



RAPIDS Patient Management Module Training for Sites (NOVELTY Study)

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Parexel, Int.



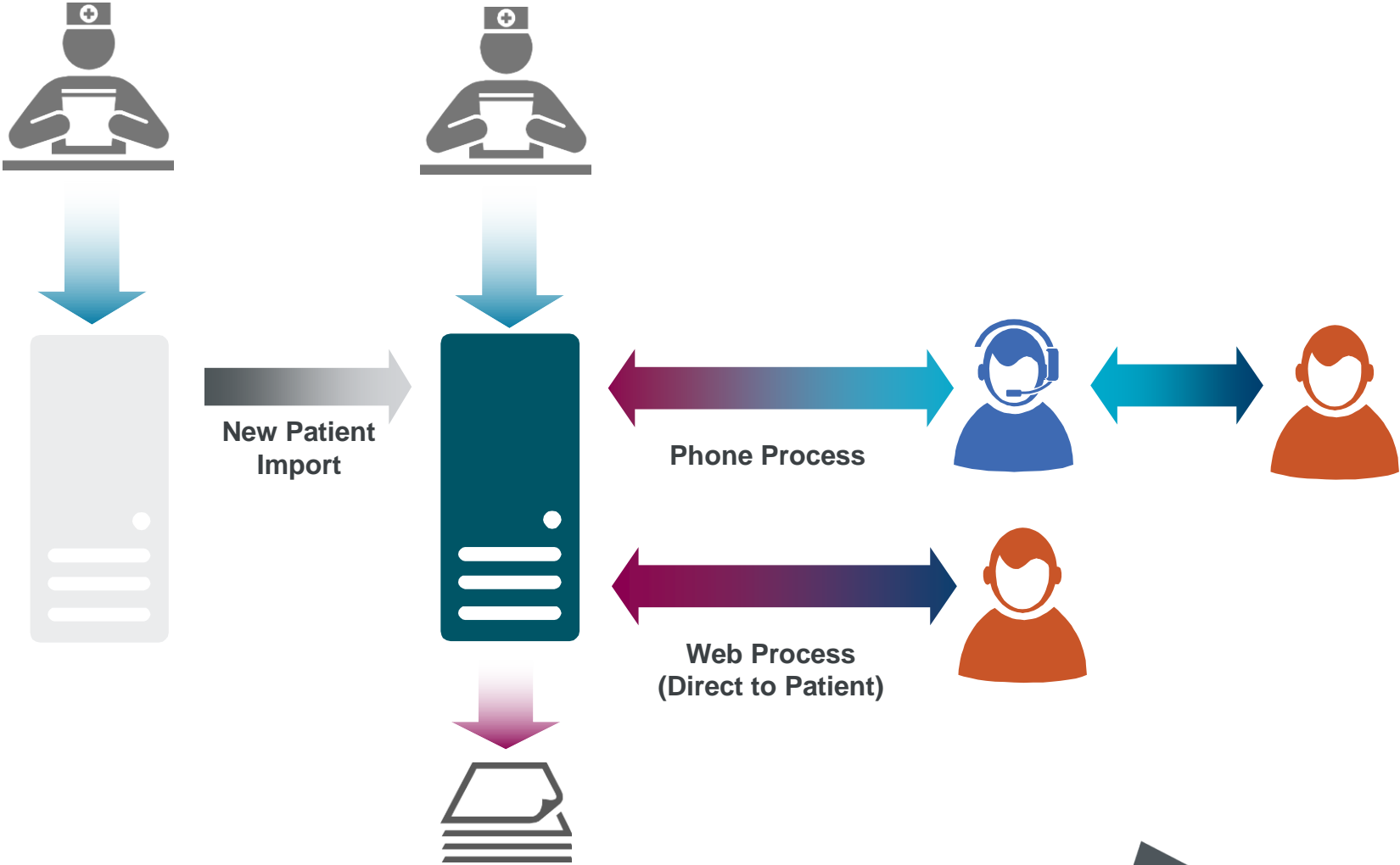
Agenda

- › RAPIDS Team
- › Project Overview
- › RAPIDS System Overview
- › Patient Experience Overview
- › Patient Management Module

RAPIDS Team

- › Rachel Michener, Senior Project Development Specialist (Primary)
- › Yamill Parodi, Senior Project Development Specialist (Secondary)

Project Overview



RAPIDS Overview

- › The RAPIDS system will be used as a:
 - › **Patient Management Module** (Site module)
 - Complete Site Profile
 - Register/un-register/update patients
 - Access Site-specific Reports
 - › **Call Center System**
 - Queues calls for call center staff to make
 - Receives responses and outcomes of calls
 - › **EPRO** (patient module)
 - Sends invitational and reminders emails to patients
 - Patient completes questionnaires online directly

Call Center Overview

- › Conducting phone calls to patients who have opted to complete the questionnaires via phone.
- › Located in Zurich, Switzerland
- › Local-language patient calls
- › Up to 3 attempts will be made to reach patients each survey period

Patient Experience Overview (Questionnaires Online)

- When it is time for them to complete a questionnaire, the patient will receive an email in their language as designated by the site.
- Patient will click on link in email.
- They must enter the codes given to them in the email in order to complete questionnaires.
- They will then be shown a list of questionnaires that need to be completed.
- Patient will go through questionnaires answering questions, clicking “next” at the bottom of each screen.

Patient Experience Overview (Cont.)

- › If patient does not complete questionnaires online by designated time, RAPIDS will queue patient for up to two reminder emails.
- › If still not completed before the designated end of the collection period, questionnaires will close.
- › Sites can review reports in real time to see if patients are completing questionnaires.
- › Patients who are having technical issues with their questionnaire should contact the site and the site can escalate to RAPIDS site support.

Patient Experience Overview (Questionnaires by Phone)

- › Call Center will call patient to complete questionnaires at designated time periods as programmed into the RAPIDS system based on the information provided during registration in RAPIDS.
- › Call Center will make up to 3 attempts to reach the patient and complete questionnaires.
- › If Call Center calls at an inconvenient time, patient can schedule a call back from the call center as long as it is within the current questionnaire collection period.
- › The Call Center will report any issues with the patient contact information, if patient refuses to complete questionnaires, or if patient asks to be withdrawn.
- › Sites can review reports in real time to see if patients are completing questionnaires.

When should RAPIDS be used the site?

› Use RAPIDS to...

- › Complete Site Information module
- › Register a Patient
- › Un-Register a Patient
- › Update Patient Information
- › Review Site Reports

› Note: Patients will not begin to receive their PRO questionnaires until they are registered in RAPIDS

Tools to Get Started

- To access RAPIDS users will need to complete this training presentation
- Authorized persons will receive emails with their login credentials (user name and password will be sent separately) and the URL to access RAPIDS*

*Save the URL to your favorites for future use.

Contacting Site Support

- Contact Site Support
- Go to the landing page and complete the web form:
 - <https://web.rapidscrm.com/NOVELTYStudy>
- Or you may email:
 - NOVELTYQuestionnaireSupport@parexel.com
- Contact Site Support if:
 - You have questions about RAPIDS
 - You entered information in error
 - You forgot your username

- If emailing the site support team, include:
 - Your site number
 - Your name
 - Phone and fax number
 - The name of your principal investigator
 - Details of your request or problem

Site support is available 8:00 a.m. to 5:00 p.m. EST (USA) Monday through Friday.

Do not include patient identifiable information in emails to Site Support

RAPIDS

Patient Management Module

Site Landing Page Overview

URL: <https://web.rapidscrm.com/NOVELTYStudy>

*Don't forget to use the "s" in the https

Live system: for entering real data and view reports

Live system in Japanese

Guide: Download this presentation

Worksheets: to pre-fill before entering data or for reference to know what data will be needed

Use the form to request support!

Example: Problem with username and/or password, Entered subject in error (specify in comments), or Other (specify in comments)

RAPIDS

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Welcome to the NOVELTY Study RAPIDS Patient Management Module.

Please have your username and password available before you begin your entry.

[Click here](#) for live system. (To enter site information or register a patient)

[Click here](#) for live Japanese system. (To enter site information or register a patient)

[Click here](#) for guide for using the RAPIDS system.

[Click here](#) for Site Profile Worksheet – Guide

[Click here](#) for NOVELTY Patient Information Worksheet

The RAPIDS system will time out after 20 minutes of inactivity.

If you are having password problems or any other issues, please fill out the form below for assistance.

Site No:

Email:

Name:

Request Types:

Comments:

[Legal Notice](#) [Privacy Policy](#)

Initial Login

1. Go to the RAPIDS PMM link on your welcome emails or on the landing page
2. Enter the Username and Password and click “LOGIN”
3. A popup will indicate that the password is expired
4. Complete the activation form including a new password

**Must be 8 digits long

**Include letters and numbers

**If you forget your password,
you will be asked to answer
the security questions!**

2

Login

Username:

Password:

Forgot your password? Enter your username and click [HERE](#)

3

Message from webpage

Your Password expired. Please provide Hint Questions and Answers and change your Password.

4

Welcome to RAPIDS. Please Login.

Old Password:

New Password:

Confirm Password:

Please select a Hint Question 1:

Question 1 Answer:

Please select a Hint Question 2:

Question 2 Answer:

RAPIDS Menu

The first screen in RAPIDS will be a menu of options. You will need to start by Completing Your Site Profile. This can only be completed once. After you complete it, you will not see this choice on the menu.

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Please select the action you would like to perform below:

- Complete Site Profile
- Register a Patient
- Un-Register a Patient
- Update Patient Information
- Review My Site Reports

Completing Site Profile

Select a type for your clinical site



← →

Site type:

- General Practice/Primary Care Center
- Private Practice
- Research Facility
- University Hospital
- Non-University Hospital

← →

Completing Site Profile

Provide the total number of registered asthma and COPD patients at your site or check the box for "unknown"



← →

Number of registered asthma and COPD patients at the site.

Number:

Unknown

← →

Completing Site Profile

Provide the physician's profile information

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← →

Physician Type:

- Primary Care Physician
- Pulmonologist
- Allergy Specialist
- Family Medicine
- General Practitioner
- Internal Medicine
- Respiratory Specialist

Physician's Year of Birth:

Physician's Sex:

- Male
- Female

Years since medically qualified:

Years in current position:

← →

Completing Site Profile

That's all!



← →

This concludes the site information form.

Click "next" to continue.

← →

Completing Site Profile

The last screen always gives you the option to go back to the main menu. Select yes to continue working in RAPIDS.



A screenshot of a mobile application interface. At the top, there are two green buttons with white arrows pointing left and right. Below these is the question "Would you like to process another request?". Underneath the question are two radio button options: "Yes" (which is selected) and "No". At the bottom of the screen, there are two more green buttons with white arrows pointing left and right. The entire screen is enclosed in a thin blue border.

Register a Patient

Now, we will register a patient.

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← →

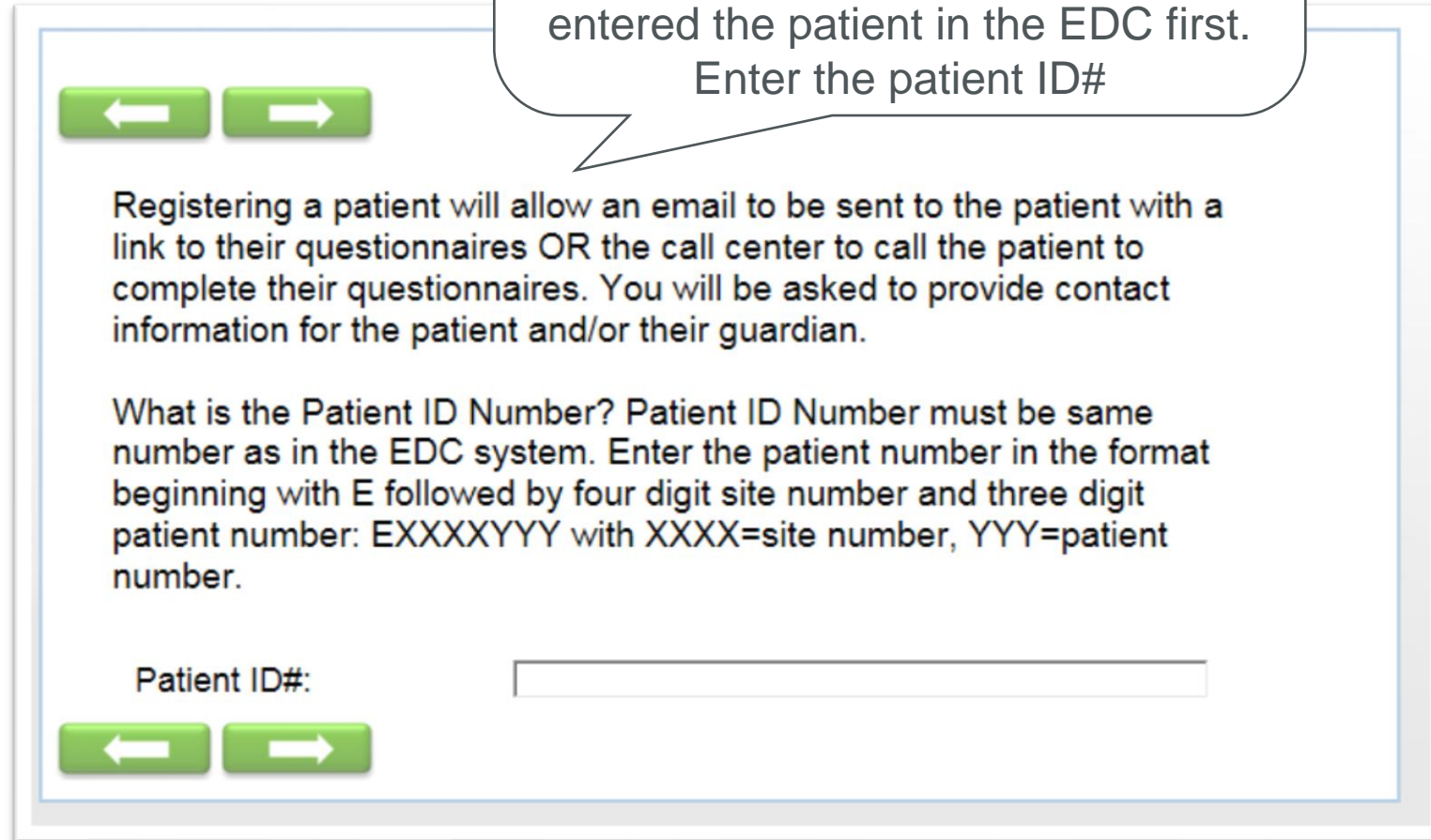
Please select the action you would like to perform below:

- Register a Patient
- Un-Register a Patient
- Update Patient Information
- Review My Site Reports

← →

Register a Patient

Remember that the patient must be entered in the EDC before you can perform this step! You will need the patient ID from the EDC. You will get an error message if you have not entered the patient in the EDC first.
Enter the patient ID#



The screenshot shows a web interface for patient registration. At the top left, there are two green buttons with white arrows pointing left and right. Below these is a paragraph of text explaining the registration process. Another paragraph explains the format for the Patient ID Number. At the bottom, there is a label 'Patient ID#' followed by a text input field. At the bottom left, there are two more green buttons with white arrows pointing left and right. A callout box from the top right points to the input field, containing a reminder to enter the patient ID in the EDC first.

Registering a patient will allow an email to be sent to the patient with a link to their questionnaires OR the call center to call the patient to complete their questionnaires. You will be asked to provide contact information for the patient and/or their guardian.

What is the Patient ID Number? Patient ID Number must be same number as in the EDC system. Enter the patient number in the format beginning with E followed by four digit site number and three digit patient number: EXXXXYYY with XXXX=site number, YYY=patient number.

Patient ID#:

Register a Patient

Use the calendar tool to enter the actual enrollment date of the patient.

For this, you will need to select the year, then the month, then day as per the instructions on the screen.



← →

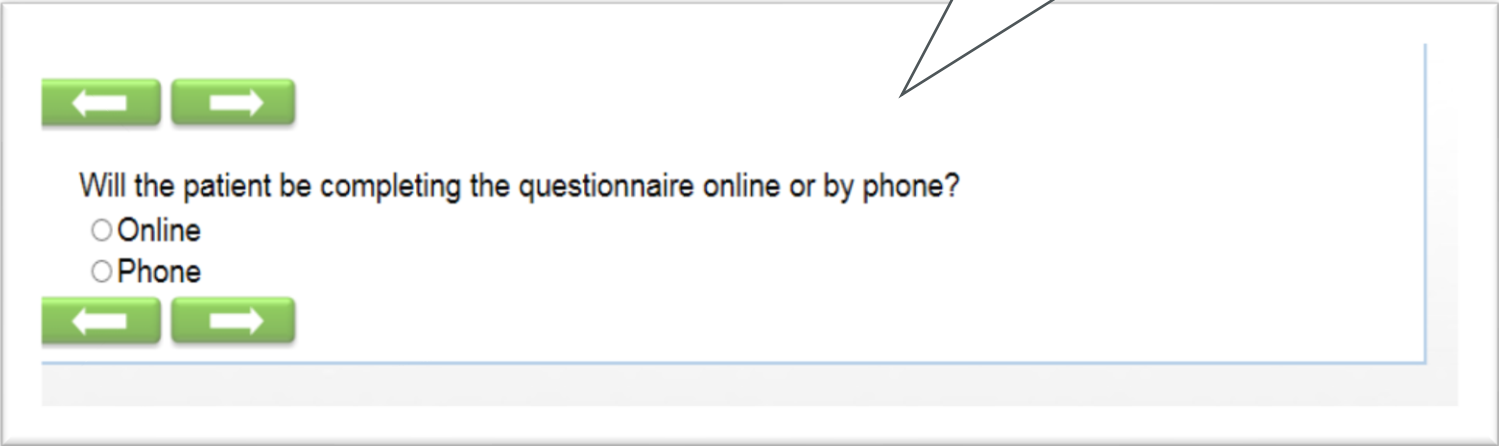
What is the actual date of enrollment for this patient? (Select year first, then month, then day)

📅

← →

Register a Patient

Answering this question lets us know how we should reach out to the patient, by phone or by email.

A screenshot of a web form for patient registration. At the top left, there are two green buttons with white arrows pointing left and right. Below these is the question "Will the patient be completing the questionnaire online or by phone?". Underneath the question are two radio button options: "Online" and "Phone". At the bottom of the form area, there are two more green buttons with white arrows pointing left and right, and a horizontal line below them.

← →

Will the patient be completing the questionnaire online or by phone?

Online

Phone

← →

Register a Patient

Let us know if the patient is an adolescent or an adult.

This will be used to determine which questionnaires they should receive, as per the protocol.

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Is the patient an adolescent or an adult?

- Adolescent
- Adult



Register a Patient

The calls and emails will be addressed to the patient or the patient's guardian. Let us know which!
(This screen only shows if you selected adolescent on the previous screen.)



← →

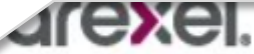
Are the questionnaires to be delivered to the patient or a guardian?

- Patient should be contacted directly
- Guardian should be contacted

← →

Register a Patient

If you need us to speak to the guardian, then we will ask for that person's name.



← →

Please provide the name of the patient's guardian to be contacted below.

You may enter more than one name. It is not necessary to provide both the first and last name. Only enter the name which the call center will use to contact this/these individual(s).

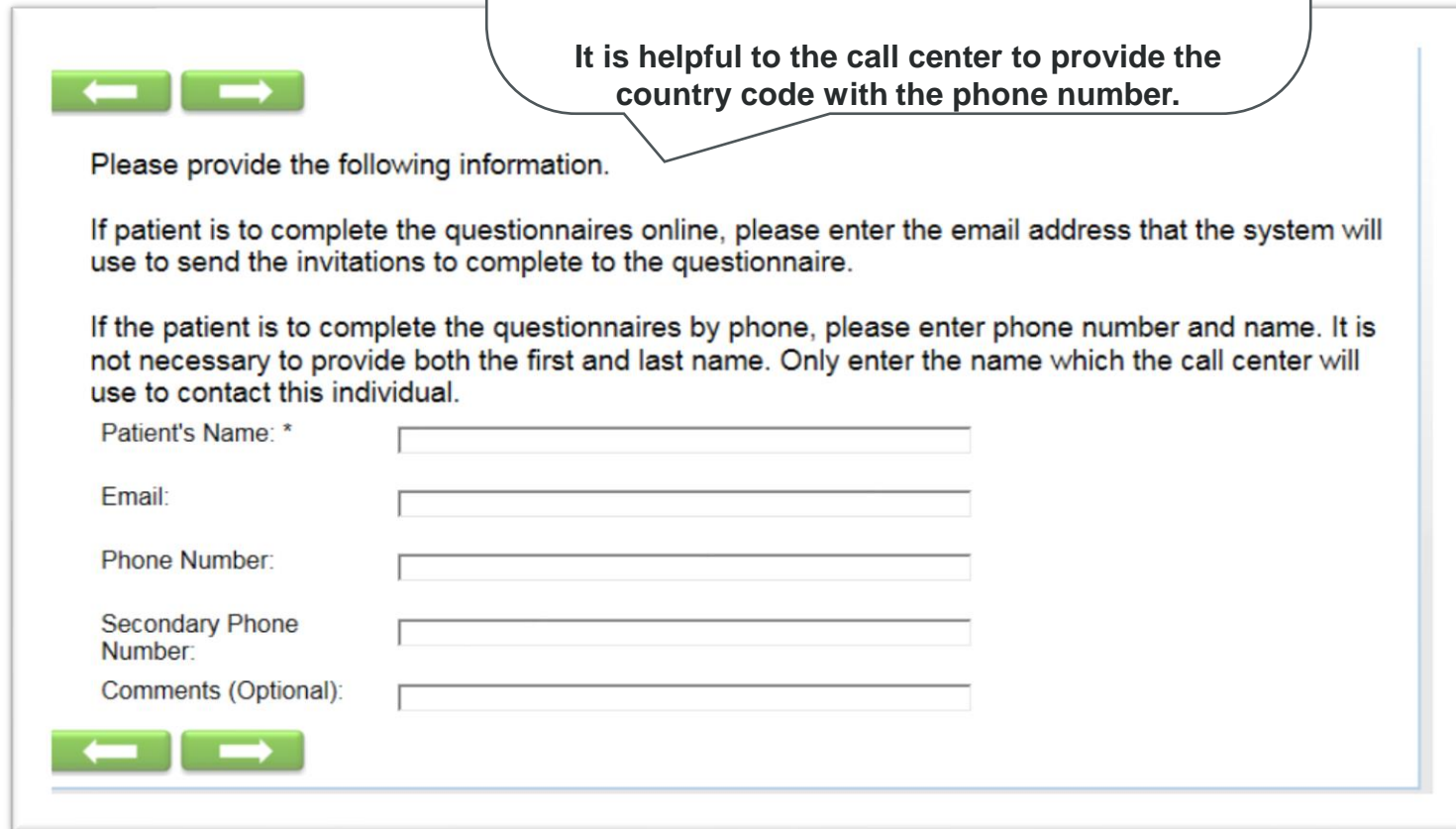
Guardian Name (s): *

← →

Register a Patient

Provide contact information.
Don't forget that if you want us to reach out by email, you must provide an email address. If we are to call, please make sure you give us at least one phone number!

It is helpful to the call center to provide the country code with the phone number.



← →

Please provide the following information.

If patient is to complete the questionnaires online, please enter the email address that the system will use to send the invitations to complete to the questionnaire.

If the patient is to complete the questionnaires by phone, please enter phone number and name. It is not necessary to provide both the first and last name. Only enter the name which the call center will use to contact this individual.

Patient's Name: *

Email:

Phone Number:

Secondary Phone Number:

Comments (Optional):

← →

Register a Patient

Select the patient's time zone here. This will help us schedule calls, since we don't have the patient's address.

Note: You will only see time zones for your country. All time zones will be in UTC + or -

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Select the time zone for this patient.

- UTC-04:00 (AST)
- UTC-05:00 (EST)
- UTC-06:00 (CST)
- UTC-07:00 (MST)
- UTC-08:00 (PST)
- UTC-09:00 (AKT)
- UTC-10:00 (HAT)



Register a Patient

We also need to know which language to use to contact this person.

Note: This list will include only languages approved in your country!



← →

Select the language to be used to perform these calls.

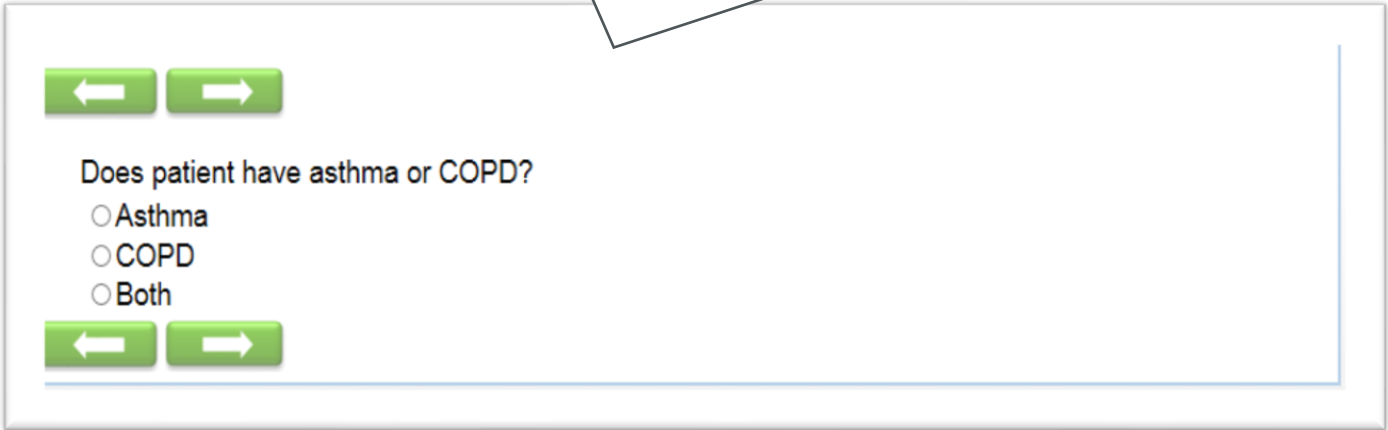
English

← →

Register a Patient

Select the patient's condition.

This is relevant to which questionnaires this patient will be required to complete.

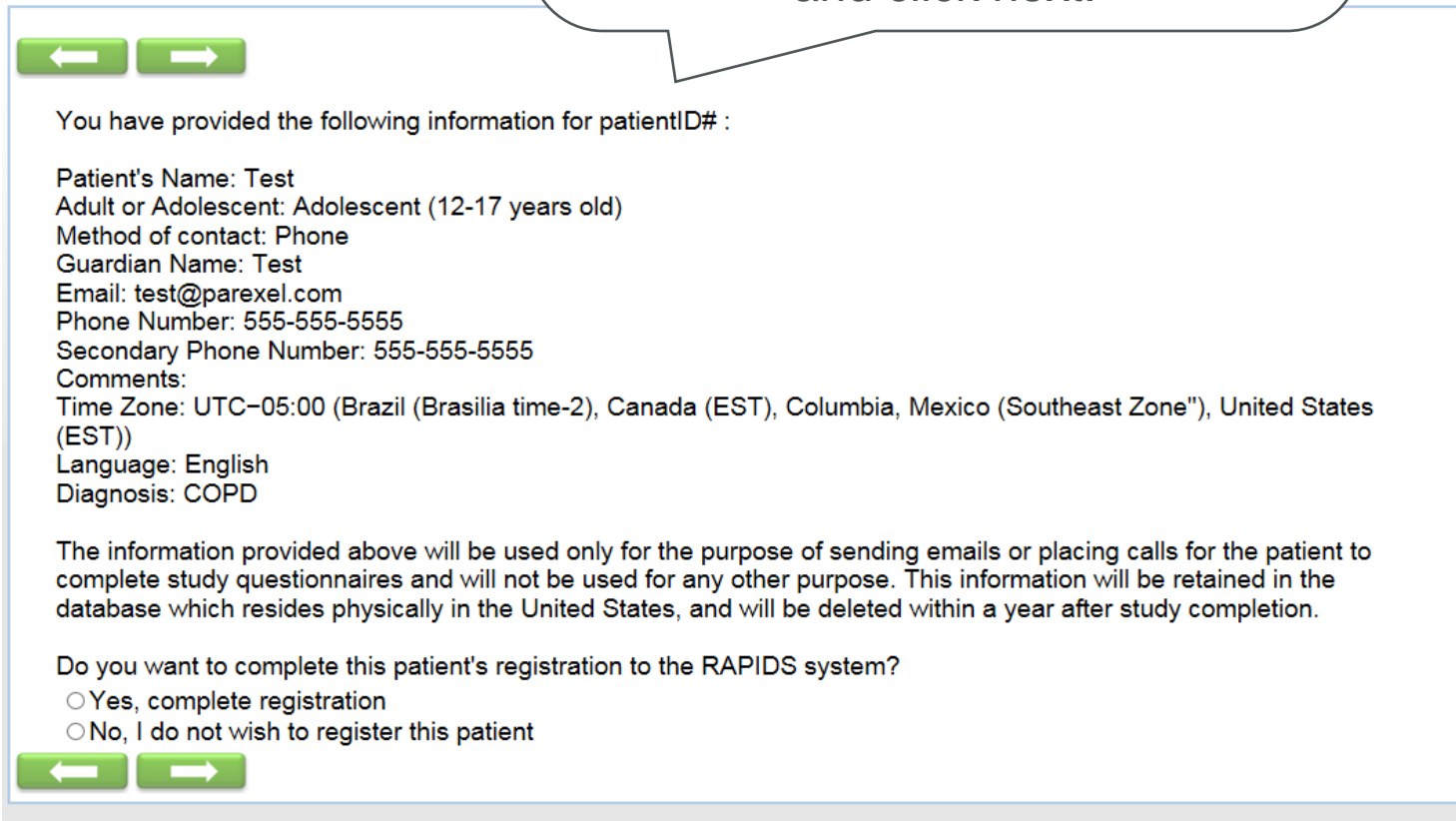


The screenshot shows a mobile application interface for patient registration. At the top, there are two green navigation buttons with left and right arrows. Below them is the question "Does patient have asthma or COPD?". Underneath the question are three radio button options: "Asthma", "COPD", and "Both". At the bottom of the form area, there are two more green navigation buttons with left and right arrows. A callout box with a white background and a black border is positioned above the form, containing the text "Select the patient's condition. This is relevant to which questionnaires this patient will be required to complete." The Parexel logo is partially visible on the right side of the form area.

Register a Patient

Carefully review the information you have provided! Take your time and go back if you need to correct anything.

Select “Yes, complete registration” and click next.



The screenshot shows a web interface for patient registration. At the top, there are two green navigation buttons: a left arrow and a right arrow. Below them, the text reads: "You have provided the following information for patientID# :". The information listed is: Patient's Name: Test; Adult or Adolescent: Adolescent (12-17 years old); Method of contact: Phone; Guardian Name: Test; Email: test@parexel.com; Phone Number: 555-555-5555; Secondary Phone Number: 555-555-5555; Comments: Time Zone: UTC-05:00 (Brazil (Brasilia time-2), Canada (EST), Columbia, Mexico (Southeast Zone"), United States (EST)); Language: English; Diagnosis: COPD. Below this information is a paragraph: "The information provided above will be used only for the purpose of sending emails or placing calls for the patient to complete study questionnaires and will not be used for any other purpose. This information will be retained in the database which resides physically in the United States, and will be deleted within a year after study completion." At the bottom, there is a question: "Do you want to complete this patient's registration to the RAPIDS system?" with two radio button options: "Yes, complete registration" and "No, I do not wish to register this patient". At the very bottom of the form, there are two more green navigation buttons: a left arrow and a right arrow.

You have provided the following information for patientID# :

Patient's Name: Test
Adult or Adolescent: Adolescent (12-17 years old)
Method of contact: Phone
Guardian Name: Test
Email: test@parexel.com
Phone Number: 555-555-5555
Secondary Phone Number: 555-555-5555
Comments:
Time Zone: UTC-05:00 (Brazil (Brasilia time-2), Canada (EST), Columbia, Mexico (Southeast Zone"), United States (EST))
Language: English
Diagnosis: COPD

The information provided above will be used only for the purpose of sending emails or placing calls for the patient to complete study questionnaires and will not be used for any other purpose. This information will be retained in the database which resides physically in the United States, and will be deleted within a year after study completion.

Do you want to complete this patient's registration to the RAPIDS system?

Yes, complete registration
 No, I do not wish to register this patient

Register a Patient

Thank you!
The patient has been registered and will be contacted to complete their questionnaires until they complete the study or until you unregister them here in RAPIDS.



PatientID# has been registered and will begin receiving questionnaires.

You may use the system to view reports to track which questionnaires this patient has completed.

Please email (insert study email) for questions or further assistance.

Please click next to continue to the main menu.



Un-Register a Patient

“Un-Register a Patient” is for a patient who no longer wishes to participate. Un-Registering a patient will remove them from the call/email queue so they will no longer be invited to complete the questionnaires.

If you have entered a patient number in error, do not use “un-register”. Contact the site support team.



Please select the action you would like to perform below:

- Register a Patient
- Un-Register a Patient
- Update Patient Information
- Review My Site Reports



Un-Register a Patient

Enter the patient ID# to be un-registered.



← →

Please enter the PatientID# to be un-registered below:

Patient ID#: *

← →

Un-Register a Patient

Confirm that you want to unregister this patient.

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If you agree to proceed, then PatientID# will be removed from the RAPIDS system and updated to un-registered status. The patient will no longer receive study questionnaires.

Are you sure you want to proceed?

- Yes, un-register this patient
- No, do not un-register this patient



Un-Register a Patient

This screen confirms that the patient has been unregistered.

The patient will no longer be contacted by the call center or emailed by RAPIDS.



← →

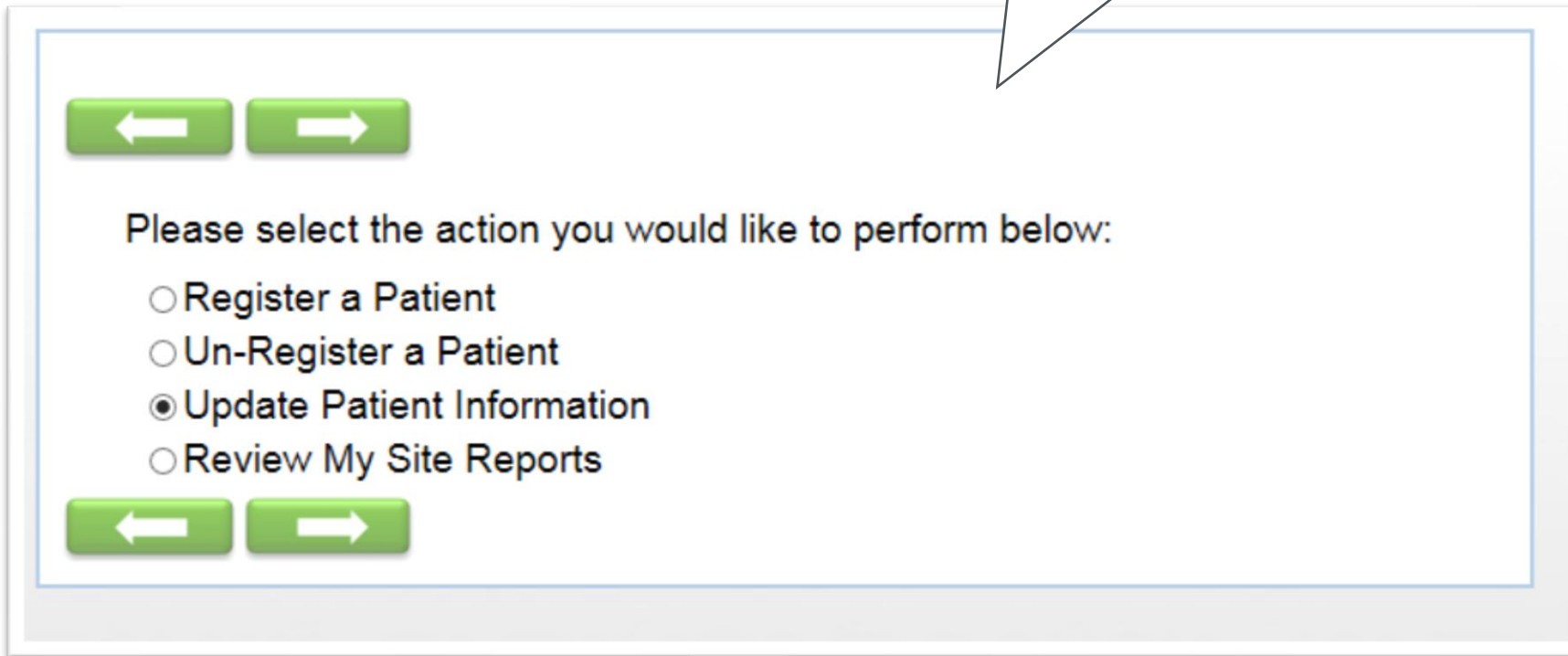
PatientID# has been un-registered.

Please click next to continue to the main menu.

← →

Update a Patient

To change a patient's information, you can send us an update.



The screenshot shows a web interface with a light blue border. At the top left, there are two green buttons with white arrows pointing left and right. Below these buttons, the text reads "Please select the action you would like to perform below:". Underneath this text is a list of four radio button options: "Register a Patient", "Un-Register a Patient", "Update Patient Information" (which is selected), and "Review My Site Reports". At the bottom of the form, there are two more green buttons with white arrows pointing left and right.

Update a Patient

Select what kind of information you want to update.

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What kind of update would you like to submit?

- Patient Contact Information
- Other Patient Information

← →

Update a Patient

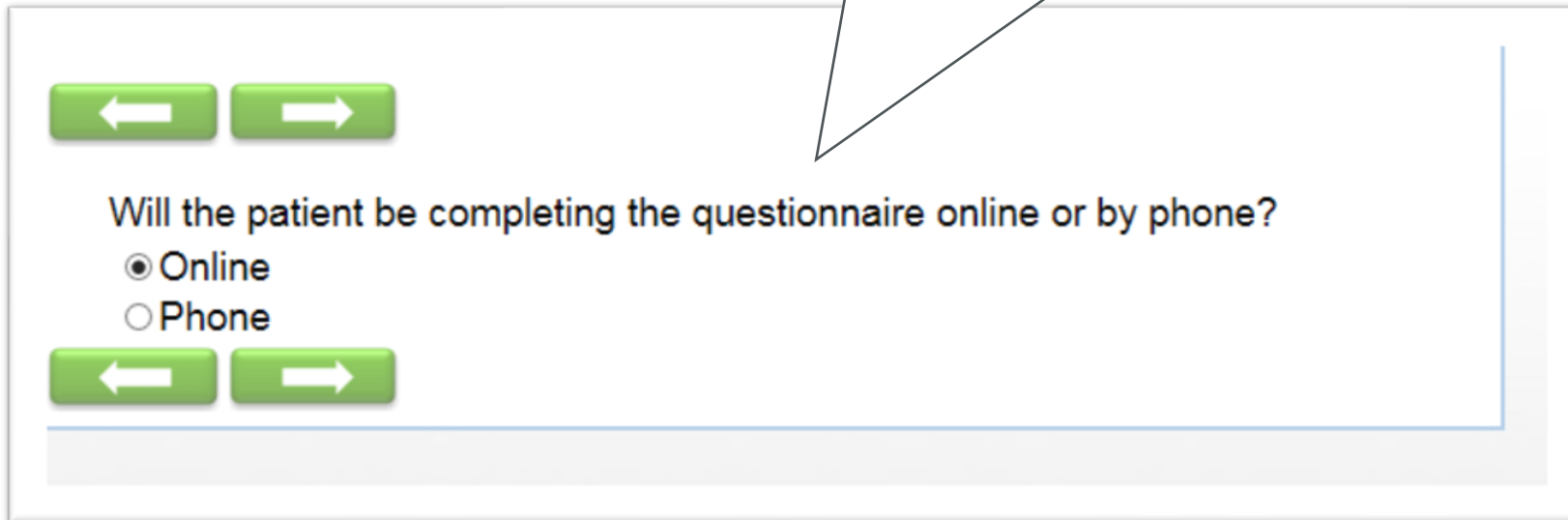
If you want to update the patient's contact information, you will enter the patient ID#

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Please enter the Patient ID# to be updated below:

Update a Patient

It is recommended that the method of contact for a patient remains the same for the entire study. However, the system does allow you to change this if necessary.



← →

Will the patient be completing the questionnaire online or by phone?



Online

Phone

← →

Update a Patient





Is the patient an adolescent or an adult?

Adolescent

Adult

Update a Patient

You can update the contact information.

el.



Please provide the following information.

If patient is to complete the questionnaires online, please enter email address.

If the patient is to complete the questionnaires by phone, please enter phone number and name. It is not necessary to provide both the first and last name. Only enter the name which the call center will use to contact this individual.

Patient's Name: *

Email:

Phone Number:

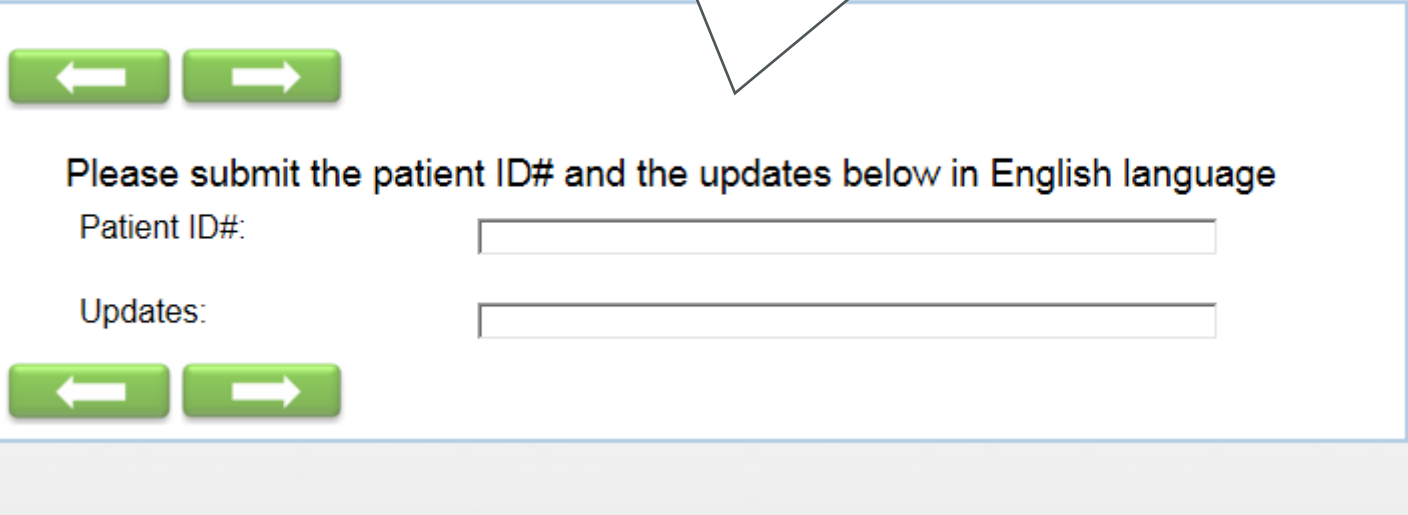
Secondary Phone Number:

Comments (Optional):



Update a Patient

If you want to send any other kind of update, then you will be able to provide a patient ID# and the updates here.



A screenshot of a web form for updating a patient. At the top left of the form are two green buttons with white arrows pointing left and right. Below these is the instruction: "Please submit the patient ID# and the updates below in English language". There are two input fields: "Patient ID#" and "Updates:". At the bottom left of the form are two more green buttons with white arrows pointing left and right. The form is set against a light gray background.

Site Reports

From the main menu, you can choose to review your site's reports.



Please select the action you would like to perform below:

- Register a Patient
- Un-Register a Patient
- Update Patient Information
- Review My Site Reports

Site Reports

Click on the report you wish to download.

The report will open in EXCEL

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The screenshot shows a web interface for viewing reports. At the top left, there are two green buttons with white arrows pointing left and right. Below these is the text "Select click to view the following reports:". Underneath this text are two grey buttons with rounded corners: "Patient Status Report" and "Patient Inquiry Outcome Report". At the bottom of the interface, there are another two green buttons with white arrows pointing left and right.

Site Reports – Patient Status Report

› Patient Status Report

- › Patient ID
- › Patient Status
- › Date Registered
- › Date Un-Registered
- › Study Enrollment Date
- › Method of Completion (online/phone)
- › Adolescent/Adult
- › Point of Contact
- › Patient Name
- › Guardian Name
- › Email
- › Phone Number
- › Secondary Phone number
- › Comments
- › Time Zone
- › Language
- › Diagnosis

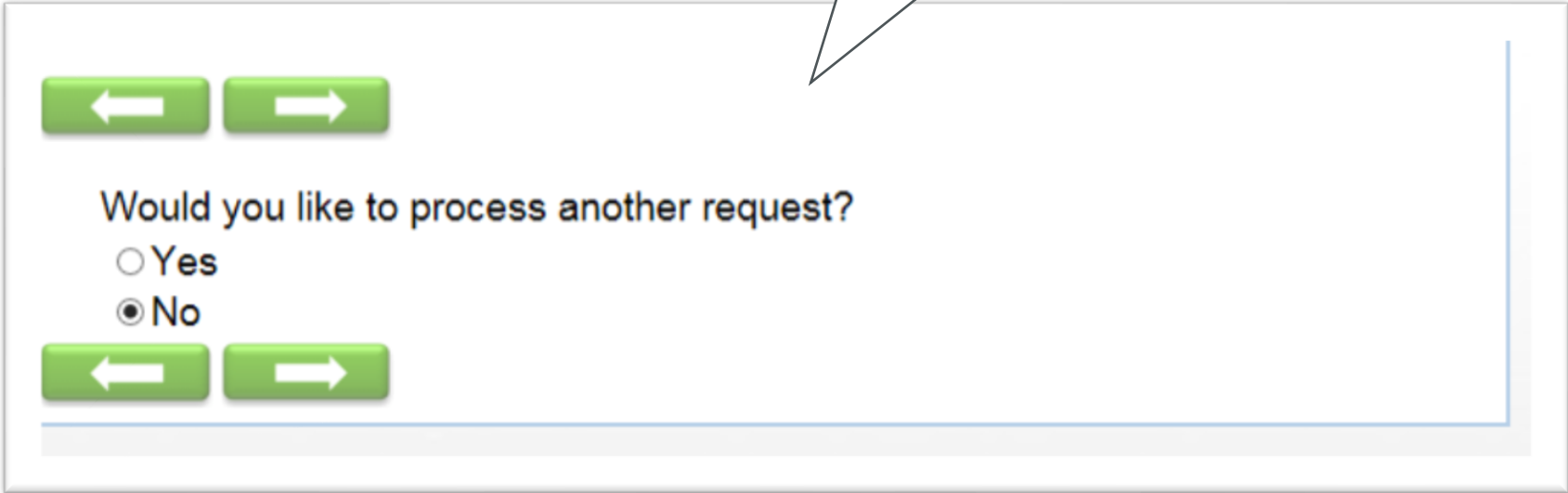
Site Reports – Patient Call Report

- Patient Inquiry Outcome Report
 - Site #
 - Patient ID#
 - Patient Status
 - Inquiry Number
 - Date of Inquiry Creation
 - Questionnaire Period
 - Questionnaire Name
 - Questionnaire Status
 - Period Status
 - Method of Completion (Phone/Web)

Closing RAPIDS

If you're done using RAPIDS, select "No" here.

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← →

Would you like to process another request?

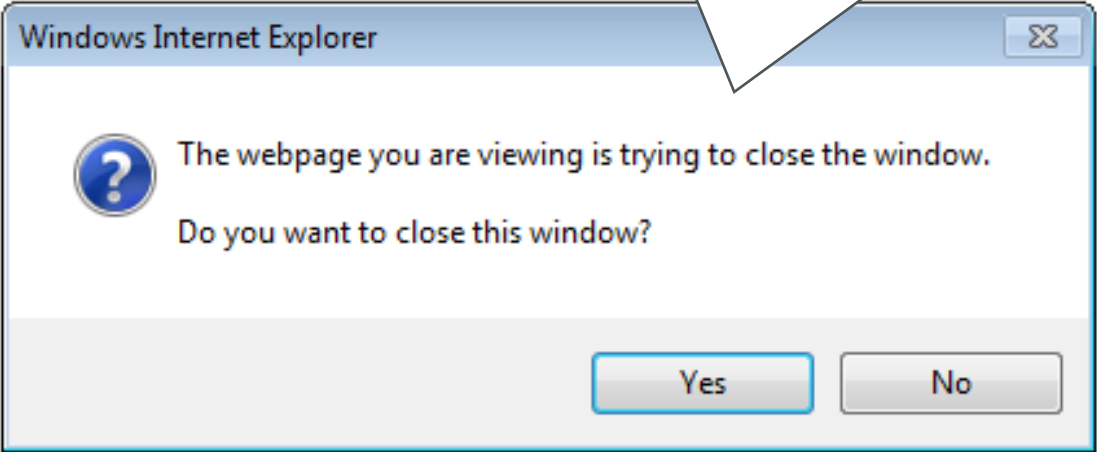
Yes

No

← →

Closing RAPIDS

Selecting "YES" will close your browser.



Site Emails

- You may receive emails for the following;
 - Welcome email (1st) giving you your username and tutorial guide to RAPIDS
 - Username email (2nd) giving you your password
 - Withdrawal email: If patient informs call center they no longer want to participate in the study.
 - You may also receive an email if patient contact information is incorrect. (The email will not contain any patient contact information.)

Time-Out

- A “time-out” will occur if you leave your computer idle before completing your entry.
 - If you should time-out and you have not completed your task, you may restart the process as long as you did not get to the confirmation page.
 - If you start entering a patient and timed out, when you go back into RAPIDS and enter the patient #, system will take you to where you left off.
 - If you should time-out after submitting patient information, do not try to enter the patient information again. If you need to change something for the Patient, select update a patient and proceed.

<https://web.rapidscrm.com/NOVELTYStudy>

OR email

NOVELTYQuestionnaireSupport@parexel.com

If You Forget Your Password

- Go to <https://web.rapidscrm.com/NOVELTYStudy>
- and type in username and then click HERE
 - Username will auto-populate
 - Enter response to security questions
 - Hit submit

Login

Username:

Password:

Forgot your password? Enter your username and click **HERE**



Login

Username:

Password:

Forgot your password? Enter your username and click HERE

Please answer the security questions to reset your password.

Question 1: Where did you spend your childhood summers?
Answer 1:

Question 2: What is your favorite car?
Answer 2:



Forget Your Password Cont.

- › Enter a new password – must have 8 characters
- › Confirm the password – type in new password again to confirm (same as above).
- › Please note your new password for future inquiries.







The image shows a screenshot of a web form titled "Login". The form contains three input fields: "Username:" with the text "TestPas" entered, "New Password:" which is empty, and "Confirm Password:" which is also empty. Below the input fields are two buttons: "Save Password" and "Clear". The form is set against a light gray background. At the bottom of the screenshot, there is a small, partially visible line of text: "site that is restricted to authorized use by PAREXEL International Corporation and their authorized agents. Use of this website or its contents is strictly prohibited by the Company. Unauthorized users and/or unau...".

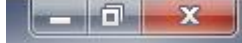
Frequently Asked Questions (FAQ's)

- ▶ Where do I get the Patient ID #
 - ▶ You will enter the subject in the RAVE system. The system will provide you with a patient #. Write the number down.
 - ▶ Use the Patient # provided from RAVE.
- ▶ Will I see error messages? Error messages will show if:
 - ▶ You try to register a patient that is already in the RAPIDS System
 - ▶ You try to un-register a patient that has already been un-registered in the RAPIDS System
 - ▶ If the patient ID is not recognized by RAPIDS
- ▶ Can I back-up in the system?
 - ▶ Yes. You may navigate back and forth in the system by using your next or previous   buttons.

FAQ's Cont.

- ▶ Corrections/errors – When can I fix them?
 - ▶ If you make an error while in the system, you may select the previous arrow , make the correction, then select the next arrow  and complete your entry.
 - ▶ If you register a patient and find an error, you may go back into RAPIDS, select update a subject, make change and complete the inquiry.
- ▶ How can I see what patients I have registered into RAPIDS?
 - ▶ Go into RAPIDS and select View Reports and next arrow. 
 - ▶ Click on Patient Status Report
- ▶ How can I see the where my patients are in the process?
 - ▶ Go to RAPIDS and select View reports and next arrow 
 - ▶ Click on Patient Inquiry Outcome Report

FAQ's Cont.

- Can I enter more than one subject at a time?
 - Yes. You may enter more than one subject at a time but you must say yes to the question “Do you want to process another request?”
 - Or if you accidentally say no, you may also restart the system at any time.
 - Or if you accidentally say yes to Do you want to process another request, and you don't have another request, use the red **x**  and exit RAPIDS.

- What if I leave the practice and someone replaces me or needs access to RAPIDS?
 - Accounts are provided for a single user. If a new account is needed for your site, please speak with your CRA or ORS about access.

FAQ's Cont.

- Will I keep my password for the entire study?
 - No. Every 90 days your password will expire and you will be required to enter new password. RAPIDS will advise you when you need to change your password. Please remember to use a security question you can remember when you initially set your password. You may also write it down for future reference.
- Will I keep my username for the entire study?
 - Yes.
- What if I get locked out of RAPIDS or forget my login information?
 - We ask you to use the “forgot your password?” function in the login screen first.
 - If no success, complete the form on the landing page:
<https://web.rapidscrm.com/NOVELTYStudy> and submit or send a detailed email to NOVELTYQuestionnaireSupport@parexel.com

Thank you

For any other assistance contact, go to
<https://web.rapidscrm.com/NOVELTYStudy>
and complete the form

Or send email to:
NOVELTYQuestionnaireSupport@parexel.com

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