



Bionical Emas

DEVELOP | ACCESS | INNOVATE



Bionical Emas

your **PATIENT ACCESS** portal

User Guide



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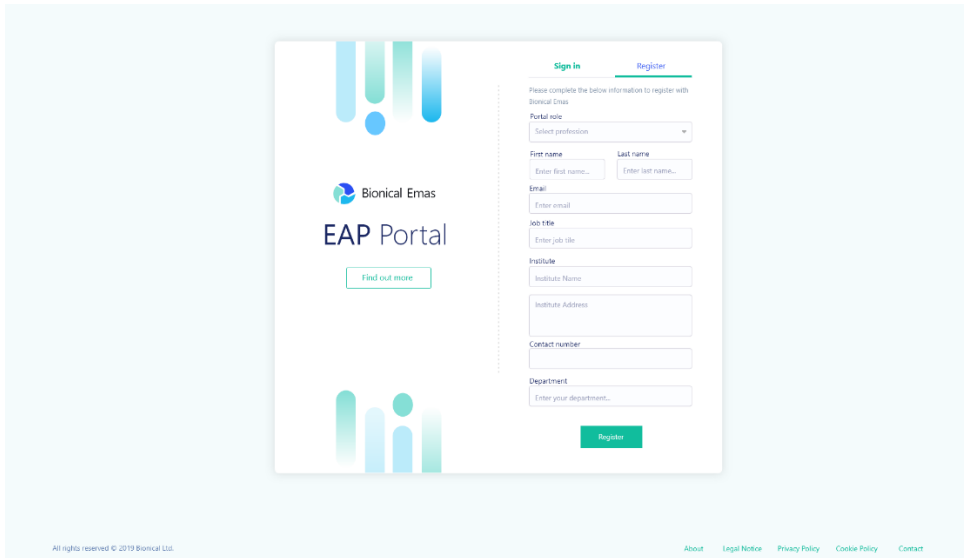
Introduction

Welcome to the Bionical Emas Your Patient Access Portal. The portal has been developed to help enable Health Care Professionals to easily request access and order treatments as well as help Bionical users to manage and facilitate these requests. This User guide contains all essential information for the user to make full use of the system and step-by-step instructions for system access and use.

Universal User

UU – 01 - Account Registration

1. Click on the Register tab at the top of the page.

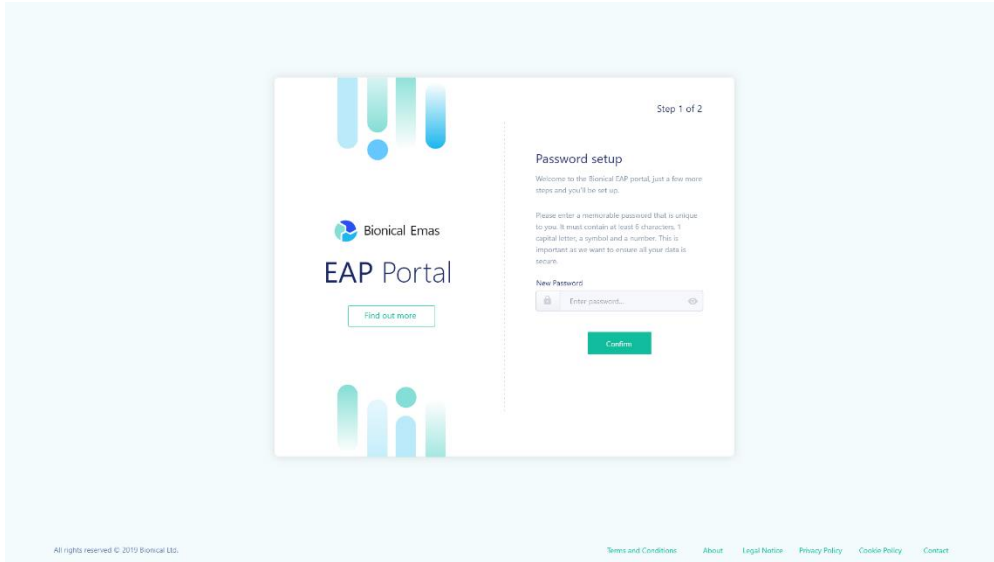


The screenshot shows the Bionical Emas EAP Portal registration form. The form is titled "Sign in Register" and contains the following fields:

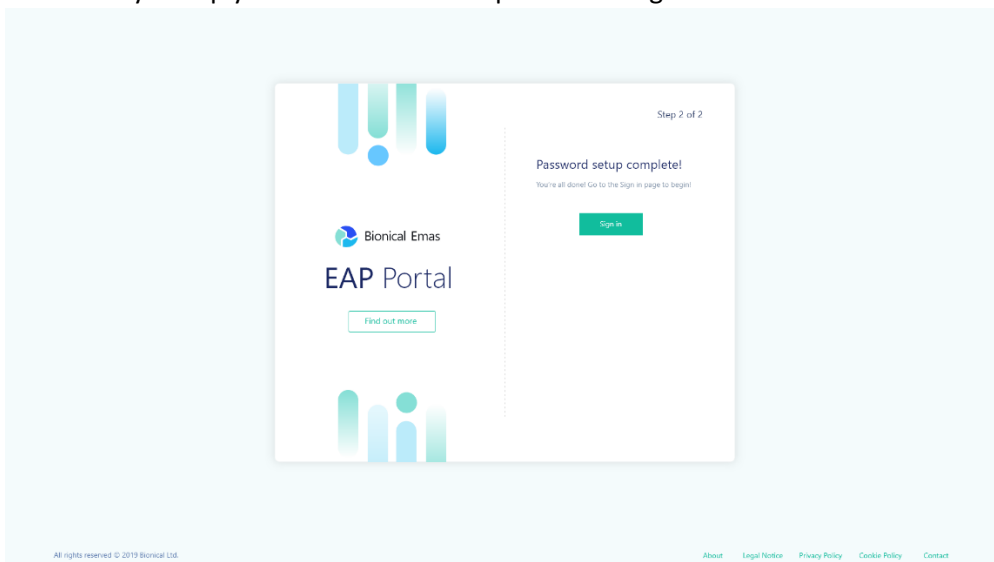
- Portal role (dropdown menu)
- First name (text input)
- Last name (text input)
- Email (text input)
- Job title (text input)
- Institute Name (text input)
- Institute Address (text input)
- Contact number (text input)
- Department (text input)

A "Register" button is located at the bottom of the form. The form is set against a light blue background with the Bionical Emas logo and "EAP Portal" text.

2. Enter details into the form ensuring all fields are complete
3. Click Register button to submit request
4. Upon successful registration you will be sent an email with a link asking to validate your email address.
5. Click on the link and you will receive a confirmation that your email has been validated and your account request is with the Bionical team to be approved.
6. Once approved you will receive an email stating your account has been approved. Click on the link and you will be able to set up your password and login to the portal.

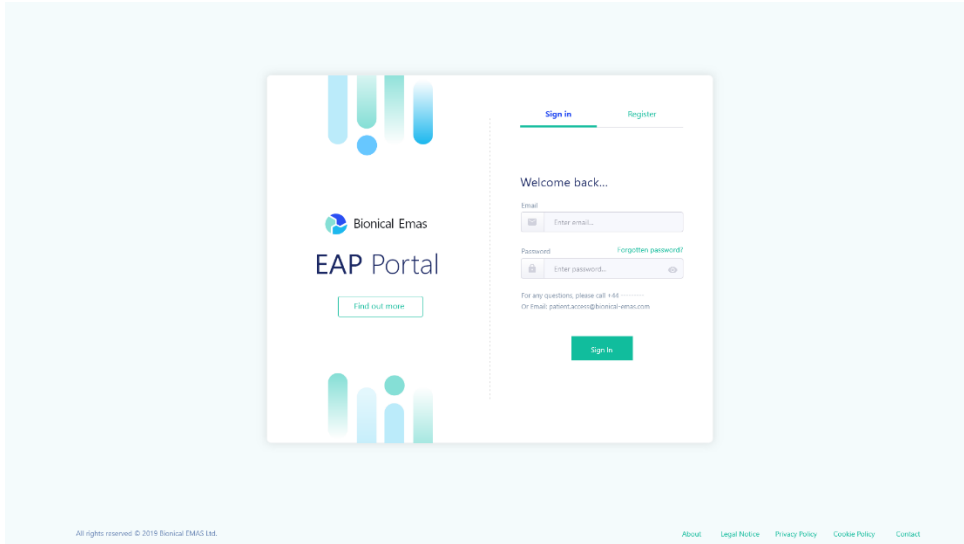


7. Enter a password that meets the minimum-security standards and click on confirm.
 - a. At least 8 characters including
 - i. At least 1 capital letter
 - ii. At least 1 symbol
 - iii. At least 1 number
8. Once a valid password has been entered you will be redirected to a page confirming you have successfully set up your account and can proceed to sign in.

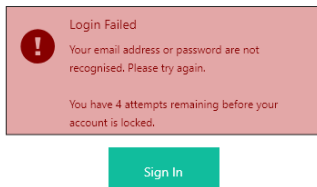


UU – 02 - User Login

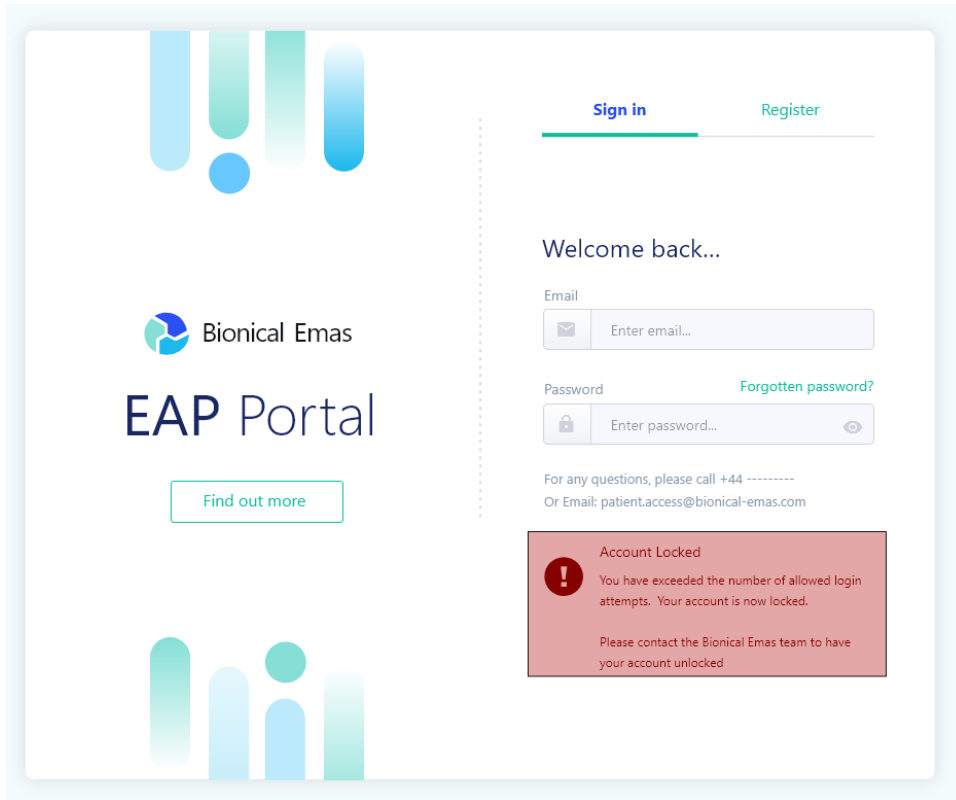
1. Enter email and password



2. If information has been correctly entered, you will be logged in and arrive at the homepage relevant to your account.
3. If unsuccessful you will receive an error stating your email address or password has not been recognised along with the number of attempts, you have been unsuccessful. If you have before the account is locked. You have a total of 5 attempts before the account is locked.



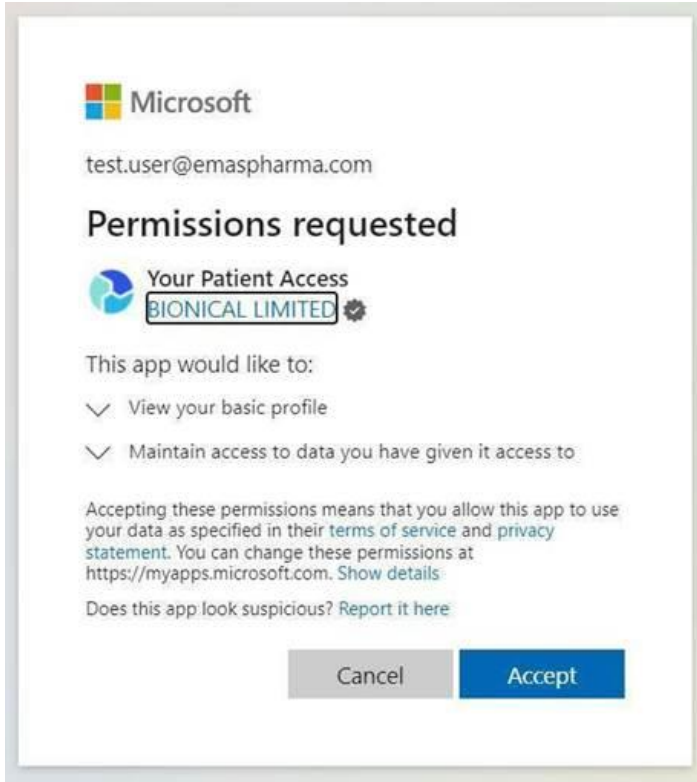
4. You have a total of 5 attempts to login. After the 5th attempt your account will receive a message stating your account has been locked and to get in contact with the Bionical team.



5. Contact the Patient access team via patient.access@bionical-emas.com to unlock the account.

UU – 03 – Single Sign On (SSO)

1. If a user has single sign on enabled on their account they will need to enter their company email address
2. This will prompt them to accept the Permission requested in the pop up

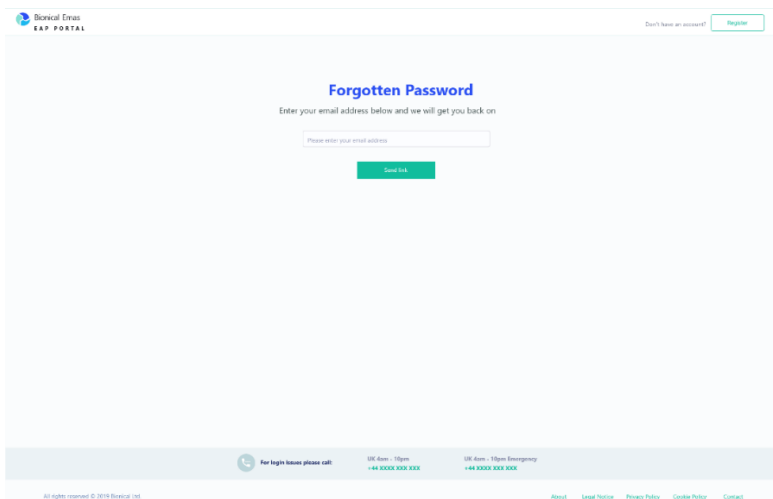


3. The user will be logged in and when prompted to enter a password they will need to enter there organisation password

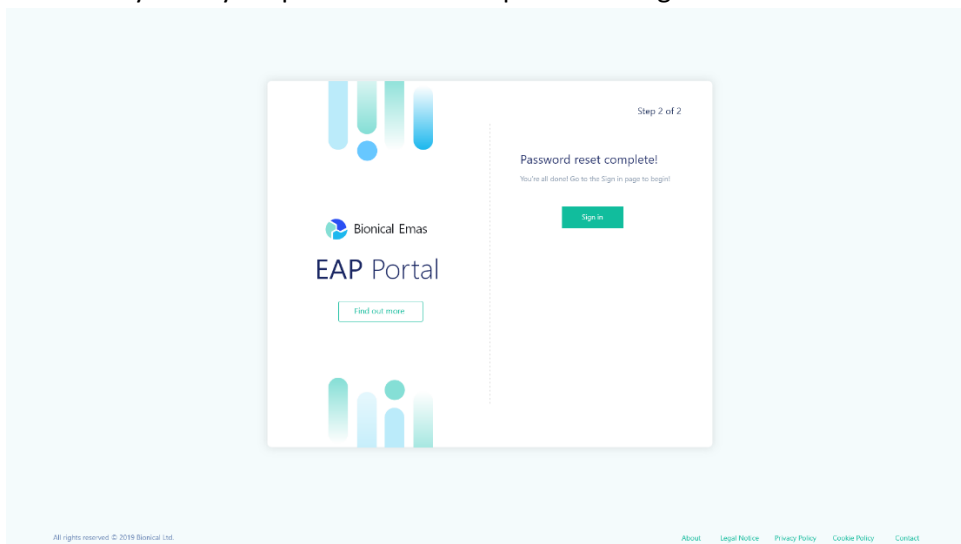
N.B the user may need to contact there IT department to consent to them logging into the EAP portal using single sign on

UU – 04 - Password Reset

1. Click on the on-screen hyperlink “Forgotten password”.
2. You will be taken to a page where you will need to enter the email address associated to the account.



3. You will receive an email with a validation link. Click on the link and you will be redirected to a page to reset your password.
4. Enter a password that meets the minimum-security standards and click on confirm.
 - a. At least 8 characters including
 - i. At least 1 capital letter
 - ii. At least 1 symbol
 - iii. At least 1 number
5. Once a valid password has been entered you will be redirected to a page confirming you have successfully reset your password and can proceed to sign in.



Bionical

BIO – 01 – Homepage

The tasks will be broken down into sections on the homepage

- New Treatment Request – A request will be visible when a HCP who has an account on the system request access to a treatment.
- New User Request – A request will be visible when a HCP self-registers on the portal
- New Patient Request – New request submitted on the portal will be visible that have not yet been assigned to a patient access manager.
- My Patient Request Tasks – All request that have been assigned to Patent Access Manager will be visible
- My Project Tasks – Tasks will be generated for when the Project Manager is creating/editing projects

Real World Data will be broken down into the following sections

- Bionical Emas Review Required – Data Queries – Entries will appear under this section when the HCP has submitted an entry and there is a query against one of the responses

- Bionical Emas Review Required - Entries will appear under this section when the HCP has submitted an entry and there is no query against one of the responses
- Baseline Data Required - Entries will appear under this section when the HCP has consented to RWD and baseline data has not been started
- In Progress – Entries will appear within this table when a HCP has saved a form but not yet submitted it.

BIO – 02 - Institute Management – Creating an Institute

1. Click on Institution Manager tab in the Main Navigation on the left.
2. Click on the Add new link.
3. This will bring you to the New institution page.

+2. New Institution/Pharmacy

✔ Institution Address Details

Enter the details of the institution below

Hospital Name	<input type="text"/>	DeliveryAddress	<div style="border: 1px solid #ccc; height: 40px;"></div>
Hospital Address	<div style="border: 1px solid #ccc; height: 40px;"></div>		
Postcode	<input type="text"/>	Postcode	<input type="text"/>
	<input type="text"/>	Select a Country	<input type="text"/>
	<input type="text"/>	Select a Country	<input type="text"/>

Delivery address same as above

<h4 style="margin: 0;">Institution Contact Details</h4> <p style="margin: 0; font-size: small;">Add the contact of the institution below</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; padding: 5px;">Lead Contact First Name</td> <td style="width: 30%;"><input type="text"/></td> <td style="width: 20%; padding: 5px;">Monday</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 10%;"><input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Lead Contact Last Name</td> <td><input type="text"/></td> <td style="padding: 5px;">Tuesday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Contact Number</td> <td><input type="text"/></td> <td style="padding: 5px;">Wednesday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Out of Hours Contact Number</td> <td><input type="text"/></td> <td style="padding: 5px;">Thursday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Contact Email</td> <td><input type="text"/></td> <td style="padding: 5px;">Friday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="padding: 5px;">Fax</td> <td><input type="text"/></td> <td style="padding: 5px;">Saturday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td></td> <td></td> <td style="padding: 5px;">Sunday</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </table>	Lead Contact First Name	<input type="text"/>	Monday	<input type="text"/>	<input type="text"/>	Lead Contact Last Name	<input type="text"/>	Tuesday	<input type="text"/>	<input type="text"/>	Contact Number	<input type="text"/>	Wednesday	<input type="text"/>	<input type="text"/>	Out of Hours Contact Number	<input type="text"/>	Thursday	<input type="text"/>	<input type="text"/>	Contact Email	<input type="text"/>	Friday	<input type="text"/>	<input type="text"/>	Fax	<input type="text"/>	Saturday	<input type="text"/>	<input type="text"/>			Sunday	<input type="text"/>	<input type="text"/>	<h4 style="margin: 0;">Institution Opening Hours</h4>
Lead Contact First Name	<input type="text"/>	Monday	<input type="text"/>	<input type="text"/>																																
Lead Contact Last Name	<input type="text"/>	Tuesday	<input type="text"/>	<input type="text"/>																																
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Fax	<input type="text"/>	Saturday	<input type="text"/>	<input type="text"/>																																
		Sunday	<input type="text"/>	<input type="text"/>																																

Sponsor1

Project 26-07 - Proj 2

Spon 1

Isazomib

Ninlaro

Pevonedistat

Please Ensure due diligence is complete before approving new institutions

Due Diligence Complete

Submit

4. Enter details into the form using the information provided by the HCP ensuring all fields are complete:
 - Institution address details
 - Institute Name
 - Institute Full Address
 - If delivery address is the same as above tick this box if not Delivery address fields will appear to be filled in

- Institute contact details
 - Lead Contact first and last name
 - Contact number
 - Out of hours number if required
 - Contact email
 - Fax number (not mandatory)
 - Institution opening hours (not mandatory)
5. Under the available treatments click on the product the site has requested.
 6. Tick the Due Diligence box to ensure or checks have been completed and institute is approved with QA.
 7. Click submit and the institute will be created.

BIO – 03 - Institution Management – Edit an Institute

1. Click on Institution Manager tab in the Main Navigation on the left.
2. Enter institute name or ID in to search field, choose country from drop down menu then click on Search Button
3. Click on the View/Edit button next to the institute to be edited
4. This will bring you to the New institution page.
5. Edit the information required to be changed and click on the submit button.
6. The changes will be saved, and you will return to the Institution Manager Page

BIO – 04a - User Management – Creating a User

1. Click on the User Manager tab in the Main Navigation on the left.
2. Click on “add User”
3. Select the user to be created

<input type="radio"/> Physician	<input type="radio"/> Pharmacist	<input type="radio"/> Bionical Emas	<input type="radio"/> Bionical Emas Medical Reviewer	<input type="radio"/> Project Sponsor
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4. Fill in the user details and the additional information depending on the user being created.

- Physician – Assign an institute
 - Pharmacist – Assign an institute
 - Bionical Emas – Select Projects and Permissions
 - Bionical Emas Medical Reviewer – Select projects
 - Project Sponsor – Select Sponsor and projects
5. When creating a Bionical Emas user – specific permissions will be set
 - Patient Access Manager - Able to process patient access requests
 - Add/edit Project - Able to create and edit projects
 - Admin role - Master User Access
 - Add/Edit Institutions - Able to create and edit Hospitals
 - Real World Data Manager Role - Amend / Edit RWD
 - Add / Edit Users - Create and edit users (Bionical users without Admin role access will be unable to amend other Bionical accounts)
 6. Click on Create Button.
 7. The user will be created, and you will return to the User Manager page.

N.B Only a Bionical Admin user has the ability to amend other Bionical Users permissions

BIO – 04b - User Management – Edit a User

1. Click on the User Manager tab in the Main Navigation on the left.
2. You can search a user by their name, institute and email address. You can filter by roles and also use the advanced filter to select all users in a particular institute.
3. Click on the edit user link next to the user.
4. This will bring you to the Add New User page.
5. Edit the information required to be changed and click on the save button.
6. The changes will be saved, and you should receive a notification in the top right corner that the user has successfully been edited.

BIO – 05 – Treatment Lookup

1. Click on Treatment Lookup Tab in the Main Navigation.
2. All the projects available on the portal will be visible
3. Click on view button next to project and you will be shown:

- Product information – Name and Sponsor
- Supporting information – Documents relating to this project at a global level and which documents are available for individual countries
- Indication

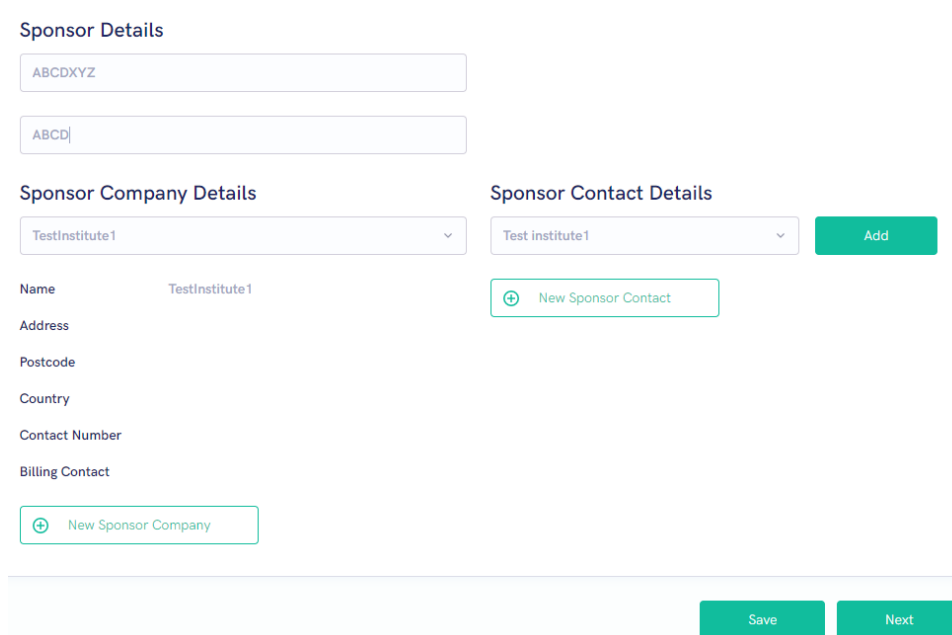
BIO – 06 - Program Management

- 1) Click on Project Manager Tab in the Main Navigation.
- 2) If you have admin permission, you will be able to access a Bulk Project Export which combines all the Projects.
- 3) Option to search for different projects will be visible.
- 4) Clicking on:
 - a) **Project Group** will take you to a page where all the individual projects under that group will be visible. Here you can see the status of each project.
 - If you select the individual project, it will take you to the dashboard for that project.
 - b) **Project** will take you straight to that project dashboard.
 - c) **Edit group** will take you to the Project Management page to allow you to:
 - Add additional projects into this group
 - Make the group visible to HCPs on the treatment lookup page
- 5) From here you can see an overview of the project along with accessing the CSV exports.
 - a) You will have the option to see the status of the project along with the last time it was updated, who it was done by and when it was approved to live
 - b) If you can click on the 3 dots you can view a read only version of the project set and view a preview of the Patient access request
 - c) You will also see draft version being edited. If you click on the 3 buttons you will have the option to go and end the project, view the project in a read only state and do a preview of the patient access request
- 6) Click on Project Manager Tab in the Main Navigation
- 7) Click on Add New Project Group (project group will need to be created to add a Project to the portal)
- 8) Enter the name of the project and select the name of the product the group will fall under
- 9) Click on create project group
- 10) Click on search and select Edit group next to the newly created project group

11) Proceed to follow steps 1-7 to create the project

12) You will now need to complete the program set up wizard which consists of 7 steps.

3.1) Enter Sponsor Details – Enter details into the form and click on the Next button



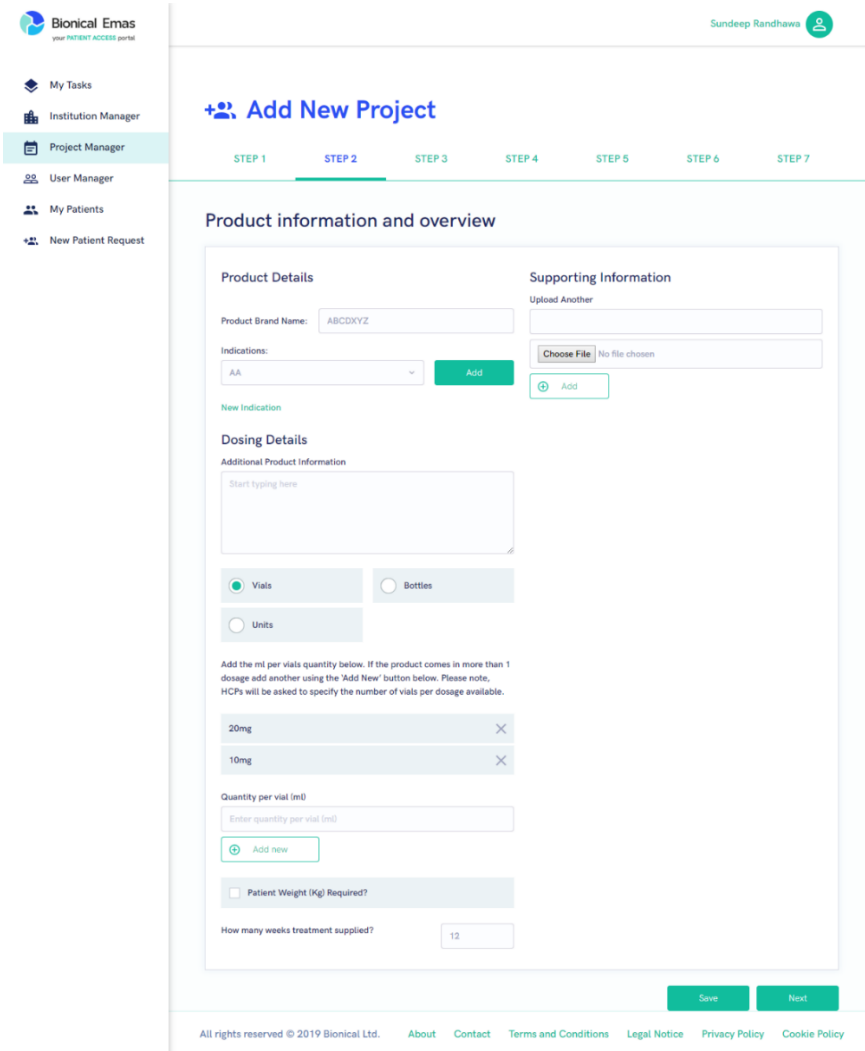
The screenshot shows a web form titled "Sponsor Details". It is divided into two main sections: "Sponsor Details" and "Sponsor Company Details".

- Sponsor Details:** Contains two text input fields. The first field contains "ABCDXYZ" and the second field contains "ABCD".
- Sponsor Company Details:** Contains a dropdown menu with "TestInstitute1" selected. Below this are labels for "Name", "Address", "Postcode", "Country", "Contact Number", and "Billing Contact". A button labeled "New Sponsor Company" is located at the bottom of this section.
- Sponsor Contact Details:** Contains a dropdown menu with "Test institute 1" selected and a green "Add" button. Below this is a button labeled "New Sponsor Contact".

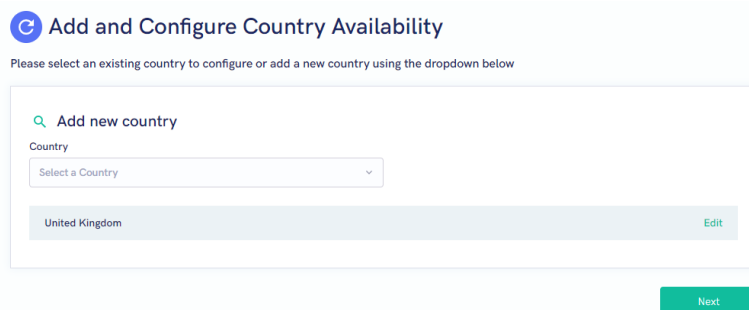
At the bottom right of the form, there are two green buttons: "Save" and "Next".

- If Sponsor Company is not visible click on New Sponsor Company button and enter details
- If Sponsor Visible is not visible click on New Sponsor Contact button and enter details. The select the contact from the drop-down menu and click on the Add button.

3.2) Product Information and Overview - Enter details into the form and click on the Next Button



- Add countries from the drop down list that will be in scope and click on edit link next to country.



- You will now be able to configure the country by adding the:
 - Product availability – control if initial and resupply request can be made
 - Select the indication the country is open to

- Support documentation specific to this country
- Adverse event information
- Will eligibility criteria be visible in treatment lookup
- Collect RWD for this country
 - Automatically opt in patients

3.3) Patient Eligibility Requirements – Enter the information into the form and upload any documents relevant to the product and click on next

- When entering supporting information and eligibility criteria, you will have the option to select the following types of questions and make them mandatory or not:
 - Single Select
 - Multi select
 - Free Text
 - Date field

You will also have the option to set rules to questions to link them together. Depending on the answer selected there will be follow up questions that will appear.

E.g Has the patient experienced an adverse event. If “yes” is answered follow up questions will appear. If “no” is selected no questions will appear.

Bionical Emas
your PATIENT ACCESS partner

- My Tasks
- Institution Manager
- Project Manager**
- User Manager
- My Patients
- New Patient Request

Sundeep Randhawa

+ Add New Project

STEP 1
STEP 2
STEP 3
STEP 4
STEP 5
STEP 6
STEP 7

Parameter	Global	First	Repeat	
Patient Height (cm)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	↕
Patient Weight (kg)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	↕
Gender	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	↕
Age	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	↕
Ethnicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	↕
Blood Pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	↕

Supporting Documents Requirements

These are documents that Bionical/Sponsor may require in order to process the medication request - for example previous medical history.

Document	First	Repeat	
<input style="width: 100%; height: 15px;" type="text" value="Add new"/> <div style="border: 1px solid #ccc; padding: 5px; min-height: 20px;">Description</div>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="button" value="Add New"/>

Supporting Information Requirements

These will appear as free text spaces for HCP's to fill out with information that Bionical/Sponsor may require in order to process the medication request - for example previous medical history.

Info	First	Repeat	
<input style="width: 100%; height: 15px;" type="text" value="Add new"/> <div style="border: 1px solid #ccc; padding: 5px; min-height: 20px;">Description</div>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="button" value="Add New"/>

Eligibility Parameters

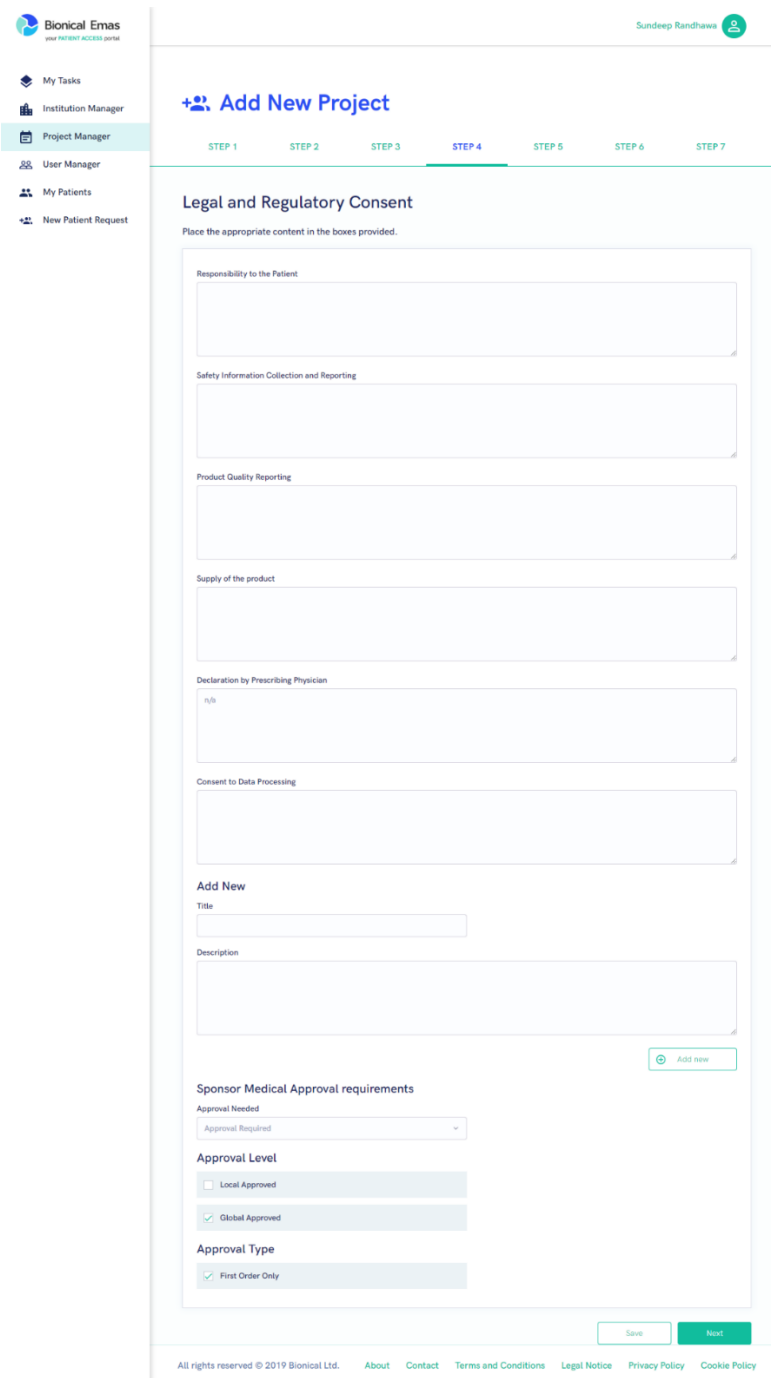
Eligibility Criteria	First	Repeat	
test	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="button" value="✖"/> <input type="button" value="↕"/>
test2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="button" value="✖"/> <input type="button" value="↕"/>

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Country Eligibility Requirements - This page allows you to configure the patient criteria per country.

- Click on the configure link next to the country you will see the patient eligibility requirements and criteria from the global page.
- Complete the form ensuring all the required fields specific to the country are completed.

3.4) Legal and Regulatory Consent – Enter the information in to the form and click on Next



The screenshot shows the 'Add New Project' interface in the Bionical Emas system. The user is logged in as Sundeep Randhawa. The interface is divided into a sidebar with navigation options (My Tasks, Institution Manager, Project Manager, User Manager, My Patients, New Patient Request) and a main content area. The main content area is titled 'Add New Project' and shows a progress bar with steps 1 through 7, with Step 4, 'Legal and Regulatory Consent', currently active. Below the progress bar, there is a heading 'Legal and Regulatory Consent' and a sub-heading 'Place the appropriate content in the boxes provided.' The form contains several text input fields for: Responsibility to the Patient, Safety Information Collection and Reporting, Product Quality Reporting, Supply of the product, Declaration by Prescribing Physician (with a pre-filled value of 'n/a'), and Consent to Data Processing. Below these fields is an 'Add New' section with a 'Title' field, a 'Description' field, and an 'Add new' button. At the bottom of the form, there are sections for 'Sponsor Medical Approval requirements' (with a dropdown menu set to 'Approval Required'), 'Approval Level' (with radio buttons for 'Local Approved' and 'Global Approved', where 'Global Approved' is selected), and 'Approval Type' (with a radio button for 'First Order Only', which is selected). At the bottom right of the form, there are 'Save' and 'Next' buttons. The footer of the page contains copyright information and links to 'About', 'Contact', 'Terms and Conditions', 'Legal Notice', 'Privacy Policy', and 'Cookie Policy'.

3.5) Draft Patient Request – This page allows you to Preview the Patient Access Form per country.

- Click on Preview link next to the country to view the form
- Click on Project Checklist to go to next step

3.6) Project checklist – This page shows all the sections of the Project set up

- Tick all the sections that have been completed
- Add a comment in the free text field for the project revision.
- Should there be any section missing you can click on the Back to set up to complete this
- Only when all the criteria have been completed can you proceed to click on the Select Sponsors button to proceed.

3.7) Project Approval – This page allows you to get the sponsors approval of the project and can be done in 2 ways.

- Pick the sponsor contact who has portal access and press submit or pick the offline approval Note* the offline approval will move the project to 'Draft Offline approval' status and generate a Task for the Project Manager to get the approval and then submit the project.
- Once approval has been received click on 'Launch Project' Button

BIO – 07a – Creating a initial request

1. Click on the Make a Patient Request tab in the Main Navigation. This will take you to the Make a Patient Request Wizard which is broken down into a 7-step process.
 - 1.1) Select the institution from the drop-down menu and then the name of the physician from the drop down that appears.
 - 1.2) Select the product, Treatment and the indication from the drop-down menus. Click the new patient box and enter the patient information. Tick the 2 tick boxes in regard to the patient responsibility will need to be ticked to proceed.
 - 1.3) Enter the dosage and quantity required and click on next. You have the option to reassign medication from another patient if required at this stage.
 - 1.4) Complete the patient eligibility information ensuring all mandatory information is all completed.
 - 1.5) Enter the delivery Details. The address will be prepopulated depending on the institute creation details. These details can be edited should another delivery location be required at the hospital.
 - 1.6) A summary will be generated. Check all the information is correct and tick the 2 tick boxes confirming all the information provided is true to the best of your knowledge and that you consent to the data being processed.
 - 1.7) Read through the information and approve your order by ticking the final box and you will have 3 options to submit the request:
 1. will submit the request directly to Bionical Emas.
 2. will submit the request to the treating physician.
 3. will submit the request directly to Bionical Emas once offline approval has been received

BIO – 07b - Creating a resupply request

1. Click on the Make a Patient Request tab in the Main Navigation. This will take you to the Make a Patient Request Wizard which is broken down into a 7-step process.
 - 1.1) Select the institution from the drop-down menu and then the name of the physician from the drop down that appears.
 - 1.2) Select the product, Treatment and the indication from the drop-down menus. Click the new patient box and enter the patient information. Tick the 2 tick boxes in regard to the patient responsibility will need to be ticked to proceed.
 - 1.3) Enter the dosage and quantity required and click on next. You have the option to reassign medication from another patient if required at this stage.
 - 1.4) Complete the patient eligibility information ensuring all mandatory information is all completed.
 - 1.5) Enter the delivery Details. The address will be prepopulated depending on the institute creation details. These details can be edited should another delivery location be required at the hospital.
 - 1.6) A summary will be generated. Check all the information is correct and tick the 2 tick boxes confirming all the information provided is true to the best of your knowledge and that you consent to the data being processed.
 - 1.7) Read through the information and approve your order by ticking the final box and you will have 3 options to submit the request:
 4. will submit the request directly to Bionical Emas.
 5. will submit the request to the treating physician.
 6. will submit the request directly to Bionical Emas once offline approval has been received

BIO – 08 - Progressing a request

1. Click on view request next to the new patient request.
2. Select the Patient Access Manager from the dropdown and click on select. A window will pop up. Click on assign to confirm. The patient Access manager assigned to the request can be changed at any time by going into the patient summary via the patient search function.
3. Review the request and you will have the option to do the following
 - Approve/decline the request
 - Edit the request on behalf of the HCP if required
 - Return the request back to the user to make amendments if required. Free text field to provide comment
4. You will have the option to perform the following

- Online medical review. Depending on the program set up, select either the internal medical review team or sponsor from the dropdown. A free text field will appear. If required, you can enter any additional information the sponsor might need to help them perform the review then click on save
 - Offline medical review. Select request summary to download a PDF and click on ok on the new pop up window. Then click on save
 - No medical review required. Click on medical review not required button
5. Only if offline approval was requested click on choose file and upload PDF of email approval and click on add and then confirm. Once confirmed click on save button
 6. If no import documentation is required, click on 'Supporting documentation not required' button. If documentation is required, click on request summary button and ok in popup window to download the PDF summary. Then click on save.
 7. Click on choose file and upload PDF of health approval and click on add and then confirm. Once confirmed click on save button
 8. Ensure delivery details and quantities are correct and tick the box to confirm and enter username and password and send to dispatch.
 9. Enter the following details and click on update:
 - SO Number - Mandatory
 - Tracking Number - Mandatory
 - Dates Shipped - Mandatory
 - Expected Delivery Date - Mandatory
 - Date Delivered - Mandatory
 10. When you click on update the follow up section at the bottom of the page will be updated. The resupply date will be automatically calculated using the number of weeks treatment provided from the date shipped (date delivered + number of weeks supplied)
 - You will have the option here to amend the dates if required
 - If you select the "follow ups required" tickbox this patient will not appear in the follow ups schedule tab when the resupply is due
 11. Go to homepage and click on close task. A notification will pop up asking for confirmation to close the task. Click on this. The Close Task option will only appear once the mandatory details in the tracking details section have been completed.

N.B The Tracking details can only be changed by an Bionical Admin user once the request has been closed
Requests can be progressed by other Patient access Managers even if they are not assigned to themselves.

1. Click on the Patient Search tab in the Main Navigation on the left.
2. Click on view details next to required request.
3. Click on green button which will indicate the status the order needs to be progressed to

BIO – 09 – Bionical Emas Medical Reviewer

Bionical Emas Medical review team can perform reviews for requests and also have the option to escalate to the sponsor should they ever require it

1. Select the request from the homepage
2. Scroll to the bottom of the page
3. The following options will be visible
 - a. Approve/decline the request – the request will be approved or declined depending on what is selected
 - b. Return for change/additional information – the request will be returned to the patient access team to acquire the additional information
 - c. Escalate to sponsor – The request will be escalated to the sponsor who is selected from the dropdown

BIO – 10 - Patient Search

1. Click on the Patient Search tab in the Main Navigation on the left.
2. Enter all or part of the patient's ID and/or select the Product in the drop-down and click on search button.
3. A list of patients matching the information entered will be shown.
4. Click on the View details link next to the patient.
5. You will be redirected to Patient Summary page. On this page you will have the option to
 - Cancel the request – scroll to the bottom of the page and click on cancel. Another window will pop up to add a reason why for the cancellation
 - Discontinue the patient. Scroll to the bottom of the page and click on the discontinue button. Another window will pop up to add a reason and date
 - Perform Reassignment and reconciliation of medication
 - See an overview of the request along with any notes associated with the request
 - The option to download a PDF copy of the patient summary
 - i. You will have the option to have PII and status history visible on the PDF

- Revert request to previous stages
 - i. Option to revert the request back to medical review
 - ii. Option to revert the request back to health authority approval
- Reopen cancelled requests

N.B An admin user has the option to reopen discontinued patients and delete requests

BIO – 11 - Patient Institute move

A Bionical user can now move the patient from one institute to another.

- 1) Go to the patient summary
- 2) Under institution details select the edit pen
- 3) From the drop down select the site you wish to move the patient to
- 4) A note can be added to explain the rationale behind the move
- 5) Enter username and password and select 'Move Patient'

Patient can only be moved to a site within the same country and where the same program has been assigned to that site

BIO – 12 - Patient Access Request statuses

Bionical

Status	Description
Incomplete	A request that has been started but not submitted to Bionical
Pending Physician Approval	Pending the physician's approval via the portal
Pending Physician Approval – Offline	Pending the physician's approval – offline
Pending Bionical Review	A request that has been submitted and is pending Bionical initial review
Pending Additional Information	Additional information has been requested from the HCP
Physician approval – Additional information	A request where additional information has been requested from the HCP and is waiting for it to be re submitted
Information Updated	A request where the HCP has resubmitted a request after amendments

Send for Global/local sponsor Approval	Request waiting to be sent to Medical review
Pending Global/local sponsor Approval	A request has been submitted to the Medical Team for their review
Pending Global/local sponsor Approval – Hard Copy	Pending approval from sponsor - offline
Medical review – Information required	Request that has been returned from the Sponsor asking for more information
Medical Review declined	A request that has been declined by medical review- request can either be fully declined or sent back to HCP for additional information
Send for Health Authority Approval	Request waiting to be sent to for import permit
Pending Health Authority Approval	A request has been medically approved and Bionical Emas is waiting for the import permit, where applicable.
Pending Health Authority Approval – Hard Copy	Pending import permit from HCP - offline
Shipped	A request has been shipped and it is currently in transit
Delivered	Request has been delivered
Closed - Declined	A request has been declined by the Medical Team
Cancelled	Request has been cancelled by any user

BIO – 13 – Organisation Manager - SSO

1. Click on search and select the organisation you would like to edit
2. The information should be prepopulated.
3. If a organisation would like to sign on to the portal select the single sign on enabled tick box
4. A list of the users associated to that organisation will be visible. If you select them it will take you to their user page
5. Click on Save to confirm the settings

BIO – 14 – Follow ups

This section will allow you to manage the follow ups for active patients. The number in the main navigation menu will state how many follows up are pending for that day.

When you select follow ups will bring you to the follow ups page. You can refine your search for a particular patient by searching for the patient ID or by physician name or email address and also use the advanced search function. You have the option to select a date range to show all the follow up scheduled between those dates.

If a patient has been selected to not receive any follow these can also be shown by selecting the “show schedule without follow ups” tick box

The Schedule Tab will show the pending follow ups

The overdue tab will show all the follow ups that haven’t been actioned and are overdue

If you select the 3 buttons next to the follow up you will have the following options

- View Schedule which will take you to the follow up scheduled for that patient

- View notes which will take you to any notes against that patient regarding follow ups
- View PAF which will take you to the patient summary

View schedule will allow you to action any follow ups scheduled by marking them as not required or mark as complete.

BIO – 15 – Real World Data

Healthcare Professionals will be able to enter RWD if the project is set up to allow this. Real World Data Mangers will have the ability to edit and query this data. The Data can be accessed via the tasks generated on the homepage or by clicking on view in the patient summary

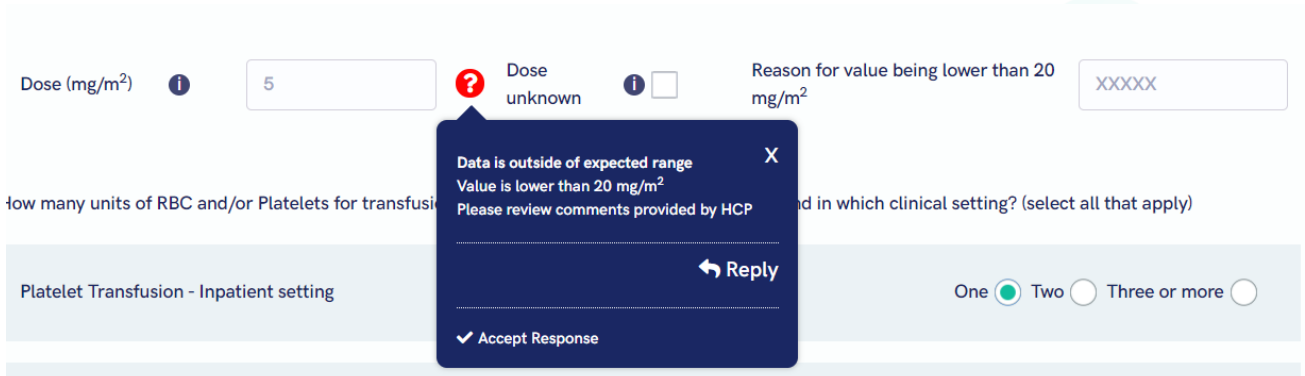
Real World Data Collection

Is Patient opted in for Real World Data collection? Yes [View](#)

Date 25 August 2020

Would you like the sponsor to contact you with potential opportunities to review, analyze, and publish clinical findings? No

1. Click on view next to the entry that needs reviewing.
2. For forms that have been entered correctly. These can be closed should if data doesn't need querying by clicking on complete at the bottom of the page
3. Should an entry flag up an issue a question mark will be highlighted next to it



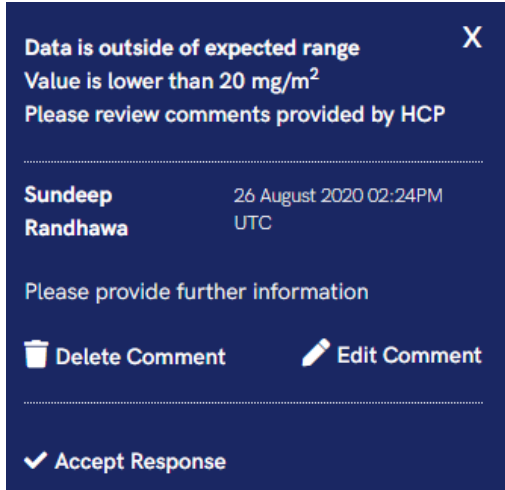
The screenshot shows a data entry form with the following fields and a validation error:

- Dose (mg/m²)**: Input field containing '5'. A red question mark icon is next to it.
- Dose unknown**: Input field containing 'unknown'. A red question mark icon is next to it.
- Reason for value being lower than 20 mg/m²**: Input field containing 'xxxxxx'.
- How many units of RBC and/or Platelets for transfusion**: Input field containing 'Platelet Transfusion - Inpatient setting'.
- Reason for value being lower than 20 mg/m²**: Input field containing 'xxxxxx'.
- How many units of RBC and/or Platelets for transfusion**: Radio buttons for 'One', 'Two', and 'Three or more'. 'One' is selected.

A dark blue modal box is overlaid on the form with the following text:

Data is outside of expected range
 Value is lower than 20 mg/m²
 Please review comments provided by HCP
 Reply
 Accept Response

4. Click on question mark and either accept the response or click on reply and enter a comment in the text field



5. Scroll to the bottom and click on return to HCP button. This will send the entry back to the HCP to review and add comments.
6. Once the HCP has provided response to query you have the option to accept the response and click on complete at the bottom of the page.

The RWD Manager has the option to cancel data collection for a patient by clicking on the Cancel data Collection button found on the Patient RWD homepage. This will delete all data collected and new data will no longer be able to be entered

BIO – 16 – Bulk Discontinuation

A bulk discontinuation of patients is available to do for a user with Admin permissions.

1. Go to settings and select Patient administration.
2. A patient search functionality page will appear allowing the user to search via patient ID or perform a advanced search to search via multiple filters
3. The search will return the matching criteria. The results are per patient and will show if the patient ahs already been discontinued or not
4. Select the patients to be discontinued.
5. Select Discontinue patient and enter the date and reason in the pop up window.
6. Select yes, Discontinue
7. A notification will appear stating the discontinue is being actioned in the background and the user will be informed by email once done.

Healthcare Professional - Physician

PHY – 01 - Creating an initial request

Click on the 'Make a Patient Request' tab in the navigation panel on the left-hand side of your 'welcome' page before completing the following 7 steps.

STEP 1 STEP 2 STEP 3 STEP 4 STEP 5 STEP 6 STEP 7

As you work through the steps, a 'Patient Access Request Saved' notification will flash at the top-right of your screen. This confirms that you have successfully completed each step.

Step 1: Select your institution in the drop-down menu; two radio buttons will appear. Click on the radio button 'Myself', ensure your personal details are correct, then click 'Next'.

Step 2: Select the product, treatment, and the indication from the drop-down menus. Click the 'New' radio button and enter the patient details. Tick the 2 boxes regarding patient responsibility should also be ticked, then click 'Next'.

Step 3: Enter the quantities required for the order. You also have the option to reassign medication from another patient. To do this click on "Add medication to be reassigned" Select the patient ID from the dropdown then select the request ID from the second drop down. Select the quantities to be reassigned and click on Save. Total quantity request will show the amount requested and the amount reassigned. To Proceed click on 'Next'.

Step 4: Complete any extra details requested, then tick the eligibility criteria that apply to your patient (these will vary by programme). A free text box is available to add an explanation. After completion, click 'Next'.

Step 5: Delivery details for your institution will be automatically populated. Please check them and amend if necessary, then click 'Next'.

Step 6: A summary of your application will be generated. After checking for errors, scroll to the bottom of the page and tick the first box to confirm the information is correct and the second to consent to data-processing, then click 'Next'. **Corrections are made** by clicking the 'pen' icon at the top-right of each section.

I confirm the above patient information to be true to the best of my knowledge

I consent to my data being processed in accordance with the reasoning as cited above

Step 7: Submit your order by ticking the box at the bottom of 'Step 7', entering your username and password and clicking on 'Submit to Bionical for Processing'. Your order will appear as 'Awaiting Bionical Review and Approval' on your 'welcome' page under 'My Patient Requests'.

I confirm and understand the above statements

Username

Password

PHY – 02 - Creating a resupply request

Click on the 'Make a Patient Request' tab in the navigation panel on the left-hand side of your 'welcome' page before completing the following 7 steps.

STEP 1 **STEP 2** **STEP 3** **STEP 4** **STEP 5** **STEP 6** **STEP 7**

As you work through the steps, a 'Patient Access Request Saved' notification will flash at the top-right of your screen. This confirms that you have successfully completed each step.

Step 1 Follow step 1 above

Step 2 Select the product, treatment, and the indication from the drop-down menus. Click the 'Existing' radio button. Select the patient ID from the drop down. Tick the 2 boxes regarding patient responsibility should also be ticked, then click 'Next'.

Step 3: Enter the quantities required for the order. You also have the option to reassign medication from another patient. To do this click on "Add medication to be reassigned" Select the patient ID from the dropdown then select the request ID from the second drop down. Select the quantities to be reassigned and click on Save. Total quantity request will show the amount requested and the amount reassigned. To Proceed click on 'Next'.

Step 4: Complete the requested data fields and tick the resupply eligibility criteria, then click 'Next'.

Step 5: Delivery details for your institution will be automatically populated. Please check them and amend if necessary, then click 'Next'.

Step 6: A summary of your application will be generated. After checking for errors, scroll to the bottom of the page and tick the first box to confirm the information is correct and the second to consent to data-processing, then click 'Next'. **Corrections are made** by clicking the 'pen' icon at the top-right of each section.

I confirm the above patient information to be true to the best of my knowledge

I consent to my data being processed in accordance with the reasoning as cited above

Step 7: Submit your order by ticking the box at the bottom of 'Step 7', entering your username and password and clicking on 'Submit to Bionical for Processing'. Your order will appear as 'Awaiting Bionical Review and Approval' on your 'welcome' page under 'My Patient Requests'.

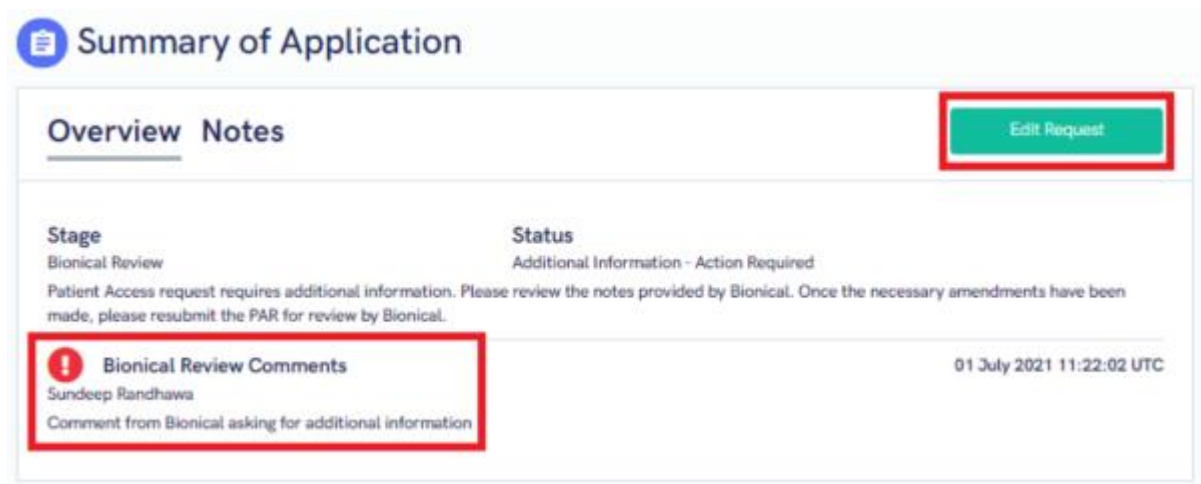
You can also create a resupply request by going to the patient request via the patient search section. Go to patient search and select the patient you would like to place a resupply request for. On the Summary of Application page select the green button 'Create Resupply Request'

Follow the above steps 1-7 to place your request

PHY – 03 – Providing Additional information

On your 'welcome' page, there will be requests that have been returned to you as more information is required. These will request will have the status 'Additional information – Action required'.

1. Click 'View Request' on the right-hand side of the request.
2. There will be a note from the Bionical team asking what additional information is required.



Summary of Application

Overview Notes Edit Request

Stage	Status
Bionical Review	Additional Information - Action Required


Patient Access request requires additional information. Please review the notes provided by Bionical. Once the necessary amendments have been made, please resubmit the PAR for review by Bionical.

! **Bionical Review Comments**

Sundeep Randhawa

Comment from Bionical asking for additional information

01 July 2021 11:22:02 UTC

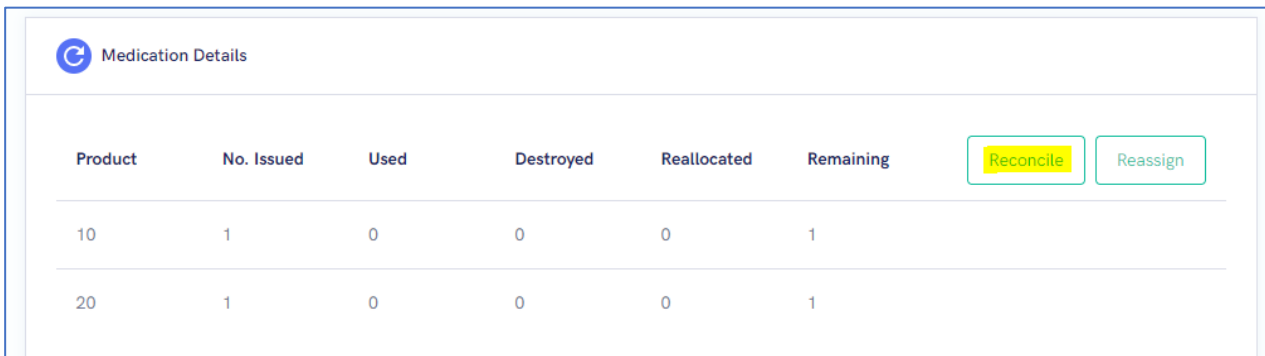
3. Click on edit request and you will have the option to edit the requests by clicking on the edit pen  next to the section that needs actioning.
4. Proceed to step 7 and submit the request

PHY – 04 - Searching for existing patients

1. Click on the 'My Patients' tab in the navigation panel on the left of your 'welcome' page.
2. Enter the patient's Bionical ID in the 'Patient Lookup' and click on the search button.
3. A list of all prior EAP patient requests will be shown.
4. Click on the 'View Detail' link to the right of the request you wish to consult.
5. You will be redirected to a summary page showing details of the specific patient request selected. Please note: requests are numbered sequentially (e.g. POTE-0268-1, POTE-0268-2, POTE-0268-3...)
6. Should the patient's ID not be known, by selecting the relevant product in the right-hand drop-down menu in the 'My Patients' tab, all relevant patient records will appear from your hospital.

PHY – 05 - Medication reconciliation

1. Click on the 'My Patients' tab in the navigation panel on the left of your 'welcome' page.
2. Enter the patient's Bionical ID and click on the search button.
3. A list of all prior requests for the patient will be shown.
4. Click on the request you wish to reconcile.
5. You will be redirected to a summary page showing details of the specific patient request selected.
6. Under the section 'Medication Details', click on the 'Reconcile' button (see image below).



Product	No. Issued	Used	Destroyed	Reallocated	Remaining	Reconcile	Reassign
10	1	0	0	0	1		
20	1	0	0	0	1		

By clicking on this button, another window will appear. Select the following:

- the quantity
 - whether the medication was used or destroyed.
 - the date of reconciliation
7. Finally, enter your username and password and click on the 'Save' button to confirm. Once confirmed the details in the 'Medication History' section will be updated to reflect your reconciliation.

PHY – 06 - Medication reassignment

A new patient request for the patient to whom you wish to reassign medication will need to be made prior to reassignment. For a reminder of how to make a new patient request, please see the steps [here](#).

Steps for reassignment

1. Return to your portal 'welcome' page and click on the 'My Patients' tab in the navigation panel on the left of the screen.
2. Enter the patient's Bionical ID and click on the search button.
3. A list of all prior requests for the patient will be shown.
4. Click on the patient request you wish to reassign medication from.
5. You will be redirected to a summary page showing details of the specific access request selected.
6. Scroll down to the section 'Medication Details'. The 'Reassign' button allows you to reassign medication received to a different patient
7. Click on this button and another section will appear. Select the following:
 - the quantity
 - select a patient from the dropdown who the medication will be reassigned to.
8. Finally, enter your username and password and click on the 'Save' button to confirm. Once confirmed, the details in the medication history section will be updated to reflect your reassignment.

PHY – 07 - Treatment Lookup

1. Click on the 'Treatment Lookup' tab in the navigation panel on the left of your 'welcome' page.
2. Select the name of your institute / hospital from the drop-down menu. A list of 'products you have access to' will appear beneath this. These are the treatments that have already been approved for your institute / hospital. By clicking 'View' next to each product, a list of documents related to the treatment will appear.
3. Scroll down to the bottom of this page to a list of treatments 'available through Bionical'. By clicking on the 'Request' button next to the desired treatment, a request will be sent to Bionical Emas for review and approval. The status of your request can be viewed in the 'My Treatment Requests Tasks' section of your 'welcome' page.
4. Once your treatment request has been approved, you will receive notification by email and the treatment will be visible in the 'products you have access to' list under your 'Treatment Lookup'.

PHY – 08 – Patient Access Request Statuses

Status	Description
Incomplete	A request has been started but not submitted to Bionical Emas. You can complete it or delete it at this stage

Pending Physician Approval	Pending the physician’s approval via the portal. Only the treating physician can approve at this stage.
Pending Physician Approval – Offline	Pending the physician’s approval – offline. Only the user that created the request can approve at this stage
Pending Bionical Review	A request that has been submitted and Bionical Emas is completing the initial review
Additional information required – Action required	If this status is showing in your screen, additional information has been requested from you
Pending Additional Information	If this status is showing in your screen, additional information has been requested from another HCP in your hospital
Pending sponsor Approval	A request has been submitted to the Medical Team for their review
Pending Health Authority Approval	A request has been medically approved and Bionical Emas is waiting for the import permit, where applicable.
Shipped	A request has been shipped and it is currently in transit
Delivered	Request has been delivered
Closed - Declined	A request has been declined by the Medical Team
Cancelled	Request has been cancelled by any user

Healthcare Professional – Pharmacist

PHA – 01 - Creating an initial request

Click on the ‘Make a Patient Request’ tab in the navigation panel on the left-hand side of your ‘welcome’ page before completing the following 7 steps.

STEP 1 STEP 2 STEP 3 STEP 4 STEP 5 STEP 6 STEP 7

As you work through the steps, a ‘Patient Access Request Saved’ notification will flash at the top-right of your screen. This confirms that you have successfully completed each step.

Step 1: Select your institution from the drop-down menu. A second drop-down menu will then appear. Select the name of the treating physician and click ‘Next’.

Step 2 Select the product, treatment, and the indication from the drop-down menus. Click the 'Existing' radio button. Select the patient ID from the drop down. Tick the 2 boxes regarding patient responsibility should also be ticked, then click 'Next'.

Step 3: Enter the quantities required for the order. You have the option to reassign medication from another patient. To do this click on "Add medication to be reassigned" Select the patient ID from the dropdown then select the request ID from the second drop down. Select the quantities to be reassigned and click on Save. Total quantity request will show the amount requested and the amount reassigned. To Proceed click on 'Next'.

Step 4: Complete any extra details requested, then tick the eligibility criteria that apply to your patient (these will vary by programme). A free text box is available to add an explanation. After completion, click 'Next'.

Step 5: Delivery details for your institution will be automatically populated. Please check them and amend if necessary, then click 'Next'.

Step 6: A summary of your application will be generated. After checking for errors, scroll to the bottom of the page and tick the first box to confirm the information is correct and the second to consent to data-processing, then click 'Next'. **Corrections are made** by clicking the 'pen' icon at the top-right of each section.

I confirm the above patient information to be true to the best of my knowledge

Step 7: You can then approve and submit your order in one of the following ways:

Option 'a' will submit the request directly to Bionical Emas. Option 'b' will submit the request to the treating physician. Option 'c' will submit the request directly you Bionical Emas once offline approval has been received

a) Submit directly to Bionical for Processing

- Select 'submit direct to Bionical for Processing
- Tick the statement to confirm you have received approval from the treating physician to submit the request and enter your log in details if not already auto populated and click on 'Submit to Bionical for Processing.

How would you like to process this Patient Access Request?

Submit Direct to Bionical for Processing

Send to Physician for Approval

Obtain Physician Approval Offline

I confirm I have received approval from the treating physician to submit this request on their behalf

Username
test.user@emaspharma.com

Password

Submit to Bionical for Processing

b) 'Send to Physician for approval'

This option will send the request directly to the physician to submit via the portal. select this option and click 'Forward to Physician to Submit'. The physician can then submit the request directly to Bionical Emas following [these instructions](#).

c) Download request summary for Offline Physician Approval

- Select 'Obtain Physician Approval Offline', then click 'Download request summary for Offline Physician Approval'. This will generate a PDF summary of your request to send to the treating physician to request approval, or for information.

How would you like to process this Patient Access Request?

Submit Direct to Bionical for Processing

Send to Physician for Approval

Obtain Physician Approval Offline

Download request summary for Offline Physician Approval

- Once approved by the treating physician, return to the 'My Tasks' section of your 'welcome' page: your request can be found here in the 'Awaiting Physician Review and Approval' section.

PDF downloaded
Action required. Please provide PDF patient summary to the treating physician for approval. If already approved, go to the homepage to submit the request to Bionical

Go to Homepage

- Here, click on 'View Request' on the right-hand side of your request, scroll to the bottom of the page, tick 'Approved by Physician', then enter username and password and 'Submit to Bionical for Processing'.

Approved by Physician

Username

Password

[🔗](#)

Submit to Bionical for Processing

PHA – 02 - Creating a resupply request

Click on the 'Make a Patient Request' tab in the navigation panel on the left-hand side of your 'welcome' page before completing the following 7 steps.

STEP 1 STEP 2 STEP 3 STEP 4 STEP 5 STEP 6 STEP 7

As you work through the steps, a 'Patient Access Request Saved' notification will flash at the top-right of your screen. This confirms that you have successfully completed each step.

Step 1 Follow steps 1 above

Step 2 Select the product, treatment, and the indication from the drop-down menus. Click the 'Existing' radio button. Select the patient ID from the drop down. Tick the 2 boxes regarding patient responsibility should also be ticked, then click 'Next'.

Step 3: Enter the quantities required for the order. You have the option to reassign medication from another patient. To do this click on "Add medication to be reassigned" Select the patient ID from the dropdown then select the request ID from the second drop down. Select the quantities to be reassigned and click on Save. Total quantity request will show the amount requested and the amount reassigned. To Proceed click on 'Next'.

Step 4: Complete the requested data fields and tick the resupply eligibility criteria, then click 'Next'. A summary will then be generated.

Step 5: Delivery details for your institution will be automatically populated. Please check them and amend if necessary, then click 'Next'.

Step 6: A summary of your application will be generated. After checking for errors, scroll to the bottom of the page and tick the first box to confirm the information is correct and the second to consent to data-processing, then click 'Next'. **Corrections are made** by clicking the 'pen' icon at the top-right of each section.

I confirm the above patient information to be true to the best of my knowledge

I consent to my data being processed in accordance with the reasoning as cited above

Step 7: You can then approve and submit your order in one of the following ways:

Option 'a' will submit the request directly to Bionical Emas. Option 'b' will submit the request to the treating physician

d) 'Download request summary for Offline Physician Approval'

- Tick the authorisation statement at the bottom of the page, then click 'Download request summary for Offline Physician Approval'. This will generate a PDF summary of your request to send to the treating physician to request approval, or for information.

I confirm and understand the above statements

Download request summary for Offline Physician Approval

Forward to Physician to Submit

- Once approved by the treating physician, return to the 'My Tasks' section of your 'welcome' page: your request can be found here in the 'Awaiting Physician Review and Approval' section.

PDF downloaded
Action required. Please provide PDF patient summary to the treating physician for approval. If already approved, go to the homepage to submit the request to Bionical
[Go to Homepage](#)

- Here, click on 'View Request' on the right-hand side of your request, scroll to the bottom of the page, tick 'Approved by Physician', then 'Submit to Bionical for Processing'.

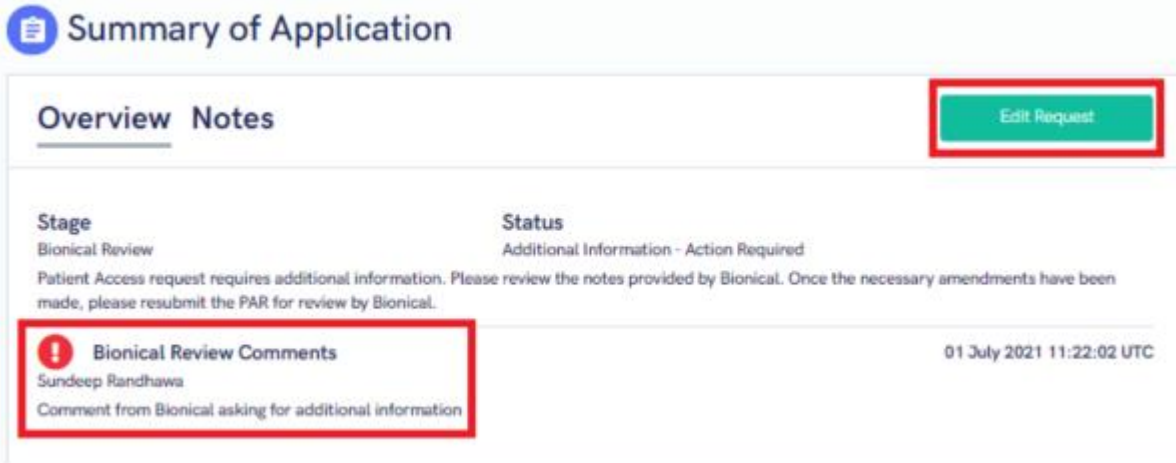
e) 'Forward to Physician to Submit'

This option will send the request directly to the physician to submit via the portal. Tick the authorisation statement at the bottom of the page and click 'Forward to Physician to Submit'. The physician can then submit the request directly to Bionical Emas following [these instructions](#).

PHA – 03 – Providing Additional information

On your 'welcome' page, there will be requests that have been returned to you as more information is required. These will request will have the status 'Additional information – Action required'.

1. Click 'View Request' on the right-hand side of the request.
2. There will be a note from the Bionical team asking what additional information is required.



Summary of Application

Overview Notes Edit Request


Stage
Bionical Review

Status
Additional Information - Action Required

Patient Access request requires additional information. Please review the notes provided by Bionical. Once the necessary amendments have been made, please resubmit the PAR for review by Bionical.

Bionical Review Comments 01 July 2021 11:22:02 UTC

Sundeep Randhawa
Comment from Bionical asking for additional information

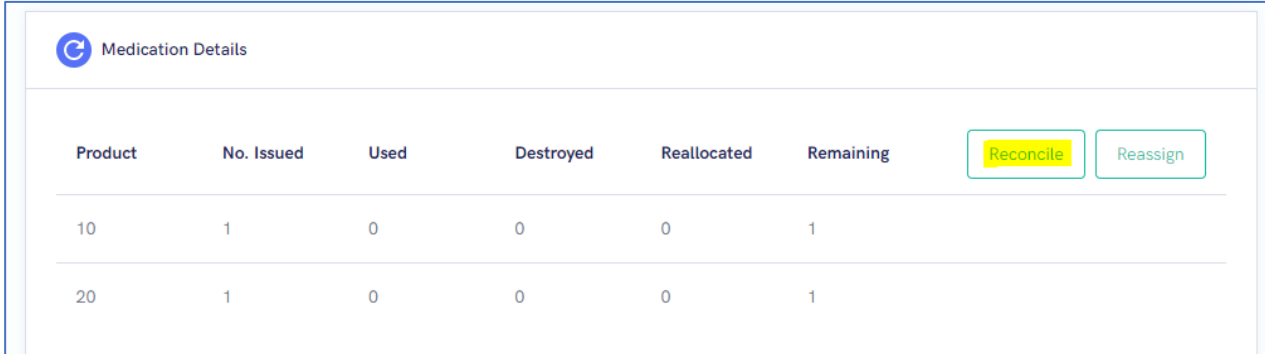
3. Click on edit request and you will have the option to edit the requests by clicking on the edit pen  next to the section that needs actioning.
4. Proceed to step 7 and submit the request

PHA – 04 - Searching for existing patients

1. Click on the 'My Patients' tab in the navigation panel on the left of your 'welcome' page.
2. Enter the patient's Bionical ID in the 'Patient Lookup' and click on the search button.
3. A list of all prior EAP patient requests will be shown.
4. Click on the 'View Detail' link to the right of the request you wish to consult.
5. You will be redirected to a summary page showing details of the specific patient request selected. Please note: requests are numbered sequentially (e.g. POTE-0268-1, POTE-0268-2, POTE-0268-3...)
6. Should the patient's ID not be known, by selecting the relevant product in the right-hand drop-down menu in the 'My Patients' tab, all relevant patient records will appear from your hospital.

PHA – 05 - Medication reconciliation

1. Click on the 'My Patients' tab in the navigation panel on the left of your 'welcome' page.
2. Enter the patient's Bionical ID and click on the search button.
3. A list of all prior requests for the patient will be shown.
4. Click on the 'View Detail' link to the right of the request you wish to reconcile.
5. You will be redirected to a summary page showing details of the specific patient request selected.
6. Under the section 'Medication Details', click on the 'Reconcile' button (see image below).



Product	No. Issued	Used	Destroyed	Reallocated	Remaining
10	1	0	0	0	1
20	1	0	0	0	1

7. By clicking on this button, another window will appear. Select the following:
 - the quantity
 - whether the medication was used or destroyed.
 - the date of reconciliation
8. Finally, enter your username and password and click on the 'Save' button to confirm. Once confirmed the details in the 'Medication History' section will be updated to reflect your reconciliation.

PHA – 06 - Medication reassignment

A new patient request for the patient to whom you wish to reassign medication will need to be made prior to reassignment. For a reminder of how to make a new patient request, please see the steps [here](#).

Steps for reassignment

1. Return to your portal 'welcome' page and click on the 'My Patients' tab in the navigation panel on the left of the screen.
2. Enter the patient's Bionical ID and click on the search button.
3. A list of all prior requests for the patient will be shown.
4. Click on the 'View Detail' link to the right of the patient request you wish to reassign medication from.
5. You will be redirected to a summary page showing details of the specific access request selected.
6. Scroll down to the section 'Medication Details'. The 'Reassign' button allows you to reassign medication received to a different patient (see image overleaf).
7. Click on this button and another section will appear. Select the following:
 - the quantity
 - select a patient from the dropdown who the medication will be reassigned to.
8. Finally, enter your username and password and click on the 'Save' button to confirm. Once confirmed, the details in the medication history section will be updated to reflect your reassignment.

PHA – 07 - Treatment Lookup

1. Click on the 'Treatment Lookup' tab in the navigation panel on the left of your 'welcome' page.
2. Select the name of your institute / hospital from the drop-down menu. A list of 'products you have access to' will appear beneath this. These are the treatments that have already been approved for your institute / hospital. By clicking 'View' next to each product, a list of documents related to the treatment will appear.
3. Scroll down to the bottom of this page to a list of treatments 'available through Bionical'. By clicking on the 'Request' button next to the desired treatment, a request will be sent to Bionical Emas for review and approval. The status of your request can be viewed in the 'My Treatment Requests Tasks' section of your 'welcome' page.
4. Once your treatment request has been approved, you will receive notification by email and the treatment will be visible in the 'products you have access to' list under your 'Treatment Lookup'.

Sponsor

SPO – 01 - Approving patient requests

1. Click on My Tasks in the main navigation menu on the left.
2. This will bring you to the homepage where there will be a section titled Patient Requests with any new requests that need approving listed below. Click on View Request to review.

Patient Requests

Patient ID	Initials	Hospital	Country	Product	Status	Date Created	
PROG-6799-1				Program1	Pending Global Sponsor Approval	05 November 2019 14:44:39 UTC	View Request

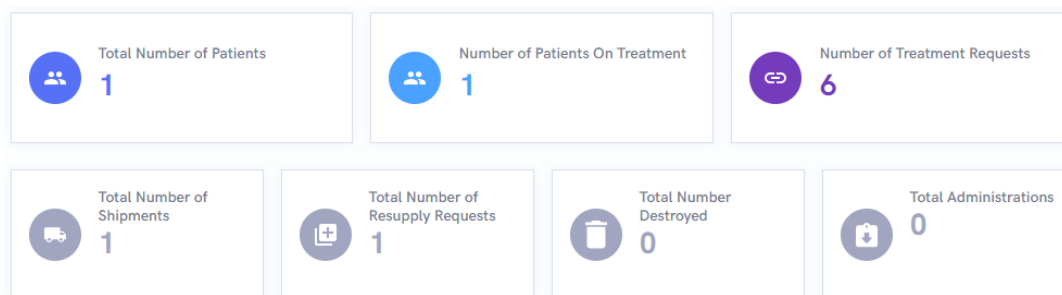
3. View the patient request and scroll to the bottom of the page.
4. Sponsor will have the following options
 - Approve the request – Option to add a comment if required
 - Decline the request – Free text field to add a reason why the request was declined
 - Return for change / additional information – Option to return the PAR to get additional information from the HCP

SPO – 02 - Approving Project requests

1. Click on My Tasks in the main navigation menu on the left.
2. This will bring you to the homepage where there will be a section titled My Project requests with any new requests that need approving listed below. Click on 3 dots to review the project.
3. Select preview next to the country you would like to see the specific form. This will take you through a patient request template that has already been completed by the Bionical Project Manager. Once gone through all the steps 2 to 6 close the tab.
4. Click on approve or decline depending on whether the project has been approved, enter username and password click on send to Bionical button.
 - a. When approving a request a optional free text field will appear should the reviewer like to provide a comment to the Patient Access team
 - b. When Declining a request a mandatory free text field is visible for the reviewer to provide the reason why the request has been declined.

SPO – 03 - Project Management

1. Click on Project Manager in main navigation menu
2. Enter project name in search field and click on search or click on search button to list all projects that have been assigned to you.
3. Click on view next to the desired project. This will give an overview of the project. This can also be provided in a PDF format if required by clicking on the PFD next to Export.



4. There is also an option to receive more information by clicking on CSV which provide a excel document with more information regarding the requests.

HCP Real World Data

Participating in Real World Data

You have indicated your interest in Real World Data (RWD) collection by ticking the 'opt in' box within your Patient Request on 'Your Patient Access Portal' (please see image below).

Real World Data Collection

The program will be capturing Real World Data (RWD) in addition to providing treatment. This data could provide vital information for the benefit of future patients, including learning more about patient populations, early safety signals and real-life experiences.

Data inputted by HCPs may be made available at a local and aggregated level on request subject to approval. The program sponsor may wish to partner with healthcare professionals and academic institutes to review, analyze and publish clinical findings.

It will require consent for inclusion to be discussed and agreed with the patient in accordance with local regulations; and can be withdrawn at any time by contacting the Bionical Emas Patient Access Team. Further information on Real World Data collection can be found on the accompanying [Real World Data Overview](#).

Would you like to take part in a Real World Data Collection Project?

 Yes

 No

Would you like the sponsor to contact you with potential opportunities to review, analyze, and publish clinical findings?

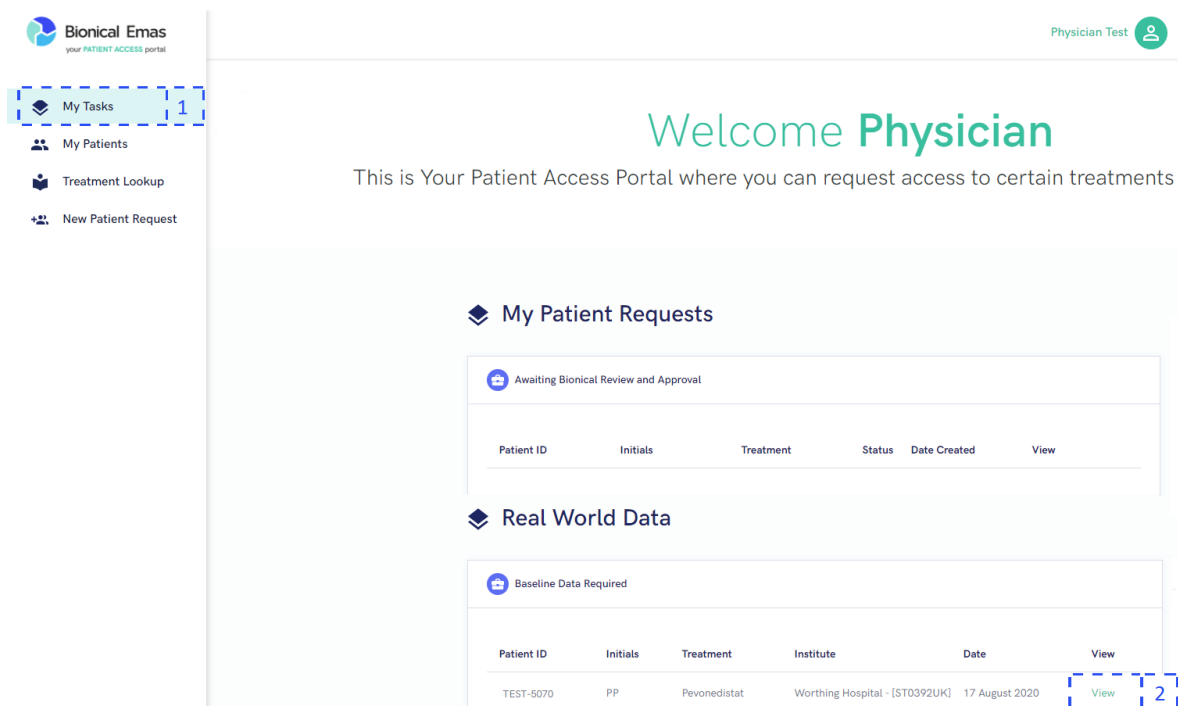
 Yes

 No

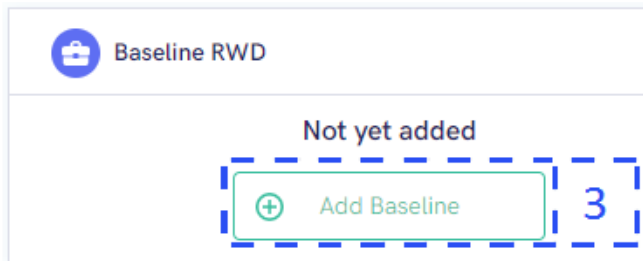
Once your Patient Request has been approved, you will be asked to confirm you understand the terms for Real World Data collection by entering your username and password for 'Your Patient Access Portal'.

Accessing Real World Data

Access for the Real World Data area is controlled by the same account details as the rest of 'Your Patient Access Portal'. If you have opted into RWD collection, this will automatically be added to your account permissions.






The screenshot shows the Bionical Emas Patient Access Portal interface. On the left is a navigation menu with items: My Tasks (highlighted with a dashed box and a '1'), My Patients, Treatment Lookup, and New Patient Request. The main content area displays a 'Welcome Physician' message and a 'My Patient Requests' section. Under 'My Patient Requests', there is a table with columns: Patient ID, Initials, Treatment, Status, Date Created, and View. A row is visible with Patient ID 'TEST-5070', Initials 'PP', Treatment 'Pevonedistat', Status 'Awaiting Bionical Review and Approval', and Date Created '17 August 2020'. The 'View' button for this row is highlighted with a dashed box and a '2'. Below this, there is a 'Real World Data' section with a 'Baseline Data Required' table. This table has columns: Patient ID, Initials, Treatment, Institute, Date, and View. A row is visible with Patient ID 'TEST-5070', Initials 'PP', Treatment 'Pevonedistat', Institute 'Worthing Hospital - [ST0392UK]', Date '17 August 2020', and a 'View' button highlighted with a dashed box and a '2'.



1	The Baseline Form can be accessed via the 'My Tasks' menu option on the top left-hand side of your 'welcome' page.
2	Scroll down to the Real World Data tasks at the bottom of the list and click 'View' within the 'Baseline Data Required' section.
3	Click the 'Add Baseline' button to access the form.

Icons

To help you understand the layout of the Real World Data sections, please see the below list.

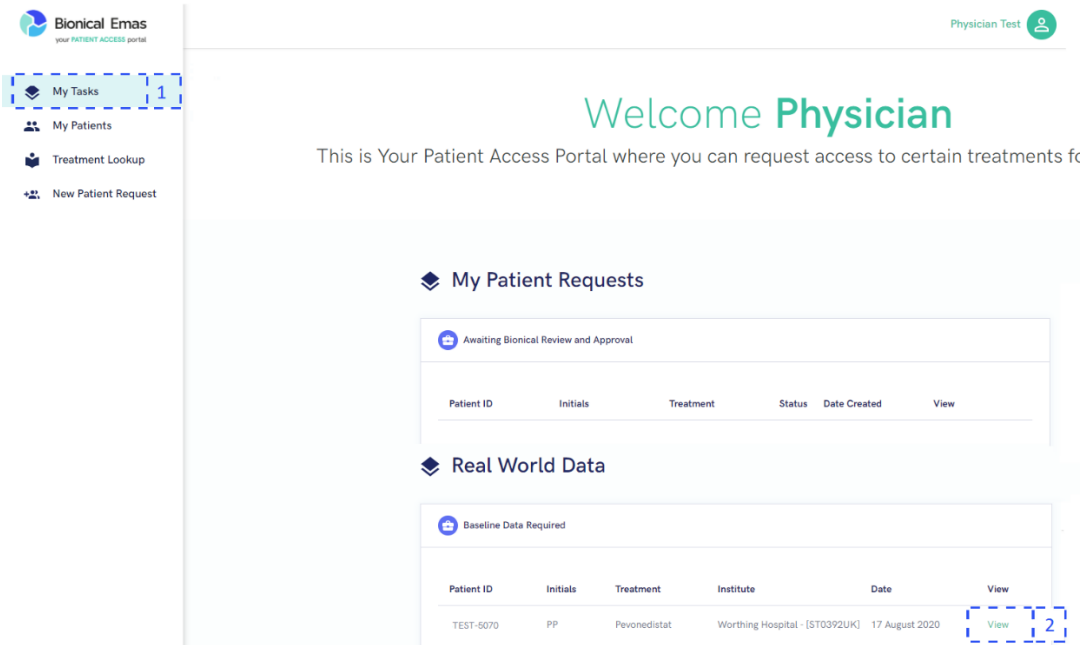
	This is an information icon. It will be placed next to questions containing additional information to help you understand what data is required.
	This is a query icon. It means this data does not meet a requirement or requires confirmation. This may be due to an automated check or it may mean that a question has been added to one of your responses by the Real World Data team.
	This is a closed query. It has been answered or corrected.

Adding the Baseline Visit

When your first product order is shipped, you will receive an email from the system inviting you to enter your patient's baseline data. We would strongly recommend you enter the data as soon as you receive this email.

When you first access the system to enter the data, an additional screen repeating the key information about Real World Data will appear. You will also be requested to confirm that you have obtained your patient's informed consent. Once you have completed this step, you can proceed to the baseline form for completion.

Completing the baseline form is a fundamental step of the Real World Data collection process. If you do not complete and submit the baseline form, you will not be able to complete any subsequent forms for RWD.



My Patient Requests

Awaiting Bionical Review and Approval

Patient ID	Initials	Treatment	Status	Date Created	View
TEST-5070	PP	Pevonedistat		17 August 2020	View

Real World Data

Baseline Data Required

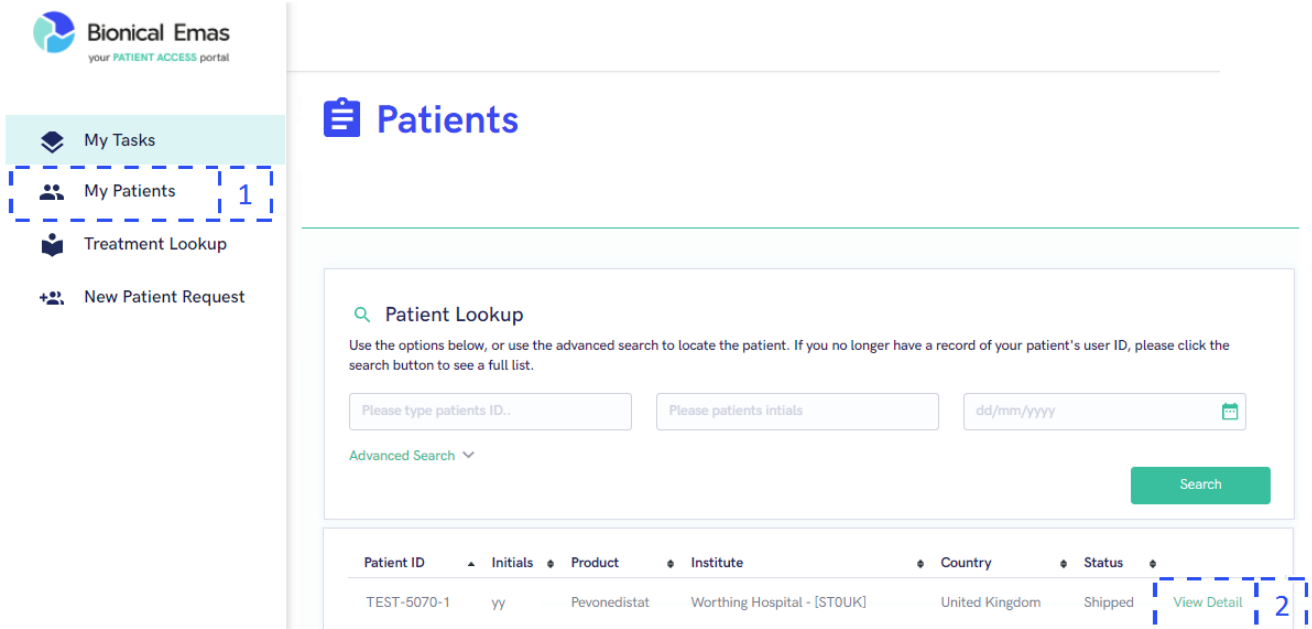
Patient ID	Initials	Treatment	Institute	Date	View
TEST-5070	PP	Pevonedistat	Worthing Hospital - [ST0392UK]	17 August 2020	View

1	Go to 'My Tasks' on your 'welcome' page (alternatively) you can click the link in the email notification for baseline data Or You can use the patient search to go a specific patient and add the baseline by clicking 'Add' in the baseline data section.
2	Scroll to the 'Baseline Data Required' section of your task list and click 'View' next to the patient.
3	Fill out the form and click 'Submit'.
Note:	You can only add 1 baseline form per patient

Adding Ongoing RWD entries

During the program you will need to add 'Ongoing' RWD entries for your patient. The frequency of these will vary from program to program. Some 'Ongoing' entries may cover the whole period between resupply requests, others may relate to monthly dosing cycles.

We would strongly recommend you enter the data on a regular basis as your patient progresses on the program, however the Real World Data section of 'Your Patent Access Portal' also gives you the flexibility to add the data in batches at the end - whichever is easiest for you. You will be able to add 'Ongoing' RWD entries at any point after completion of your initial baseline entry form, and will still be able to add them after you have discontinued a patient.



My Patients

1

Patient Lookup

Please type patients ID.. Please patients initials dd/mm/yyyy

Advanced Search

Search

Patient ID	Initials	Product	Institute	Country	Status	
TEST-5070-1	yy	Pevonedistat	Worthing Hospital - [STOUK]	United Kingdom	Shipped	View Detail

2

1	Go to 'My Patients' on your 'welcome' page and find your patient using the search bar.
2	Click 'View Detail'.
3	A new tab will open. Under the summary of application click the green button 'View Real World Data'.
4	Scroll to the 'Ongoing RWD' section and click 'Add Entry'.
5	Fill out the form and click 'Submit'.
Note:	You can add multiple forms.



+👤 New Patient Request

📄 Summary of Application

Status - Shipped

Patient Access Request has been shipped. Tracking details can be found below

[View Real World Data](#)

3

👤 Treating Physician Details

Name	Job Title	Contact No.	Email address	Department
Physician Test	Physician	0000	test.user@bionical-emas.com	Bionical

📄 Baseline RWD

Date Created	Date Updated	Status	View
07 August 2020	07 August 2020 13:46 UTC	Complete	View

📄 Ongoing RWD

Entry No.	Date Created	Date Updated	Status	View
1	11 August 2020	17 August 2020 10:12 UTC	Bionical Emas Review Required	View
2	11 August 2020	11 August 2020 08:26 UTC	Complete	View
3	11 August 2020	11 August 2020 08:44 UTC	Response Required	Edit

[+ Add Entry](#)

4

Discontinuation

There are 3 key steps to ensure a patient’s discontinuation is registered correctly on the system (please see recommended process below). The steps can be carried out in any order and you will still

be able to add any missing entries and complete 'Ongoing' entries (including discontinuation data), even after you have completed the steps below.

Step 1


The first step is to ensure the product supply is discontinued by informing the Patient Access team, including any intentions to reallocate stock. How to do this is covered [here](#).

Step 2

The second step is to make sure all the cycles have been added as 'Ongoing' entries. If your patient discontinues between resupply orders or mid-cycle, you can still fill out a final 'Ongoing' RWD entry and tick the 'Incomplete cycle or treatment discontinued prior to cycle start' box on the top right of each question (shown below). This box is available on each cycle and is also available for the hospitalization period. For the 'Response Assessment' question, you can fill in the final response assessment recorded, it does not need to cover a full 12-week period.

Ongoing RWD - Entry

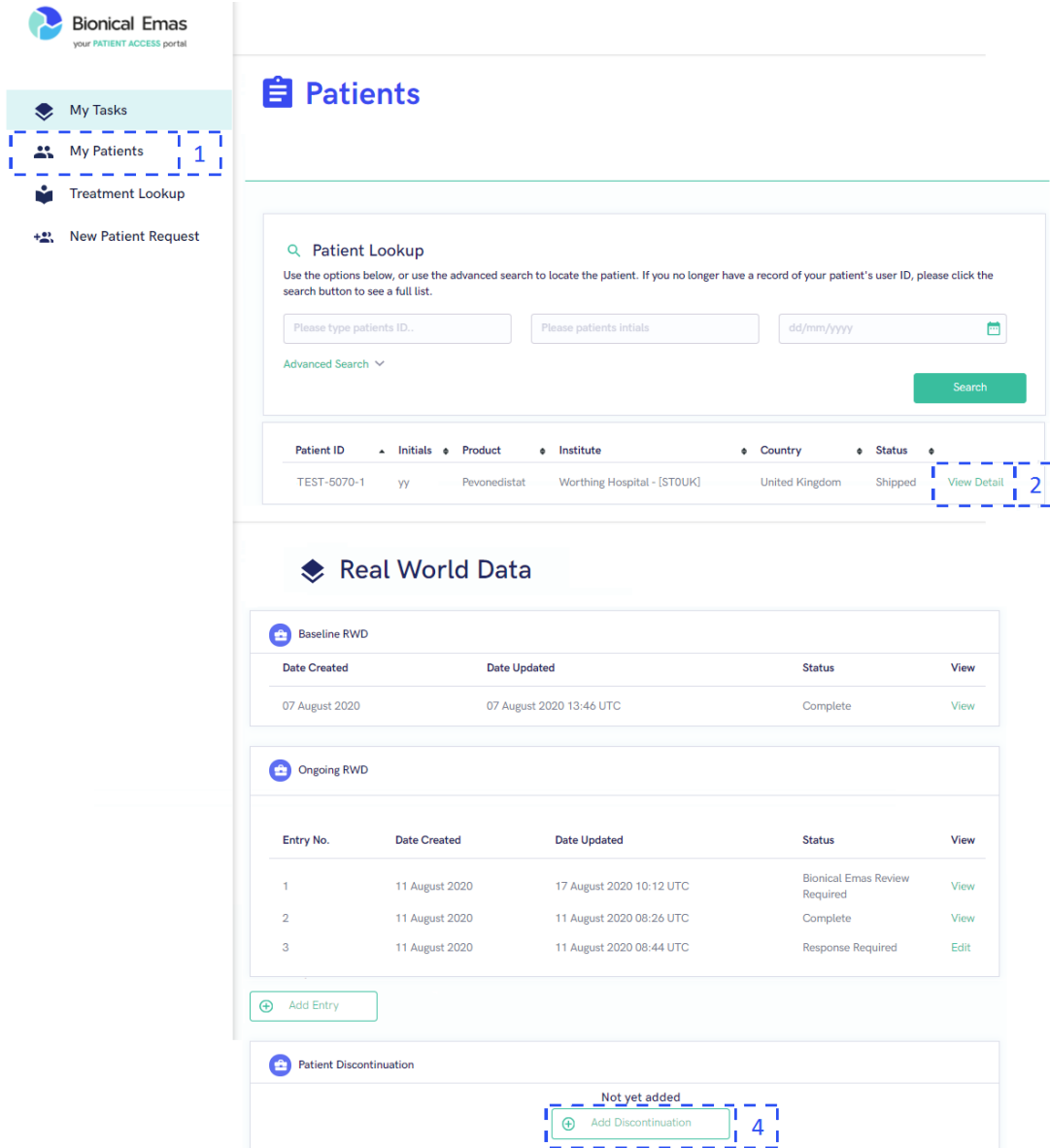
Please complete the following questions for the patient. You can save at any point and submit when completed.

Cycle Number	Incomplete cycle or treatment discontinued prior to cycle start <input type="checkbox"/>
Date (Day 1 of 28 day cycle)	<input type="text" value="dd/mm/yyyy"/> 
Dose (mg/m ²)	<input type="text"/> Dose unknown <input type="checkbox"/>

Step 3

The third step is to complete the 'Discontinuation' page for RWD. This is a short summary of the date and reason for ending participation. This signals to the Real World Data team that your patient's data can now be frozen ready for analysis later.

(See image overleaf).



Patients

My Patients 1

Patient Lookup

Please type patients ID... Please patients initials dd/mm/yyyy

Advanced Search Search

Patient ID	Initials	Product	Institute	Country	Status	
TEST-5070-1	yy	Pevonedistat	Worthing Hospital - [STOUK]	United Kingdom	Shipped	View Detail 2

Real World Data

Baseline RWD

Date Created	Date Updated	Status	View
07 August 2020	07 August 2020 13:46 UTC	Complete	View

Ongoing RWD

Entry No.	Date Created	Date Updated	Status	View
1	11 August 2020	17 August 2020 10:12 UTC	Bionical Emas Review Required	View
2	11 August 2020	11 August 2020 08:26 UTC	Complete	View
3	11 August 2020	11 August 2020 08:44 UTC	Response Required	Edit

[Add Entry](#)

Patient Discontinuation

Not yet added

[Add Discontinuation](#) 4

1	Go to 'My Patients' on the homepage and find your patient using the search bar.
2	Click 'View Detail'.
3	A new tab will open. Under the summary of application click the green button 'View Real World Data'.
4	Scroll to the 'Discontinuation' section and click 'Add Discontinuation'.
5	Fill out the form and click 'Submit'.
Note:	You can only add 1 Discontinuation Form per patient.

Data Queries

Queries are used to verify data collected. There are two types of query that may appear; automated system queries and manual queries (see explanations below).


Automated system queries: These are queries that are automatically generated when you try to submit data. They are caused by set data requirements not being fulfilled (e.g. compulsory fields left blank, dates in the future or out-of-range measurements).

Manual queries: These are queries raised by the program team manually. They usually address matters that are more complex and not easily built into the system, such as ambiguous text.

Please see the image below for an example of an automated system query. The icons used for manual queries are identical.

Ongoing RWD - Entry 3

There may be some issues with some of the responses provided.

Please review the comments below by clicking on the  icon. You may either amend the response and select 'Data updated', or select 'No change needed'. You can save at any point, and submit once you have updated all the comments.

Cycle Number 9

Date (Day 1 of
28 Day cycle)



09/08/2020



Dose (mg/m²)



20



Dose
unknown

1



1

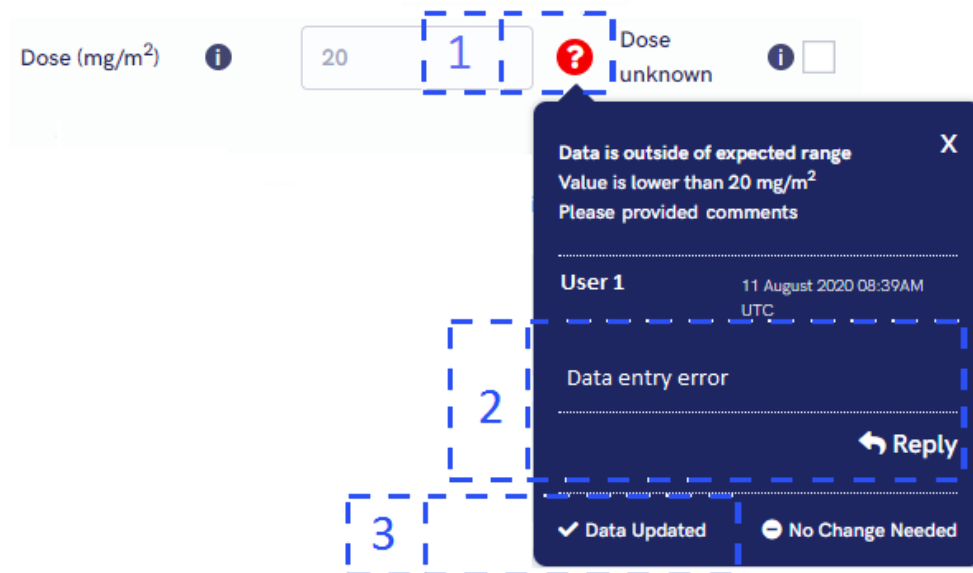
Each page with a query to be reviewed will have a  next to it.





Answering a query

There are two ways of answering a query. You can amend the data if it is wrong or missing, or you can respond to the query with a comment if the data you have entered is correct. The query should then resolve itself and the query icon will change to a green tick (see steps below).

Data Queries: Correcting Data

1	Click the  icon.
2	Click 'Reply' to use the comments box to communicate with the data team, if useful.
3	Click 'Data Updated'.
Note	The icon will change to  when completed.




Dose (mg/m²)  20   Dose unknown 

Data is outside of expected range X
 Value is lower than 20 mg/m²
 Please provided comments

.....
 User 1 11 August 2020 08:39AM
 UTC

Data entry error



 Reply

Data Updated No Change Needed

Data Queries: Answering

When a query appears but you have entered information correctly, you can respond to the query with a comment. This should close the query and the icon will turn green. ✓



1	Click the  icon.
2	Click 'Reply' to use the comments box to give a reason for not changing the data.
3	Click 'No Change Needed'.
Note	The icon will change to  when completed.

Support

Should you require any additional support please contact us at Patient.Access@Bionical-Emas.com