zolgensma®
(onasemnogene abeparvovec-xioi)
suspension for intravenous infusion

Electronic Health Record Build Guide – Epic®

Please see Indication and Important Safety Information on pages 11 and 12 and accompanying full Prescribing Information including Boxed WARNING for Serious Liver Injury and Acute Liver Failure.

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, labs, 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 labs. 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 labs, providing necessary order details.

To create a SmartGroup, complete the following tasks:

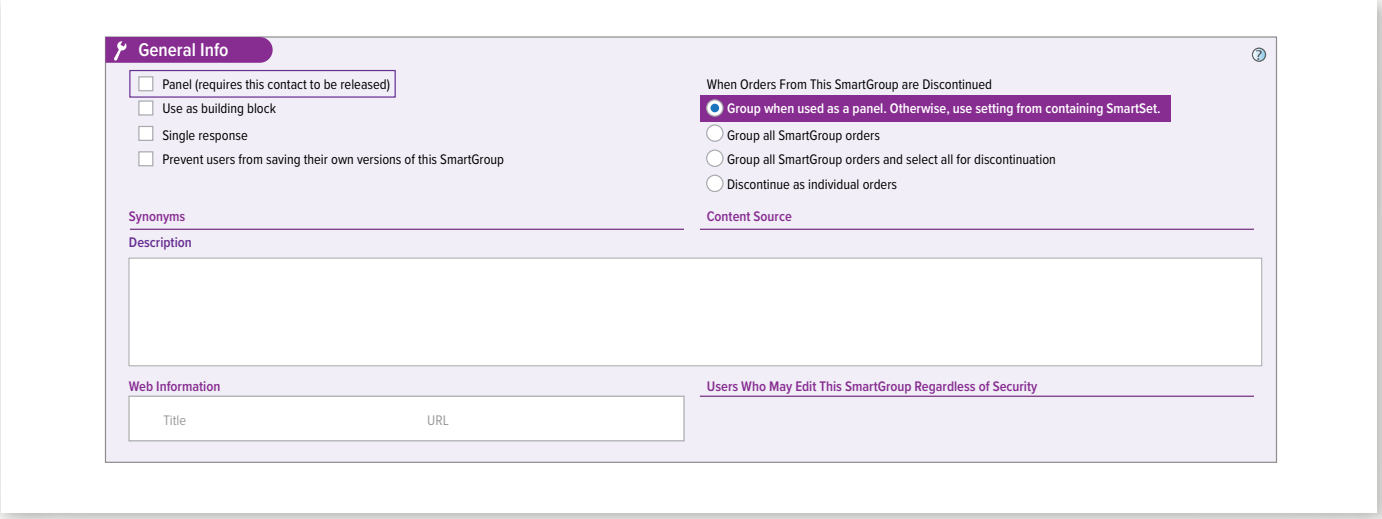
- Create and configure a new SmartGroup.
- Add items to a SmartGroup.
- Determine how orders are discontinued in a SmartGroup.

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**.

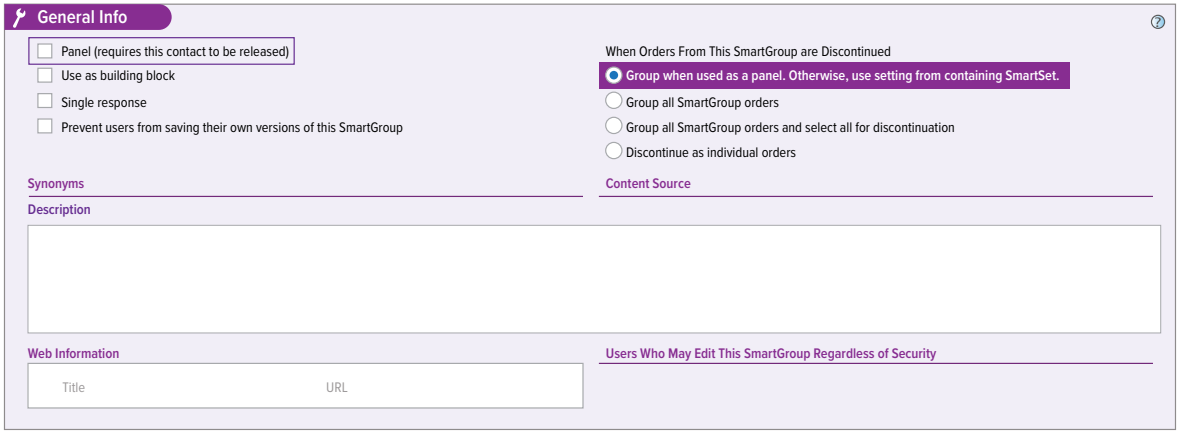


This image is intended for illustrative purposes only.

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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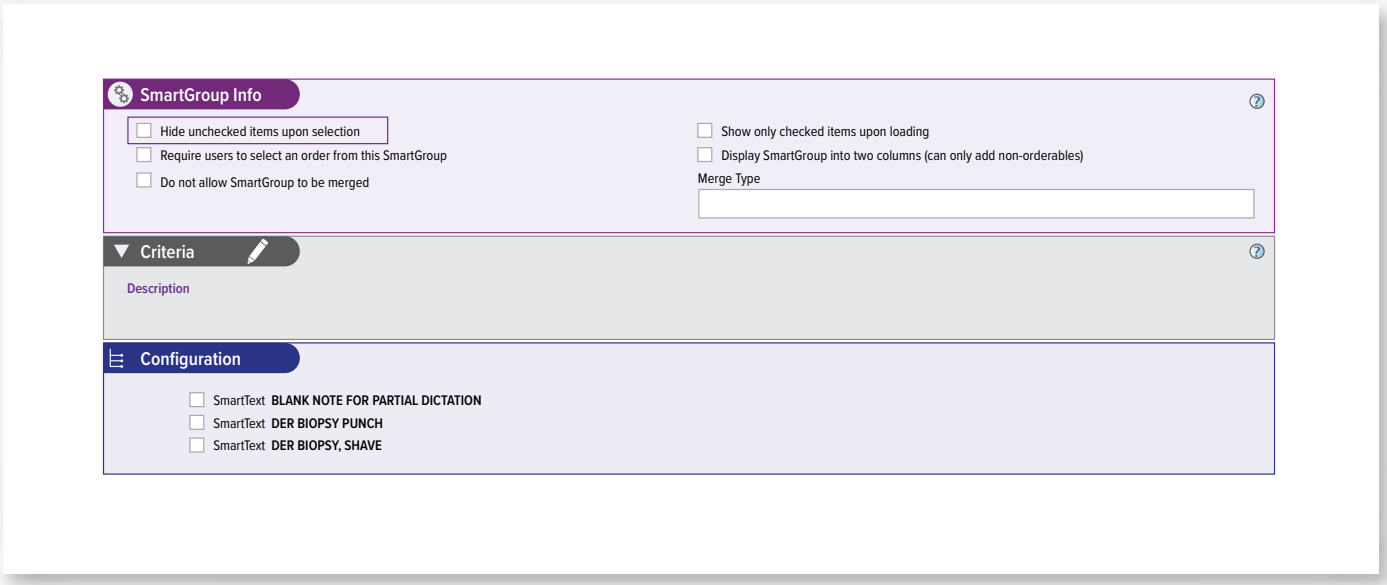
Add Items to a SmartGroup (continued)



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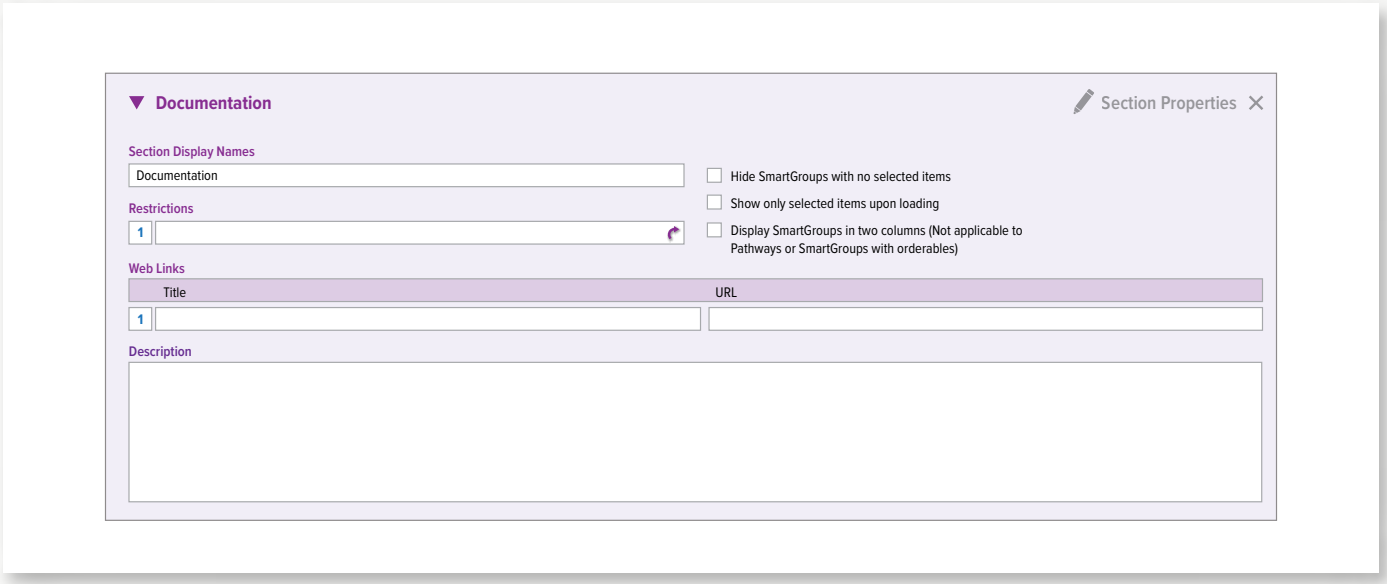

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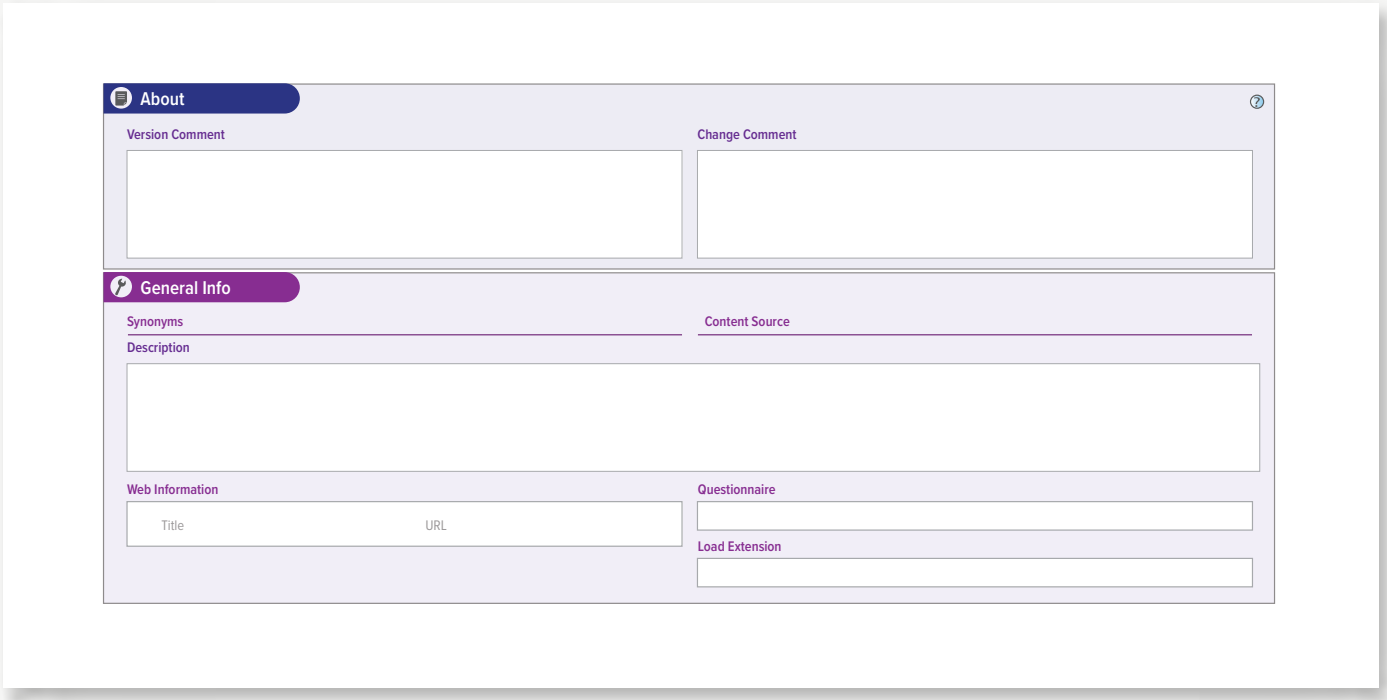
Create a New SmartSet or Order Set and Configure the General Info Form

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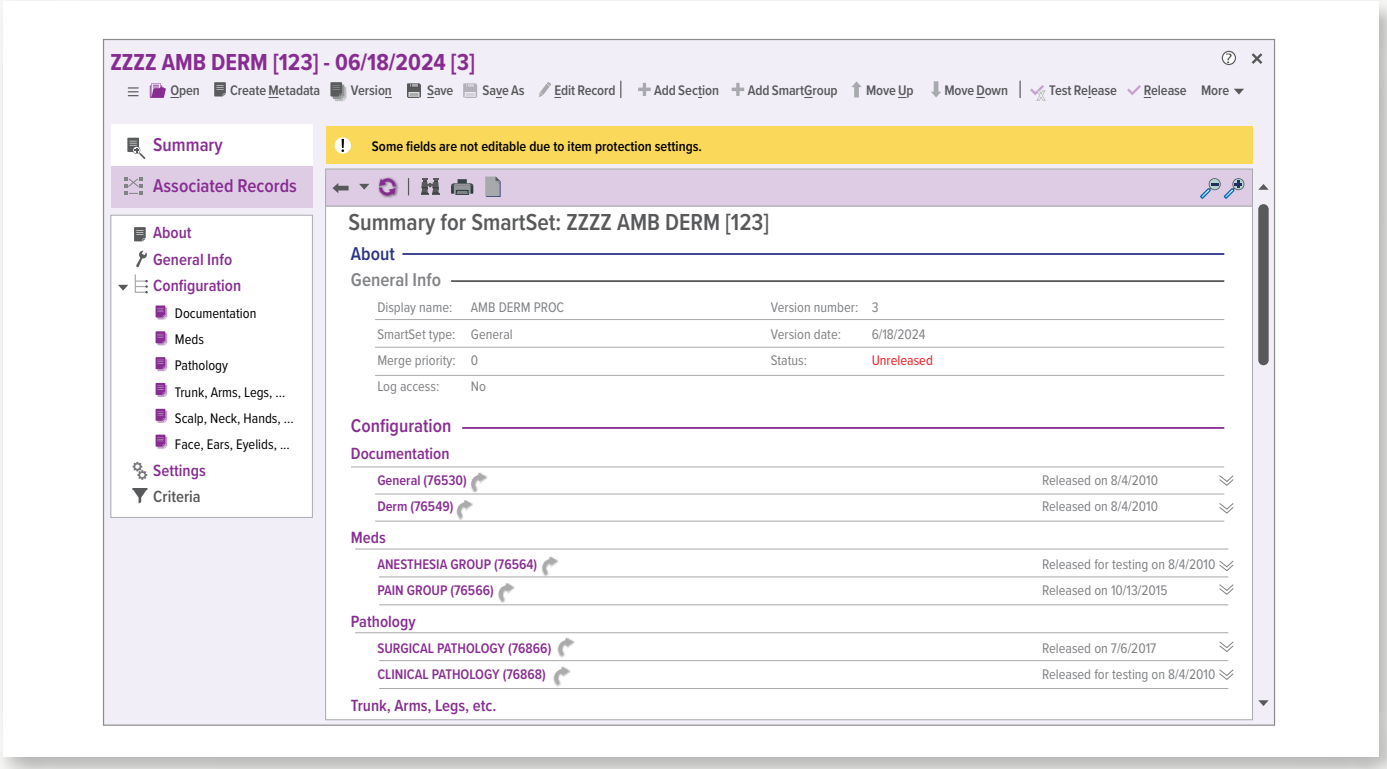
Create a New SmartSet or Order Set and Configure the General Info Form (continued)



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The name you gave the **SmartSet** record appears automatically 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.

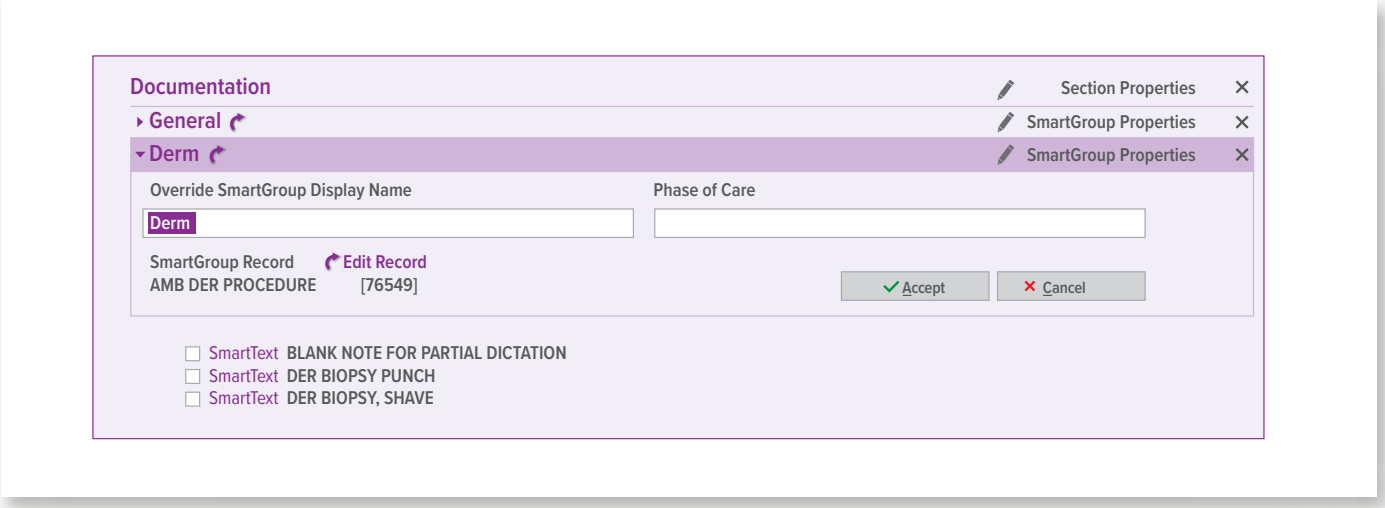
Create a New SmartSet or Order Set and Configure the General Info Form (continued)

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

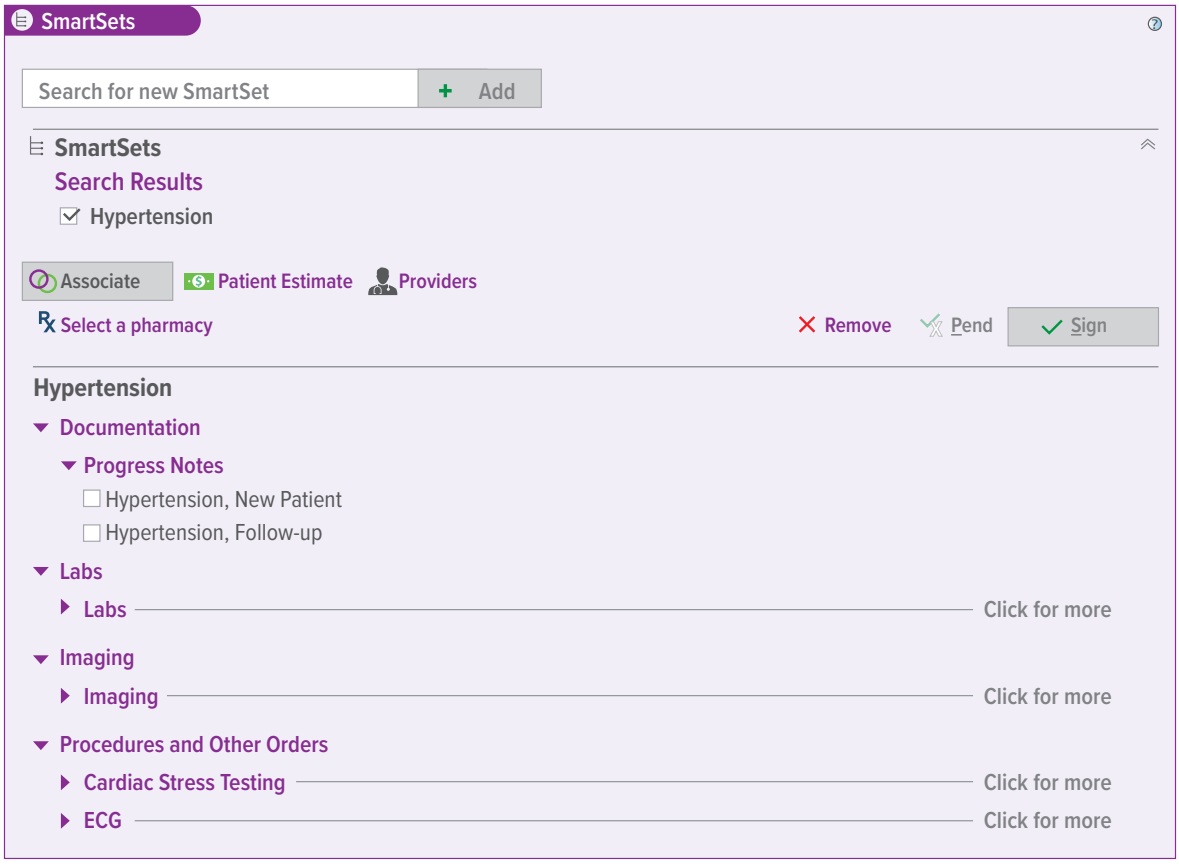
To release an individual **SmartSet** or **Order Set**:

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 healthcare professionals (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
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INDICATION

ZOLGENSMA is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the *survival motor neuron 1* (*SMN1*) gene.

Limitations of Use

The safety and effectiveness of repeat administration or the use in patients with advanced SMA (eg, complete paralysis of limbs, permanent ventilator dependence) has not been evaluated with ZOLGENSMA.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: Serious Liver Injury and Acute Liver Failure

Cases of acute liver failure with fatal outcomes have been reported. Acute serious liver injury, acute liver failure, and elevated aminotransferases can also occur with ZOLGENSMA. Patients with preexisting liver impairment may be at higher risk. Prior to infusion, assess liver function of all patients by clinical examination and laboratory testing. Administer systemic corticosteroid to all patients before and after ZOLGENSMA infusion. Continue to monitor liver function for at least 3 months after infusion, and at other times as clinically indicated. If acute serious liver injury or acute liver failure is suspected, promptly consult a pediatric gastroenterologist or hepatologist.

WARNINGS AND PRECAUTIONS

Systemic Immune Response

Patients with underlying active infection, either acute or chronic uncontrolled, could be at an increased risk of serious systemic immune response. Administer ZOLGENSMA to patients who are clinically stable in their overall health status (eg, hydration and nutritional status, absence of infection). Postpone ZOLGENSMA in patients with infections until the infection has resolved and the patient is clinically stable.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Thrombocytopenia

Transient decreases in platelet counts, some of which met the criteria for thrombocytopenia, were typically observed within the first 2 weeks after ZOLGENSMA infusion. Monitor platelet counts before ZOLGENSMA infusion and on a regular basis for at least 3 months afterwards.

Thrombotic Microangiopathy

Cases of thrombotic microangiopathy (TMA) were reported to occur generally within the first 2 weeks after ZOLGENSMA infusion. TMA can result in life-threatening or fatal outcomes. Obtain baseline creatinine and complete blood count before ZOLGENSMA infusion. Following infusion, monitor platelet counts closely as well as other signs and symptoms of TMA. Consult a pediatric hematologist and/or pediatric nephrologist immediately to manage as clinically indicated.

Elevated Troponin-I

Increases in cardiac troponin-I levels were observed following ZOLGENSMA infusion. Monitor troponin-I before ZOLGENSMA infusion and on a regular basis for at least 3 months afterwards. Consider consultation with a cardiologist if troponin elevations are accompanied by clinical signs or symptoms.

AAV Vector Integration and Risk of Tumorigenicity

There is a theoretical risk of tumorigenicity due to integration of AAV vector DNA into the genome. Cases of tumor have been reported in patients who received ZOLGENSMA post-approval; a causal relationship has not been established based on tumor analysis. In some cases, limited information was available. Report cases of tumor development in patients who received ZOLGENSMA to Novartis Gene Therapies, Inc. at 1-833-828-3947.

ADVERSE REACTIONS

The most commonly observed adverse reactions (incidence ≥5%) in clinical studies were elevated aminotransferases and vomiting.

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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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