



**INPATIENT HOSPITAL
PHARMACY FREE TRIAL
PROGRAM
CUSTOMER ENROLLMENT &
ORDERING STEPS GUIDE**

1 Enroll

1.1 Returning User

Step 1 Access the Free Trial Program (FTP) Home Page

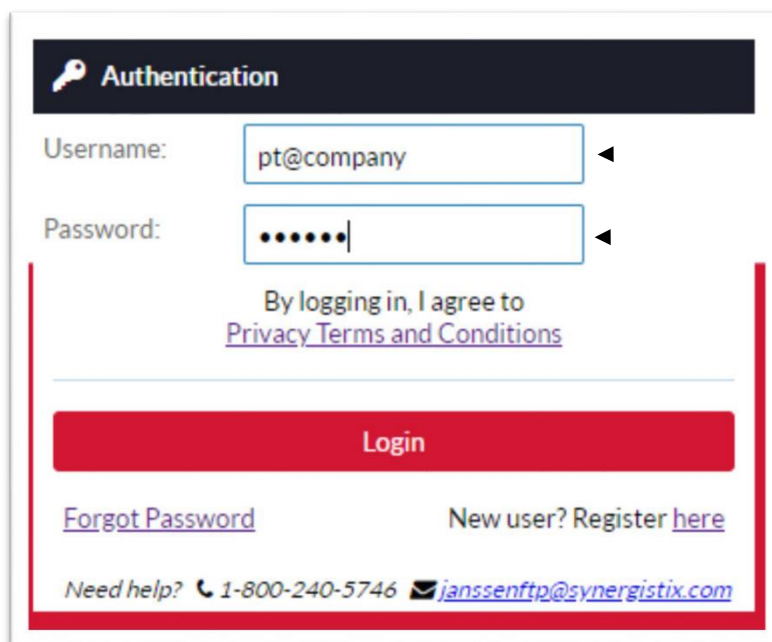
- Go to www.inpatientfreetrialprogram.com

Step 2 Log In

- Read the program rules.



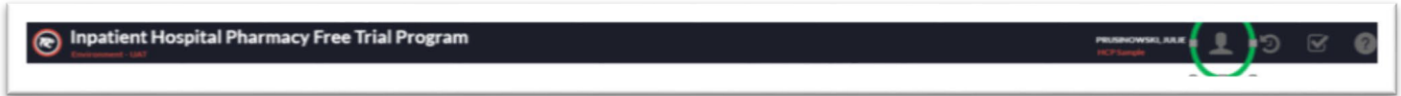
- Click 'CLICK HERE' Enter your username (the email address used to enroll)
- Enter your password, then click "Login."

A screenshot of a web page titled 'Authentication'. It has a dark header with a key icon and the word 'Authentication'. Below the header, there are two input fields: 'Username:' with the text 'pt@company' and 'Password:' with six dots. To the right of each field is a small black triangle icon. Below the password field, there is a line of text: 'By logging in, I agree to [Privacy Terms and Conditions](#)'. At the bottom, there is a large red button labeled 'Login'. Below the button, there are two links: '[Forgot Password](#)' and 'New user? Register [here](#)'. At the very bottom, there is a footer with the text 'Need help? ☎ 1-800-240-5746 ✉ janssenftp@synergistix.com'.

Step 3

Update/Review Enrollment

- If you would like to update or review the enrollment information submitted, you can do so by accessing the “My Account” screen.



- Review and update your personal information in the upper section of the screen.

- To edit an existing Pharmacy, Inpatient Hospital, or Prescriber, tap the desired record and edit the desired field(s). Click SAVE.

- To add a new Pharmacy, Inpatient Hospital, or Prescriber, click the ‘+’ icon for the desired entity type.
- ☐ To remove a Pharmacy, Inpatient Hospital, or Prescriber, select the desired record and click the trashcan icon (only one record may be selected at a time for deletion).

Important:

- **Adding new records and certain edits to existing records require validation and may impact your ability to place orders. Please allow up to 7 business days for processing.**

1.2 New User

Step 1 Access the FTP Home Page


- Go to www.inpatientfreetrialprogram.com


Step 2 Create an account

- Read the program rules.
- Click 'CLICK HERE'.



- Click 'New user? Register [here](#)'
- Enter a valid email address and password

 **Authentication**

Username: 

Password:

By logging in, I agree to [Privacy Terms and Conditions](#)

[Forgot Password](#) New user? Register [here](#)

Need help? ☎ 1-800-240-5746 ✉ janssenftp@synergistix.com

Step 3 Pharmacist Registration and Enrollment

- Enter all required information.
- Review & accept the program rules.
- Click on the “Accept” button to complete registration.

First Name*:	<input type="text"/>	SLN*:	<input type="text"/>
Last Name*:	<input type="text"/>		
Professional Designation*:	<input type="text"/>	State of Licensure*:	<input type="text"/>
Address1*:	<input type="text"/>		
Address 2*:	<input type="text"/>		
City*:	<input type="text"/>	State*:	<input type="text"/>
		ZIP*:	<input type="text"/>

Important:

You must first dispense a unit of INVEGA SUSTENNA® before you can receive a free trial unit. Free trial unit requests must be placed within 30 days of dispense date of the unit to be replaced and include the serial number of a recently dispensed trade product (unit purchased or an FTP unit).

INVEGA SUSTENNA® Inpatient Hospital Pharmacy Free Trial Program Customer Enrollment and Ordering Guide

Pharmacist Pharmacy Inpatient Hospital* Prescriber

will receive an email copy of these rules for your future reference, and you can also access them at any time by returning to this website. Check each mandatory box (noted with an asterisk) to indicate your agreement that you understand and will follow that rule:

- * **ELIGIBILITY** - The free trial product requested must be for an inpatient hospital licensed as a hospital under applicable state law that is unable to accept PDMA (Prescription Drug Marketing Act) samples. Pharmacy agrees that in its capacity as a pharmacy of a healthcare entity,¹ it would be eligible to receive samples under PDMA, even if it elects not to do so as a matter of pharmacy or inpatient hospital policy. Retail pharmacies are not eligible for program participation. Participating pharmacist(s), pharmacy(ies), hospital(s), and prescriber(s) must be licensed or authorized under state law to dispense and/or prescribe the prescription drug product requested. There is no requirement for subsequent use of INVEGA SUSTENNA® for any patient receiving a free trial unit
- * **ANNUAL ENROLLMENTS** - Enrollments must minimally include one of each of the following valid² state license numbers: (1) inpatient hospital pharmacists, (2) inpatient hospital pharmacy, (3) inpatient hospital, and (4) inpatient hospital prescriber.³ If there is a change to any of the information provided, you are required to notify us immediately.
- * **PATIENT & PRESCRIBER QUANTITY LIMITS** - For patients determined to be appropriate, pharmacists may order and receive up to 2 free trial units per calendar year per patient. Orders will ship directly to the hospital pharmacy. Additional quantity limits are up to 96 units per prescriber and no more than 480 units per institution, each within a 6-month period. Inpatient hospital pharmacies and inpatient hospitals must have the ability to track utilization of this program by each patient and establish adequate controls to ensure that product received under this program is appropriately segregated and tracked as if it were a PDMA sample. Janssen Pharmaceuticals Inc., reserves the right to audit these controls.
- * **PROHIBITION ON SEPARATE BILLING** - This product is being provided free of charge. Free trial units are commercially labeled as trade product and not labeled as sample products. Do not separately bill the patient, the patient's insurance carrier, or the government for any INVEGA SUSTENNA® dispensed as part of this program. Free trial product received pursuant to this program may not be sold, traded, bartered, or returned for credit.
- * **EXCLUSIONS** - The program is only available for any inpatient hospital that is unable to accept PDMA samples. The inpatient hospital agrees that it is not utilizing samples. If samples and free trial units are being shipped to the same address, the inpatient hospital must be able to provide a distinct location (floor, suite, office) for shipment of samples within the hospital for outpatient use.
- * **DISPENSE DATE** - Orders requesting free trial units must be submitted within 30 days of the dispense date. The dispense date may not be in the future. The initial request for a free trial unit must be based on a unit taken from inventory purchased by the pharmacy.
- * **SERIAL NUMBER** - The package serial number for the INVEGA SUSTENNA® medication is required each time an order is placed. The serial number of a recently dispensed trade product is required. The serial number is found on the bottom of the carton of the medication. If a serial number is not entered, the order cannot be processed. If a duplicated serial number is entered, the order will be rejected.
- * **PHARMACIST ACKNOWLEDGMENT OF RECEIPT (AOR)** - Failure to complete AOR(s) within ninety (90) days will result in a suspension of the program for the pharmacist, pharmacy, and hospital.
- * **HOSPITAL VERIFICATION LETTER (HVL)** - For hospitals that do not have an on-site owned and operated pharmacy, the hospital may receive free trial units for its patients through an off-site pharmacy owned by the hospital or pharmacy operated by a third party on behalf of the hospital, if the hospital designates the pharmacy and the pharmacy provides the required certification. Twice a year, hospitals receiving free trial units from a pharmacy that is not on-site owned and operated by the hospital will be required to acknowledge their receipt of the free trial units requested by the pharmacy, provide confirmation of a tracking mechanism, confirm only 2 units were dispensed per patient per year, and confirm compliance with program requirements.
- * **ELECTRONIC SIGNATURE & SECURITY** - You agree that you are creating an electronic signature and that this electronic signature is the legal and binding equivalent of your handwritten signature. Precautions to safeguard your email account against unauthorized access, disclosure, alteration, and destruction must be taken. Password and security answers must be confidential, and all information provided must be true.
- * **TRANSPARENCY** - Hospital, pharmacy, pharmacist, and prescriber information and the free trial disbursement(s) that you receive may be reported as required by state or federal law. Once reported, this information may be made available for public view.
- * **TERM AND SCOPE** - Program terms expire at the end of each calendar year. Program available only in the United States and Puerto Rico.

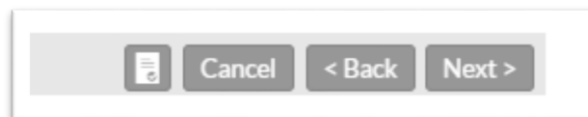
¹Healthcare entity means any person who provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a healthcare entity and a retail pharmacy or wholesale distributor.

Cancel Accept

Step 4

Enroll

- Enter the required enrollment information.
 - ✓ Follow the steps to enroll inpatient hospital pharmacy(ies), inpatient hospital(s), and inpatient hospital prescriber(s) supporting the program.
 - ✓ Use the Back and Next buttons to navigate the enrollment pages



Step 5

Review & Accept Program Rules & Execute Your Electronic Signature

- Review and accept the program rules.
- Execute your electronic signature.
- Complete CAPTCHA.
- Click on the “Enroll” button to proceed.

Register for the Inpatient Hospital Pharmacy Free Trial Program


Program Rules

In order to receive free trial units for your patients, you must agree to follow program rules. The full program rules are listed below. You are required to check all mandatory boxes (noted with an asterisk) to indicate your agreement that you understand and will follow that rule.

Failure to follow program rules may result in termination of your ability to receive free trial units for your patients under this program. In some program correspondence, you will see an overview version of key program rules as a helpful reminder. You are responsible for following all program rules, as set forth below. You will receive an email copy of these rules for your future reference, and you can also access them at any time by returning to this website. Check each mandatory box (noted with an asterisk) to indicate your agreement that you understand and will follow that rule

- * **ELIGIBILITY** -The free trial product requested must be for an inpatient hospital licensed as a hospital under applicable state law that is unable to accept PDMA (Prescription Drug Marketing Act) samples Pharmacy agrees that in its capacity as a pharmacy of a healthcare entity,1 it would be eligible to receive samples under PDMA, even if it elects not to do so as a matter of pharmacy or inpatient hospital policy Retail pharmacies are not eligible for program participation Participating pharmacist(s), pharmacy(ies), hospital(s), and prescriber(s) must be licensed or authorized under state law to dispense and/or prescribe the prescription drug product requested There is no requirement for subsequent use of INVEGA SUSTENNA® for any patient receiving a free trial unit.
- * **ANNUAL ENROLLMENTS** - Enrollments must minimally include one of each of the following valid2 state license numbers: (1) inpatient hospital pharmacists, (2) inpatient hospital pharmacy, (3) inpatient hospital, and (4) inpatient hospital prescriber,3 If there is a change to any of the information provided, you are required to notify us immediately.
- * **PATIENT & PRESCRIBER QUANTITY LIMITS** - For patients determined to be appropriate, pharmacists may order and receive up to 2 free trial units per calendar year per patient. Orders will ship directly to the hospital pharmacy. Additional quantity limits are up to 96 units per prescriber and no more than 480 units per institution, each within a 6-month period. Inpatient hospital pharmacies and inpatient hospitals must have the ability to track utilization of this program by each patient and establish adequate controls to ensure that product received under this program is appropriately segregated and tracked as if it were a PDMA sample. Janssen Pharmaceuticals, Inc., reserves the right to audit these controls.
- * **PROHIBITION ON SEPARATE BILLING** - This products is being provided free of charge. Free trial units are commercially labeled as trade product and not labeled as sample products. Do not separately bill the patient, the patient's insurance carrier, or the government for any INVEGA SUSTENNA® dispensed as part of this program. Free trial product received pursuant to this program may not be sold, traded, bartered, or returned for credit.
- * **EXCLUSIONS** -The program is only available for any inpatient hospital that is unable to accept PDMA samples The inpatient hospital agrees that it is not utilizing samples If samples and free trial


Please Sign Here:


I'm not a robot  reCAPTCHA
Privacy - Terms

Step 6

Confirmation Page

- A thank you message will display advising that your enrollment application will be processed within 7 business days.

Enrollment Complete 

 Thank you, we have received your enrollment information.
Please allow up to seven (7) business days for processing.

When the enrollment processing is completed, you will receive an email with the program rules, a time stamp of your electronic signature, and confirmation as to whether enrollment has been approved or denied.

OK

Step 7

Ready to Place Orders?

- Once your enrollment application has been approved, you will be notified via email. At that time, you may begin to request free trial units directly online.

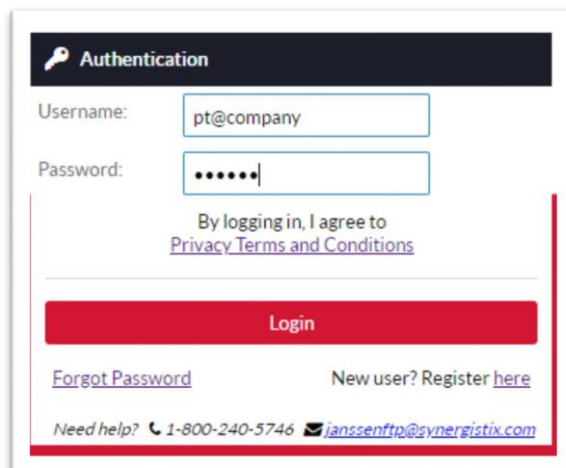
2 Order Placement

Step 1 Access the FTP Home Page

- Go to www.inpatientfreetrialprogram.com

Step 2 Log In

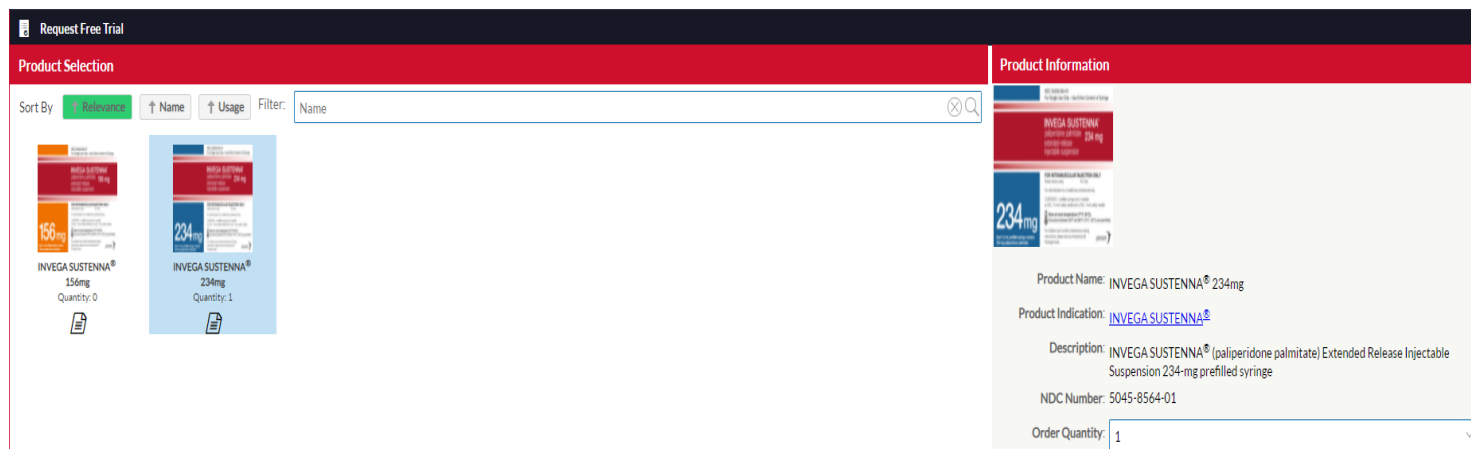
- Enter your username (the email address used to enroll) & password.



The screenshot shows a web form titled "Authentication". It includes a "Username:" field with the text "pt@company" and a "Password:" field with masked characters. Below the fields is a checkbox area with the text "By logging in, I agree to [Privacy Terms and Conditions](#)". A prominent red "Login" button is centered below. At the bottom, there are links for "Forgot Password" and "New user? Register here". A footer contains the text "Need help? 1-800-240-5746" and an email address "janssenftp@synergistix.com".

Step 3 Access the View/Order Products Page

- You will be taken directly to the Request Samples screen upon successful login.
- Click on a product on the left and select quantity on the right.
- You may request one free trial unit per strength per order.
- Click on the "Next" button to proceed to the next page.



The screenshot displays the "Request Free Trial" interface. The top navigation bar is red with the text "Request Free Trial". Below it, the "Product Selection" section features a search bar with "Name" as the filter and sorting options for "Relevance", "Name", and "Usage". Two product cards are visible: "INVEGA SUSTENNA® 156mg" with a quantity of 0, and "INVEGA SUSTENNA® 234mg" with a quantity of 1. The right-hand side of the page is titled "Product Information" and provides details for the selected 234mg product, including the product name, indication, description, and NDC number. An "Order Quantity" dropdown menu is set to 1.

INVEGA SUSTENNA® Inpatient Hospital Pharmacy Free Trial Program Customer Enrollment and Ordering Guide

- Select the correct inpatient hospital pharmacy “Pharmacy Ship To.”
- Select the correct inpatient hospital Prescriber.
- Enter the Dispense Date.
- Enter serial number that coincides with the product dispense date.
- Review shipping information.
- Execute your electronic signature.
- Click on the “Next” button to review the order before placing the order.

The screenshot displays the 'Request Free Trial' web application interface. The top navigation bar includes the program name, 'Environment - Dev', and user profile icons. The main content area is titled 'Request Free Trial' and contains a 'Select Delivery Preferences' section with the following fields: 'Pharmacy Ship To*', 'Inpatient Hospital*', 'Inpatient Hospital Prescriber*', 'Product Dispense Date*', and 'Serial Number'. A note below these fields states: 'If order is completed after 1.00PM Eastern, order is not guaranteed for next day delivery.' Below the preferences section is a 'Signature' section containing a detailed disclaimer text, a 'Please Sign Here' box, and a 'Name' field with the following information: 'Prof. Desig.: RPh', 'SLN Number:', and 'Date: 7/1/2021 11:08 AM'. At the bottom of the signature section are 'Clear' and 'Accept' buttons. The footer of the application shows navigation buttons: '< Back', 'Next >', 'Cancel', and 'Submit Req'.

Important:

If a pharmacy, hospital, or Prescriber in your profile is not listed in the drop-down, you can check the status in your account. Please see page 3.

Step 4

Place Order

- Review the order information and click on “Submit Req” to submit your request.

The screenshot displays the 'Review Order Summary' page of the Inpatient Hospital Pharmacy Free Trial Program. The page is titled 'Request Free Trial' and shows the following information:

- Order for:** FTP Portal
- Date:** 10/10/2020, 9:28:56 PM

Preview	Product Name	Quantity
	INVEGA SUSTENNA® 156mg	1
		1
		1

Additional Information

Ship To

480 Sawgrass Corp, Suite 200
Sunrise FL, 33325


To modify your order, please go back to the previous screen.

Navigation buttons: < Back, Next >, Cancel, **Submit Req**

Step 5

Order Confirmation

- Once your order has been successfully created, an order confirmation page will display.
- You will receive an email confirming your order has been placed and another email once your order has shipped.

Inpatient Hospital Pharmacy Free Trial Request			
Request Date:	6/18/2020	Order Number:	FTP263157
Practitioner's Name:	ROBERT JANE	State License:	ME0096486
Ship To Address1:	480 SAWGRASS CORP	Professional Designation:	MD
Ship To Address2:		Specialty:	P
Ship To City, State, Zip:	SUNRISE, FL 33325		
Phone:	3525964306		
Inpatient Hospital:		Ordered By:	
Inpatient Pharmacy:			
Product Code	Product Description	Qty	
5045-8564-01	INVEGA SUSTENNA® (paliperidone palmitate) Extended Release Injectable Suspension 234-mg prefilled syringe	1	
<p>My signature certifies that I am a licensed pharmacist eligible to receive and dispense this product and the HCP is licensed or authorized under state law to prescribe INVEGA SUSTENNA®. I have requested the products for patient(s) of inpatient hospital(s) served by my pharmacy. The product received pursuant to this request will be used for patient(s) determined to be appropriate for a new trial and each patient shall receive no more than 2 free trial units per calendar year, used within the dosing regimen set forth in the product label. I am responsible for ensuring my pharmacy can track utilization of this program by each patient. I acknowledge that free trial product received pursuant to this program will not be sold, traded, bartered, returned for credit or separately billed to the patient, the patient's insurance, or the government. I understand that additional quantity limits may apply by institution, and that my pharmacy may be required to provide additional evidence of eligibility for this program. I understand that either my signature or the signature of a responsible person at the receiving facility is required as a receipt of delivery. Ohio Only: I attest that by requesting shipment of these free trial drug units, I am in compliance with the State of Ohio ORC 4729.51 (TDDD license).</p> <p>INVEGA SUSTENNA® (paliperidone palmitate) is manufactured by: Janssen Pharmaceutica NV, Beerse, Belgium. Distributed by: Priority Solutions International.</p>			
Signature:		Date:	6/18/2020

Program Rules			
In order to receive free trial units for your patients, you must agree to follow program rules. The full program rules are listed below.			

INVEGA SUSTENNA® Inpatient Hospital Pharmacy Free Trial Program Customer Enrollment and Ordering Guide

Step 6 View Order Status & History

- Once you have successfully placed orders online, you can view your order status and history by accessing the "History" screen.



- You will be able to view all orders placed online as well as details within each order.
- Visibility into other pharmacists at pharmacy placing orders.
- Visibility into serial numbers previously used.
- You will be able to print the order confirmation by clicking the printer icon in the upper left corner.
- You will be able to export to excel.
- You will be able to cancel an order if it has not yet been submitted to fulfillment by clicking the trashcan icon in the upper left corner.

Request ID	Request Date	Status	Ship to Address	Pharmacist Name	Pharmacy Name	HCP Name	Dispense Date	SerialNumber	Product Name
499104	05/19/2021	Completed	1234 Main Street, Sunrise, FL 33322	JOHN SMITH	HEALTHCARE PHARMACY	JANE FORD	04/19/2021	100002350...	INVEGA SUSTENNA® 156mg
499103	05/19/2021	Completed	1234 Main Street, Sunrise, FL 33322	JOHN SMITH	HEALTHCARE PHARMACY	JANE FORD	04/27/2021	100002350...	INVEGA SUSTENNA® 156mg
499102	05/19/2021	Completed	1234 Main Street, Sunrise, FL 33322	JOHN SMITH	HEALTHCARE PHARMACY	JANE FORD	04/19/2021	100002340...	INVEGA SUSTENNA® 156mg
499100	05/19/2021	Completed	1234 Main Street, Sunrise, FL 33322	JOHN SMITH	HEALTHCARE PHARMACY	JANE FORD	04/19/2021	100002265...	INVEGA SUSTENNA® 156mg
499097	05/19/2021	Completed	1234 Main Street, Sunrise, FL 33322	JOHN SMITH	HEALTHCARE PHARMACY	JANE FORD	04/20/2021	100002265...	INVEGA SUSTENNA® 156mg

246 records

Signature

My signature certifies that I am a licensed pharmacist eligible to receive and dispense this product and the HCP is licensed or authorized under state law to prescribe INVEGA SUSTENNA®. I have requested the products for patient(s) of inpatient hospital(s) served by my pharmacy. The product received pursuant to this request will be used for patient(s) determined to be appropriate for a new trial and each patient shall receive no more than 2 free trial units per calendar year, used within the dosing regimen set forth in the product label. I am responsible for ensuring my pharmacy can track utilization of this program by each patient. I acknowledge that free trial product received pursuant to this program will not be sold, traded, bartered, returned for credit or separately billed to the patient, the patient's insurance, or the government. I understand that additional quantity limits may apply by institution, and that my pharmacy may be required to provide additional evidence of eligibility for this program. I understand that either my signature or the signature of a responsible person at the receiving facility is required as a receipt of delivery. Ohio Only: I attest that by requesting shipment of these free trial drug units, I am in compliance with the State of Ohio ORC 4729.51 (TDDD license). INVEGA SUSTENNA® (palliperidone palmitate) is manufactured by: Janssen Pharmaceutica NV, Beerse, Belgium. Distributed by: Priority Solutions International.

Please Sign Here:

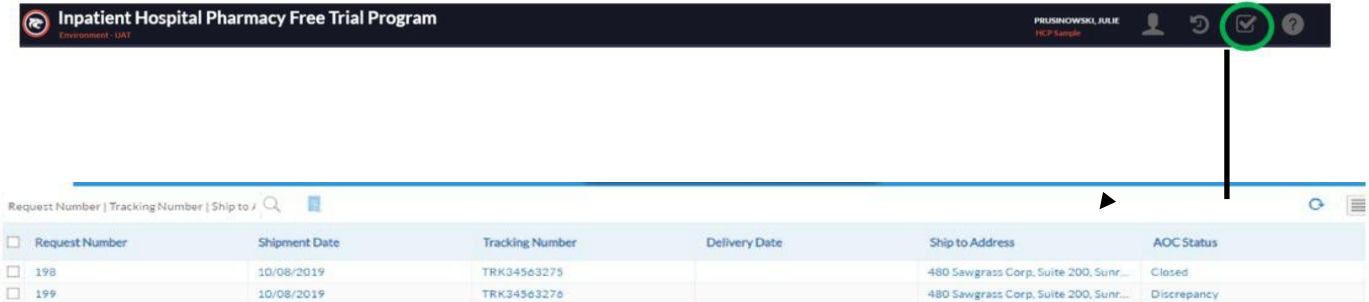
Name: _____
 Prof. Desig.: RPh
 SLN Number: _____
 Date: 7/1/2021 11:08 AM

Clear Accept

< Back Next > Cancel Submit Req

Step 7 Content Acknowledgment

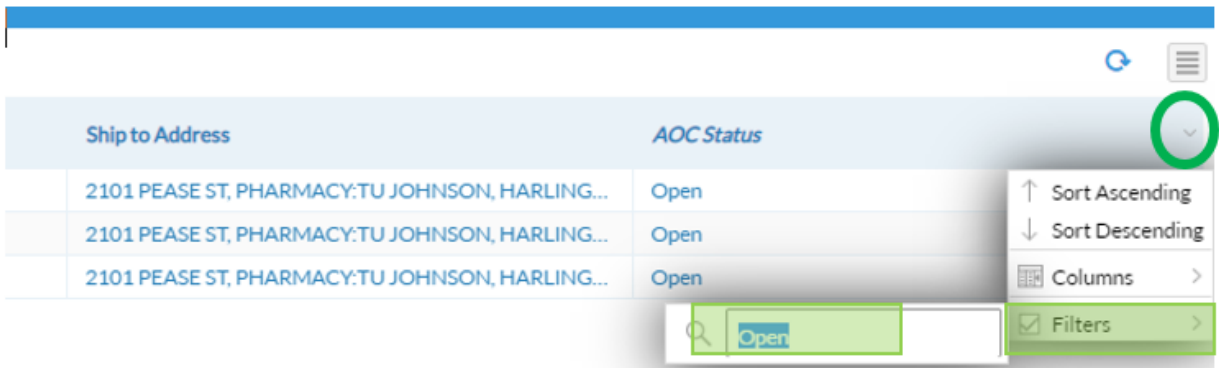
- Below is the 3-step process for acknowledging the AOC:
 - 1) Locate the order (request)



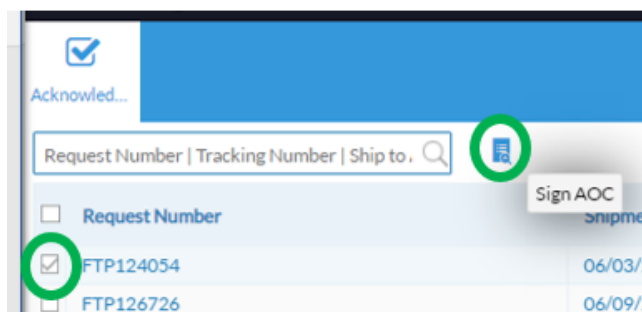
- Use the Search box to search for a specific request or tracking number.



- Or, filter the AOC status column to display only Open requests.



- 2) Select the order # by checking the box
- 3) Go to 'Sign AOC' icon and select to acknowledge



INVEGA SUSTENNA® Inpatient Hospital Pharmacy Free Trial Program
Customer Enrollment and Ordering Guide

- Enter all required information.

Order Number: FTP124054
Order Date: 06/02/2020
Ship to: [Redacted]

Requested by:
Degree: RPh
Specialty:
SLN: [Redacted]

Products

NDC	Product	Lot Number	Expiration Date	Requested Qty	Shipped Qty	Qty
5045-8564-01	INVEGA SUST...	JKB5A00	10/31/2021	1	1	1

1 record (1 selected)

Yes, I received all of the items listed above. **2** No, I did not receive all of the items listed.

Received By:

First Name: [Input Field]
Last Name: [Input Field]
Degree: [Input Field] **3**

Signature: [Signature Box] **4**

Clear Accept **5**

Date: 08/02/2020

6 Cancel Save

- 1 Enter the received quantity.
 - 2 Select Yes/No received all option.
 - 3 Enter Name and Degree of person acknowledging receipt (does not need to be the requesting pharmacist).
 - 4 Enter electronic signature using mouse or finger if using touchscreen.
 - 5 Select 'Accept' to capture signature.
 - a. Select Clear to clear signature box; re-enter electronic signature.
 - 6 Select 'Save' to submit Acknowledgment.
- Screen will return user to the AOC screen and list of orders.
 - Select the refresh icon to refresh screen; AOC Status will now display 'Closed'.

Important:

Only orders in the status of 'Delivered' will show on the AOC screen

INVEGA SUSTENNA® Inpatient Hospital Pharmacy Free Trial Program Customer Enrollment and Ordering Guide

Annual Re-Enrollment

- 1 Go to My Account.
- 2 Review account, edit as needed.
- 3 Review and attest to program rules.
- 4 Execute electronic signature.
- 5 Click Save.

The screenshot displays the 'Inpatient Hospital Pharmacy Free Trial Program' interface. A red box highlights the 'Re-enrollment accessed at the bottom of the Edit Profile view.' text, with an arrow pointing to the user profile icon in the top right corner. The main content area shows the 'Re-Enrollment' section with 'Program Rules' and a 'Please Sign Here' field. The 'Program Rules' section contains the following text:

In order to receive free trial units for your patients, you must agree to follow program rules. The full program rules are listed below. You are required to check all mandatory boxes (rated with an asterisk) to indicate your agreement that you understand and will follow that rule. Failure to follow program rules may result in termination of your ability to receive free trial units for your patients under this program.

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- * **SERIAL NUMBER** - The package serial number for the INVEGA SUSTENNA® medication is required each time an order is placed. The serial number of a recently dispensed trade product is required. The serial number is found on the bottom of the carton of the medication. If

The 'Please Sign Here' field contains a dashed box for a signature and 'Clear' and 'Accept' buttons. At the bottom of the modal are 'Cancel' and 'Save' buttons.

INDICATION

INVEGA SUSTENNA® (paliperidone palmitate) is indicated for the treatment of:

- Schizophrenia in adults.
- Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants in adults.

IMPORTANT SAFETY INFORMATION FOR INVEGA SUSTENNA® (paliperidone palmitate)

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

See full prescribing information for complete Boxed Warning.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. INVEGA SUSTENNA® is not approved for use in patients with dementia-related psychosis.

Contraindications: INVEGA SUSTENNA® is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any excipients of the INVEGA SUSTENNA® formulation.

Cerebrovascular Adverse Reactions: Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported at a higher incidence in elderly patients with dementia-related psychosis taking risperidone, aripiprazole, and olanzapine compared to placebo. No studies have been conducted with oral paliperidone, INVEGA SUSTENNA®, or the 3-month paliperidone palmitate extended-release injectable suspension in elderly patients with dementia. These medicines are not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported in association with antipsychotic drugs, including paliperidone.

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

If NMS is suspected, immediately discontinue INVEGA SUSTENNA® and provide symptomatic treatment and monitoring.

QT Prolongation: Paliperidone causes a modest increase in the corrected QT (QTc) interval. Avoid the use of drugs that also increase QTc interval and in patients with risk factors for prolonged QTc interval. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. Certain circumstances may increase the risk of the occurrence of torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Tardive Dyskinesia (TD): TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients will develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing TD and the likelihood that it will become irreversible appear to increase with the duration of treatment and the cumulative dose. The syndrome can develop after relatively brief treatment periods, even at low doses. It may also occur after discontinuation. TD may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

If signs and symptoms of TD appear in a patient on INVEGA SUSTENNA®, drug discontinuation should be considered. However, some patients may require treatment with INVEGA SUSTENNA® despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, have been reported in patients treated with all atypical antipsychotics (APS). Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia during treatment should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension and Syncope: INVEGA SUSTENNA® may induce orthostatic hypotension in some patients due to its alpha-adrenergic blocking activity. INVEGA SUSTENNA® should be used with caution in patients with known cardiovascular disease, cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia, treatment with antihypertensive medications). Monitoring should be considered in patients for whom this may be of concern.

Falls: Somnolence, postural hypotension, motor and sensory instability have been reported with the use of antipsychotics, including INVEGA SUSTENNA®, which may lead to falls and, consequently, fractures or other fall-related injuries. For patients, particularly the elderly, with diseases, conditions, or medications that could exacerbate these effects, assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including INVEGA SUSTENNA®. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or drug-induced leukopenia/neutropenia, perform a complete blood count frequently during the first few months of therapy. Consider discontinuing INVEGA SUSTENNA® at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue INVEGA SUSTENNA® in patients with severe neutropenia (absolute neutrophil count <1000/mm³) and follow their WBC until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D₂ receptors, INVEGA SUSTENNA® elevates prolactin levels, and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to risperidone, which is associated with higher levels of prolactin elevation than other antipsychotic agents.

Potential for Cognitive and Motor Impairment: Somnolence, sedation, and dizziness were reported as adverse reactions in subjects treated with INVEGA SUSTENNA®.

INVEGA SUSTENNA® has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities that require mental alertness such as operating hazardous machinery, including motor vehicles, until they are reasonably certain that INVEGA SUSTENNA® does not adversely affect them.

Seizures: INVEGA SUSTENNA® should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold. Conditions that lower seizure threshold may be more prevalent in patients 65 years or older.

Administration: For intramuscular injection only by a healthcare professional using only the needles provided in the INVEGA SUSTENNA® kit. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: Avoid using a strong inducer of CYP3A4 and/or P-gp (e.g. carbamazepine, rifampin, St. John's Wort) during a dosing interval for INVEGA SUSTENNA®. If administering a strong inducer is necessary, consider managing the patient using paliperidone extended-release tablets.

Pregnancy/Nursing: INVEGA SUSTENNA® may cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare professional if they become pregnant or intend to become pregnant during treatment with INVEGA SUSTENNA®. Patients should be advised that there is a pregnancy registry that monitors outcomes in women exposed to INVEGA SUSTENNA® during pregnancy. INVEGA SUSTENNA® can pass into human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for INVEGA SUSTENNA® and any potential adverse effects on the breastfed infant from INVEGA SUSTENNA® or the mother's underlying condition.

Commonly Observed Adverse Reactions for INVEGA SUSTENNA®: The most common adverse reactions in clinical trials in patients with schizophrenia ($\geq 5\%$ and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder. No adverse events occurred at a rate of $\geq 5\%$ and twice placebo during the 15-month double-blind, placebo-controlled study in patients with schizoaffective disorder. The following adverse reactions occurred more frequently (a $\geq 2\%$ difference vs. placebo) in the long-term study in patients with schizoaffective disorder: weight increased, nasopharyngitis, headache, hyperprolactinemia, and pyrexia.

Please [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

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