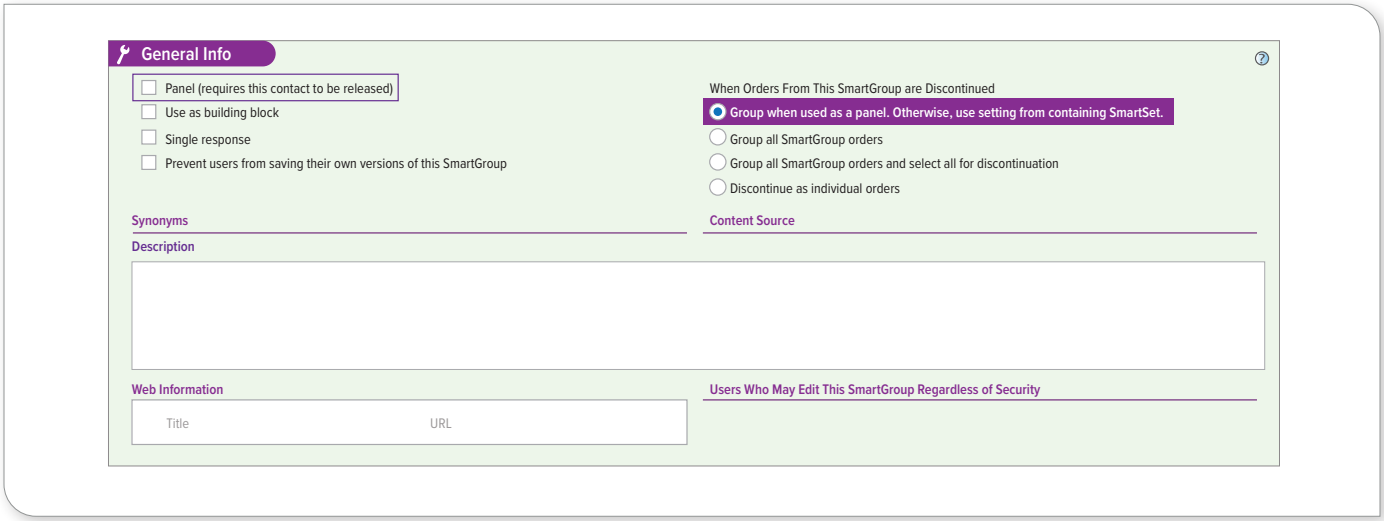
- **Create and configure a new SmartGroup**
- **Add items to a SmartGroup**
- **Determine how orders are discontinued in a SmartGroup**

Create and Configure a New SmartGroup

1. In **Hyperspace**, open the **SmartGroup Editor** (search: SmartGroup) and create a new **SmartGroup record**. Click **General Info** from the table of contents.
2. The name you gave the **SmartGroup** appears automatically in the **Record name** and **Display name** fields underneath the toolbar. In the **Display name** field, enter the title you want clinicians to see.

After you create your new SmartGroup, configure general settings to determine how the SmartGroup appears and which items clinicians can select.

3. To allow clinicians to select only one item in the **SmartGroup**, select **Single response**.
4. If you want to provide clinicians with decision support information about this **SmartGroup**, you can add text, images, or links, which appear at the top of this **SmartGroup** in the **SmartSet** or **Order Set**.

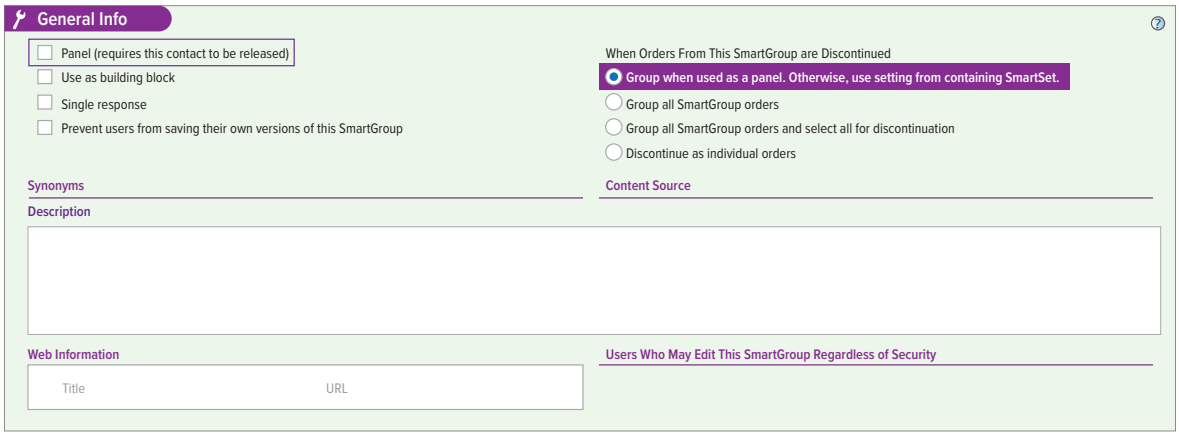


This image is intended for illustrative purposes only.

5. Enter text or images in the **Description** field. To add an image, copy and paste the image into the field or **select the Insert Image action** for the **Description** field. Enter external links in the **Web Information** table. In the **Title** column, enter user-friendly display text for the link. In the **URL** column, enter a web address earlier, these settings are in the **General Info** section: To require clinicians to choose at least one item from this SmartGroup, select **Require users to select an order** from this **SmartGroup**.
6. To expand all available items in the **SmartGroup** when a clinician opens the **SmartSet** or **Order Set**, clear the **Show only checked items upon loading** checkbox. Clinicians see items that are selected even when a SmartGroup is collapsed. By default, this checkbox is selected, so the clinician must expand the **SmartGroup** in the set to see available items that are not selected.

Add Items to a SmartGroup

1. In **Hyperspace**, in the **SmartGroup Editor** (search: SmartGroup) select the **SmartGroup** you want to configure if it is not already open.
2. To add an item, click **Add Item** in the toolbar. Then, select the type of order or clinical content you want to add, such as **Order**.
3. Select an item and click **Accept**. The item appears in the **Configuration section** with fields to customize its details in the **SmartGroup**.
4. Edit the item's details as necessary. If you do not edit details for the item, the system looks to that item's record, such as a procedure record, for details.
5. To make an item selected by default when the clinician adds a **SmartSet** that contains the **SmartGroup**, select the checkbox that appears to the left of the item's name.
6. To move an item up or down in the **SmartGroup**, select that item and click the **Move Up** or **Move Down** buttons in the toolbar. To remove an item, select that item and click the **X** button.
7. Continue creating **SmartGroups** for each individual section of orders, medications, post-care notes, follow-up appointments, instructions, etc.



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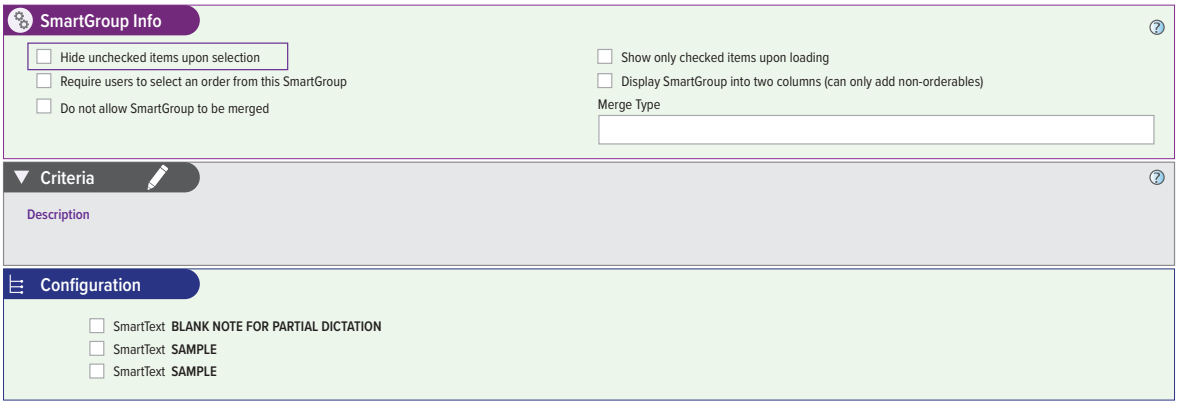
Add Items to a SmartGroup (continued)



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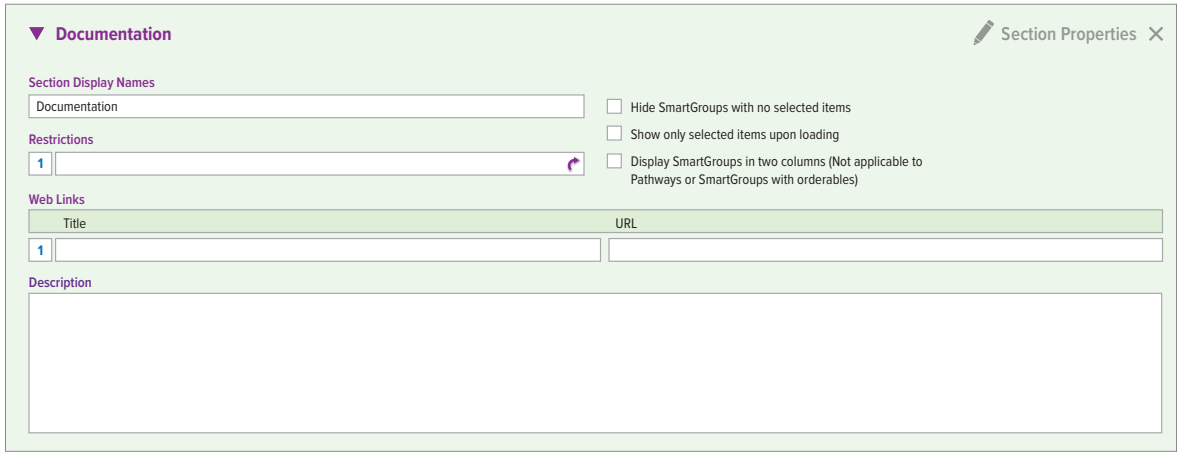

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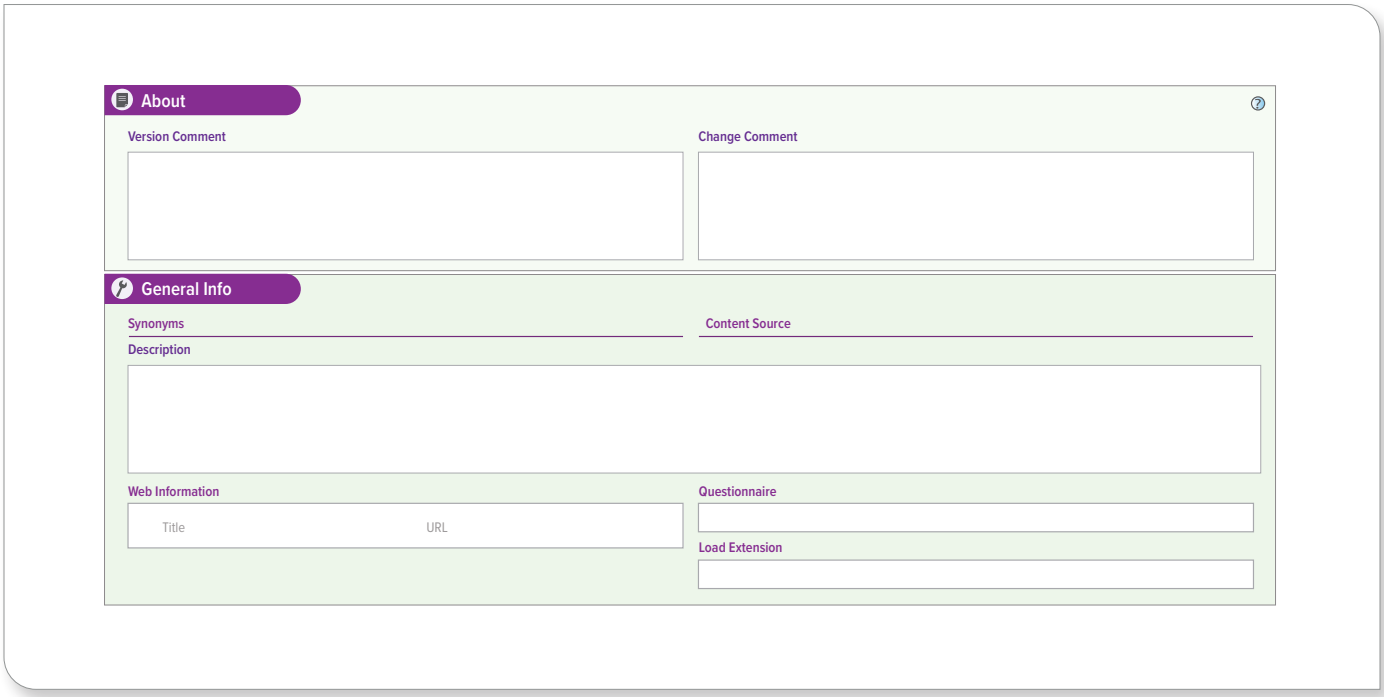
Create a New SmartSet or Order Set and Configure the General Info Form

1. In **Hyperspace**, open the **SmartSet Editor** (search: SmartSet).

2. In the **Select a SmartSet** window, do one of the following, depending on whether you are building from scratch or using a copy template:

- If you are building from scratch, go to the **Create** tab, and create a new SmartSet record.
- If you are using a copy template, search for your copy template and open it. In the **SmartSet Editor**, click **Save As** to make a new copy of your copy template that you can then customize to build your new **SmartSet** or **Order Set**.

3. Go to the **General Info** section:



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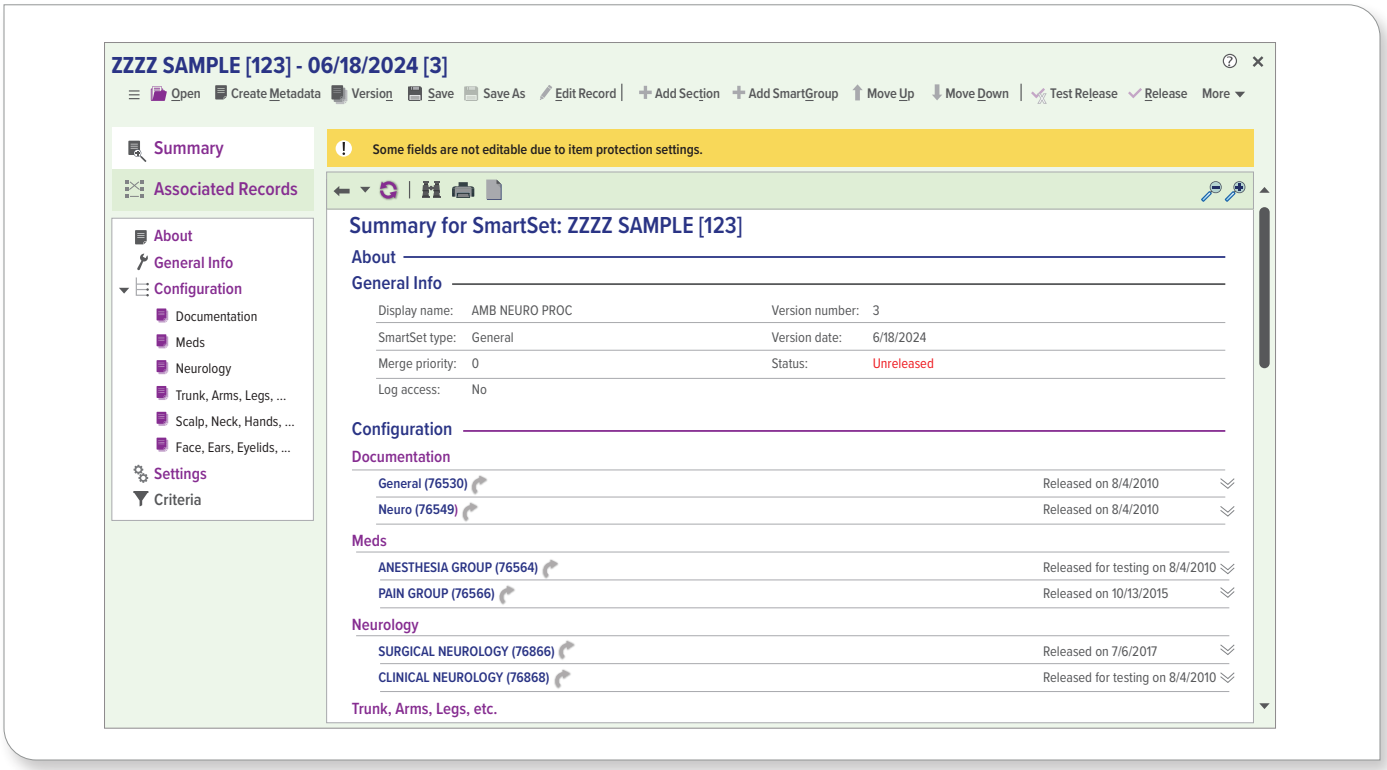
Create a New SmartSet or Order Set and Configure the General Info Form (continued)



This image is intended for illustrative purposes only.

The name you gave the **SmartSet** record automatically appears in the **Record** name and **Display name** fields. In the **Display name** field, enter the name you want clinicians to see.

Then, add **SmartGroups** to a section:

1. Click **Add SmartGroup**. Use the **Show only released** and **Show only SmartGroups** marked as building block options to narrow down the **SmartGroups** to the ones you want to add.
2. Optionally, specify a display name for the **SmartGroup** when it is used in this **SmartSet** or **Order Set**. We recommend that you change the display name in the **SmartGroup**, not in this field, to help ensure that clinicians order the **SmartGroup** they want. Continue adding sections and **SmartGroups** as needed. Use the up and down arrows to move a section or **SmartGroup** up or down.

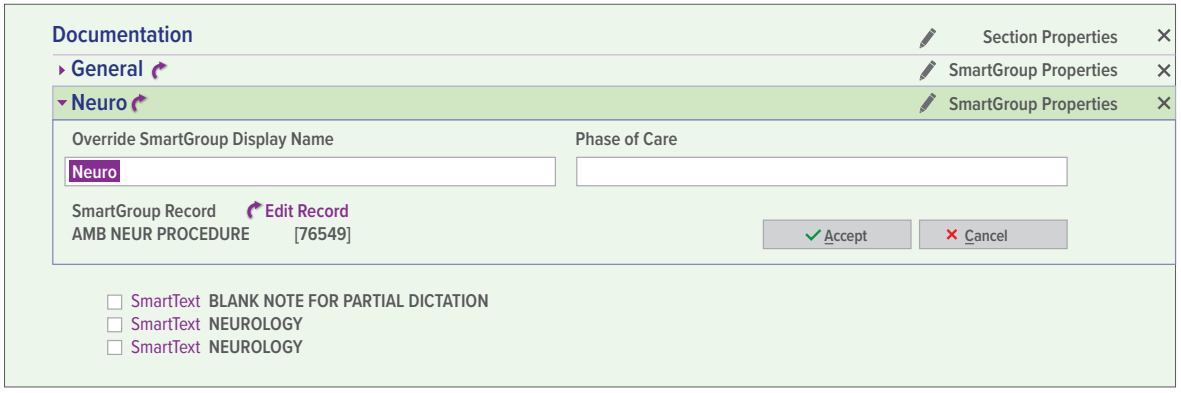
Create a New SmartSet or Order Set and Configure the General Info Form (continued)

Finally, determine whether each section should appear collapsed when a clinician opens the **SmartSet** or **Order Set**:

1. On the **Configuration form**, select a section and click **Edit Section**.

2. Select one of the following options:

- To make the section appear collapsed by default when no orders in the section's **SmartGroups** are selected by default or required, select **Hide SmartGroups** with no selected items.
- To only show orders that are selected by default in a section's SmartGroups, select **Show only selected items** upon loading.
- Leave both of these check boxes blank to show the section expanded when the clinician opens the **SmartSet** or **Order Set** regardless of whether any orders are selected.



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Review, Test, and Release SmartGroups, SmartSets, and Order Sets

To ensure that the **SmartGroups**, **SmartSets**, and **Order Sets** you create are useful to clinicians and contain the orders and clinical content clinicians need, send them to clinicians to review and test before releasing them for use in **Hyperspace**.

Release SmartSet and Order Set Content to End Users

After users have tested a **SmartSet** or **Order Set** in **Hyperspace** and have verified that its content is appropriate and easy to use, you can release the **SmartSet** or **Order Set** and its **SmartGroups**. When you take this final step in the content management process, you can no longer make changes to this released contact of the set or its **SmartGroups**.

You should release your **SmartGroups**, **SmartSets**, and **Order Sets** in your build or **proof of concept** (POC) environment. If you use **Data Courier**, you can then move this released content into your production environment where users can access it.

Release Individual SmartGroups

To release an individual **SmartGroup**:

1. In **Hyperspace**, open a **SmartGroup** in the **SmartGroup Editor**:
   Search: SmartGroup Path: Epic button > Tools > Management Console > Decision Support > SmartGroup.
2. Click **Release**.

Release Individual SmartSets or Order Sets

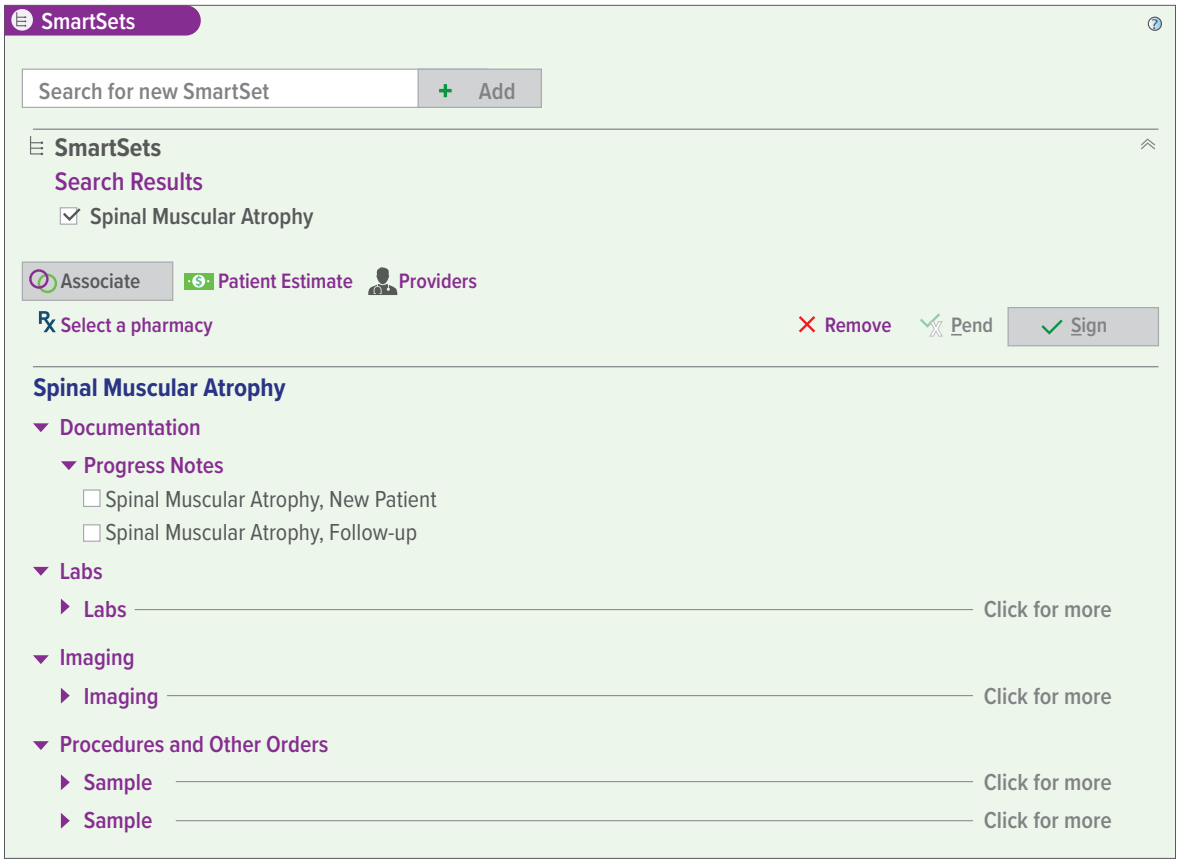
To release an individual **SmartSet** or **Order Set**:

1. In **Hyperspace**, open a **SmartSet** or **Order Set** in the **SmartSet Editor**:
   Search: SmartSet Path: Epic button > Tools > Management Console > Decision Support > SmartSet.
2. Click **Release**.

Tailor the **data courier** and change process steps to align with your organization's specific requirements.

The content provided should be regarded as suggested material and should undergo thorough validation and review by clinical **subject matter experts**. It is important to acknowledge that all clinical decisions ultimately rest with the HCPs, and the examples furnished in this guide are not intended as definitive guidance for medical treatment.

Release SmartSet and Order Set Content to End Users (continued)



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NOTES

- **The customers (ie, physician, medical group, or integrated delivery network [IDN]) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system**
- **Capabilities, functionality, and set-up (customization) for each individual EHR system vary. Novartis shall not be responsible for revising the implementation instructions it provides to any customer in the event that the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Novartis**
- **While Novartis tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Novartis shall have no liability thereto**
- **While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Novartis shall have no liability thereto**
- **The instructions have not been designed to and are not tools and/or solutions for meeting Meaningful Use, Advancing Care Information, and/or any other quality/accreditation requirement**
- **All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of Novartis and/or its affiliates**

INDICATION

ITVISMA is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in *survival motor neuron 1 (SMN1)* gene.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: Serious Liver Injury

Acute serious liver injury can occur with ITVISMA. Hepatotoxicity, with elevated alanine transaminase (ALT) and/or aspartate transaminase (AST) levels, has occurred with ITVISMA. Patients with preexisting hepatic impairment or acute hepatic viral infection may be at higher risk of liver injury. To mitigate potential aminotransferase elevations, administer systemic corticosteroid before and after ITVISMA injection. Prior to ITVISMA injection, assess liver function by clinical examination and laboratory testing. Continue to monitor liver function for at least 3 months after ITVISMA administration, and at other times as clinically indicated. In case hepatic injury is suspected, further testing is recommended. Promptly consult with a gastroenterologist or hepatologist, as necessary.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Thrombocytopenia

Transient decreases in platelet counts were observed within the first week after ITVISMA administration. Monitor platelet counts before ITVISMA injection and on a regular basis afterwards until platelet counts return to baseline.

Peripheral Sensory Neuropathy

Peripheral sensory neuropathy has occurred with ITVISMA administration with onset seen at approximately 3 weeks post-injection in clinical studies. Consider complete neurologic evaluation and other testing and/or symptom management based on the patient's clinical presentation.

Thrombotic Microangiopathy

Thrombotic microangiopathy (TMA) may occur with ITVISMA administration and can result in life-threatening or fatal outcomes. Monitor platelet counts on a regular basis following ITVISMA injection, as well as signs and symptoms of TMA. Consult a hematologist and/or nephrologist immediately to manage TMA as clinically indicated.

Elevated Cardiac Troponin I

Increases in cardiac troponin I levels have occurred following ITVISMA administration. Consider cardiac evaluation after ITVISMA administration and consult a cardiologist as needed.

AAV Vector Integration and Risk of Tumorigenicity

There is a theoretical risk of tumorigenicity due to integration of AAV vector DNA into the genome. The clinical relevance of individual integration events is unknown, but it is acknowledged that individual integration events could potentially contribute to a risk of tumorigenicity. Report cases of tumor development in patients who received ITVISMA to Novartis Gene Therapies, Inc. at 1-833-828-3947.

ADVERSE EVENTS

The most common adverse reactions that occurred in ≥2% of patients treated with ITVISMA were upper respiratory tract infection, pyrexia, upper gastrointestinal symptoms, hepatic enzymes increased, headache, dizziness, pain in extremity, thrombocytopenia, and sensory disturbance.

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For more information on how the Novartis Health Information Technology Team can collaborate with your organization to identify shared priorities, please email: HIT.Novartis@novartis.com

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