# Study-Specific Content Guide for Study Teams

Epic provides a variety of study-specific tools to help study teams facilitate various research activities, including recruitment, electronic consenting, data capture, and more. This guide outlines the tools available, the benefits of utilising each tool, and additional considerations for implementing that tool for a specific study. This content is built for specific study needs, and using these tools effectively requires close collaboration between the SDPR team and study teams.

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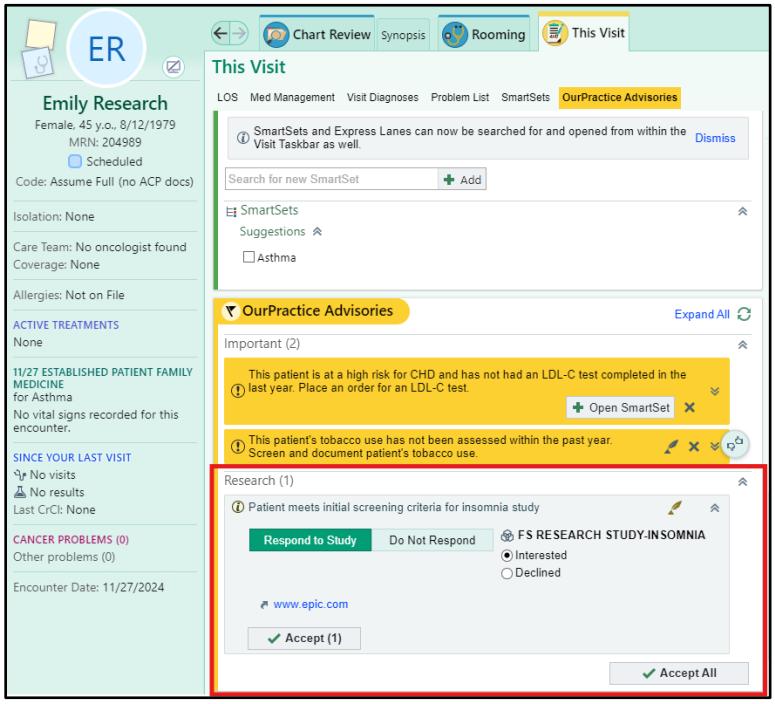
# Research Recruitment OurPractice Advisories

## Description

OurPractice Advisories (OPAs) is a decision support tool within SDPR, which can be customised to trigger and drive workflows based on clinical needs. For Research, Research Recruitment OurPractice Advisories (OPAs) can be used as an initial screening tool at the point of care. Recruitment advisories display basic study information in a patient's chart and prompt the clinician to ask whether the patient is interested in participating in that research study. When a clinician indicates the patient's response, the system automatically alerts study team members via In Basket and updates the patient's enrolment status if necessary.

Research recruitment advisories can be triggered by a variety of criteria such as reason for visit or chief diagnosis. If the patient meets the criteria for the study, the recruitment advisory appears alongside the patient's other OPAs.




## Use Considerations

Studies that have discrete criteria (e.g. patient demographics, problem list/diagnosis, medication history, pathology results, etc) or that encourage patients to talk with their care provider prior to involvement are good candidates for this tool. These alerts can be especially helpful when candidate identification and enrolment must happen quickly, such as stroke studies and other studies conducted in the ED. OPA criteria should be a good balance of specificity and broadness as to not necessarily include too many or too little potential candidates. OPA is not suitable for Oncology/Haematology

clinical trials as recruitment to oncology and haematology trials are usually based on referrals. As a recruitment tool, prior HREC approval for the use of OPA is required.

## Additional Features

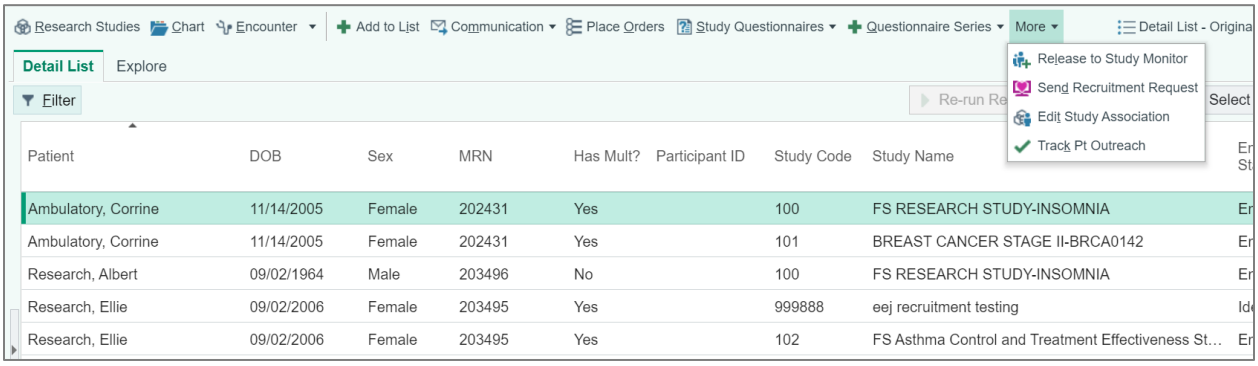
Study teams can include a description or a link to more information regarding the study to provide more context for clinicians.

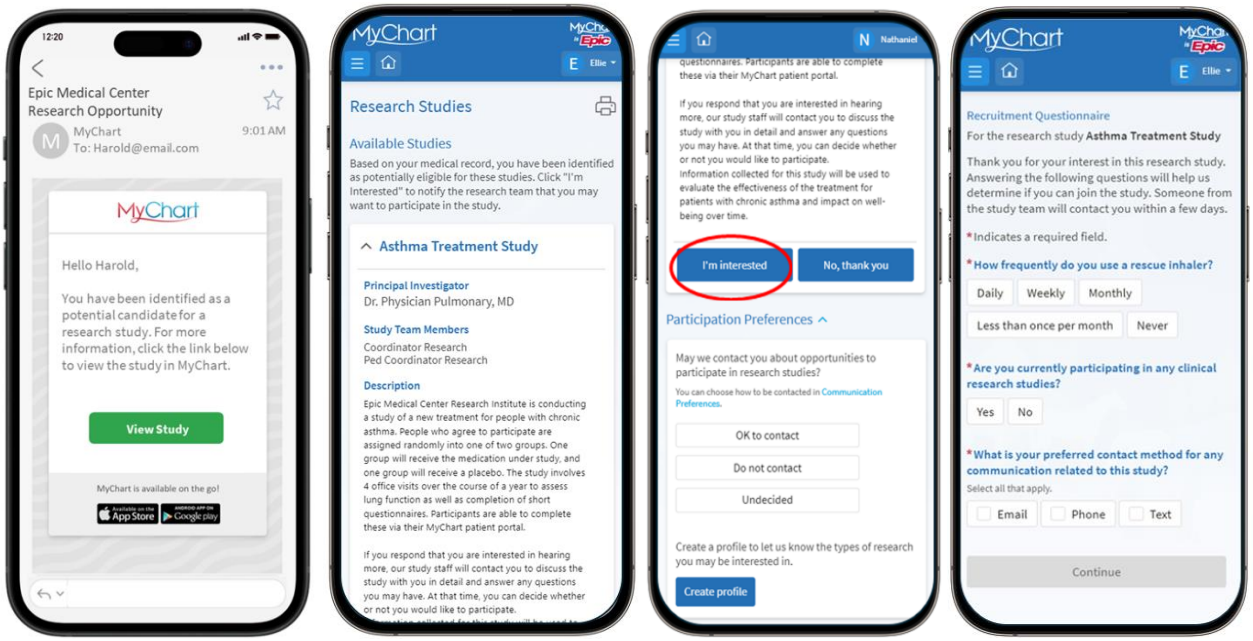
# Research Recruitment via MyNSWHealth

## Description

Research recruitment requests can be sent to a potentially eligible patient through MyNSWHealth. When a patient is sent a recruitment request, details about the study appear in the patient portal along with other studies the patient is or has been involved in. When the patient responds to the recruitment request, the response is then sent to the study team and the patient's enrolment status is also updated accordingly.

To use recruitment requests through MyNSWHealth, patient-facing information must be created and approved by the HREC prior, in line with the NHMRC *National Statement on Ethical Conduct in Human Research 2025*.



*The patient is notified and sees the research study on their MyNSWHealth home page. They can click View Study to see more information about the study and indicate interest. If they are interested, a recruitment questionnaire can help determine whether they qualify for enrolment.*

## Use Considerations

Studies that may struggle to recruit a diverse patient population using traditional recruitment methods might consider using MyNSWHealth. This process could simplify outreach to potential participants and save time for studies that do mass outreach for recruitment. For Tranche A – MyNSWHealth is only being provisioned for antenatal patients. As a recruitment tool, a HREC approval for the use of Recruitment via MyNSWHealth is required.

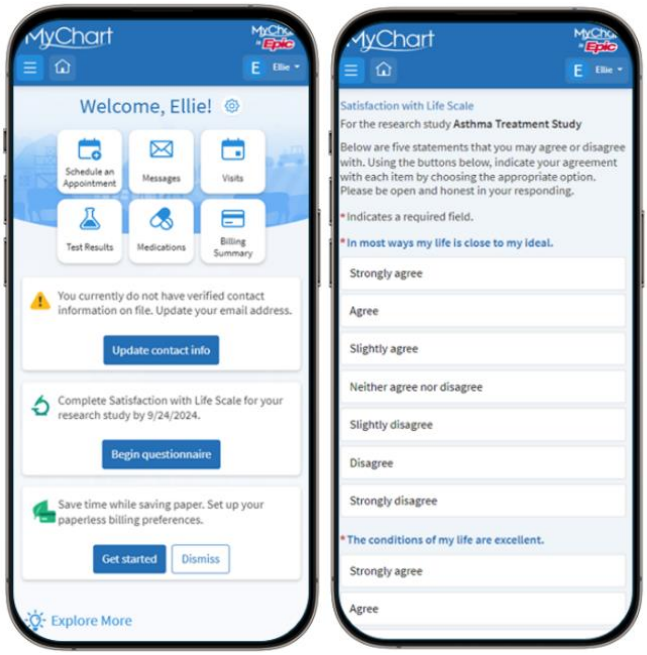
## Additional Features

You can run reports from Reporting Workbench or use SlicerDicer to select the patient population that might meet study criteria and send study recruitment messages en masse to all selected patients.

# Patient Research Recruitment Questionnaires

## Description

Patient research recruitment questionnaires can be leveraged in conjunction with MyNSWHealth recruitment to streamline the study candidate identification and screening process. Once a patient is in a particular enrolment status, such as 'Interested,' a questionnaire with more detailed screening questions can be automatically assigned to the patient. This questionnaire can be completed via the patient portal, or within SDPR directly during a visit. The study team can see the questionnaire responses in Hyperspace in the participant's Research Studies activity.




## Use Considerations

This tool is best suited for studies that require additional screening questions to be assessed during the recruitment process. For Tranche A – MyNSWHealth is only being provisioned for antenatal patients. As a recruitment tool, HREC approval for the use of Recruitment Questionnaire is required prior to recruitment proceeding.

## Additional Features

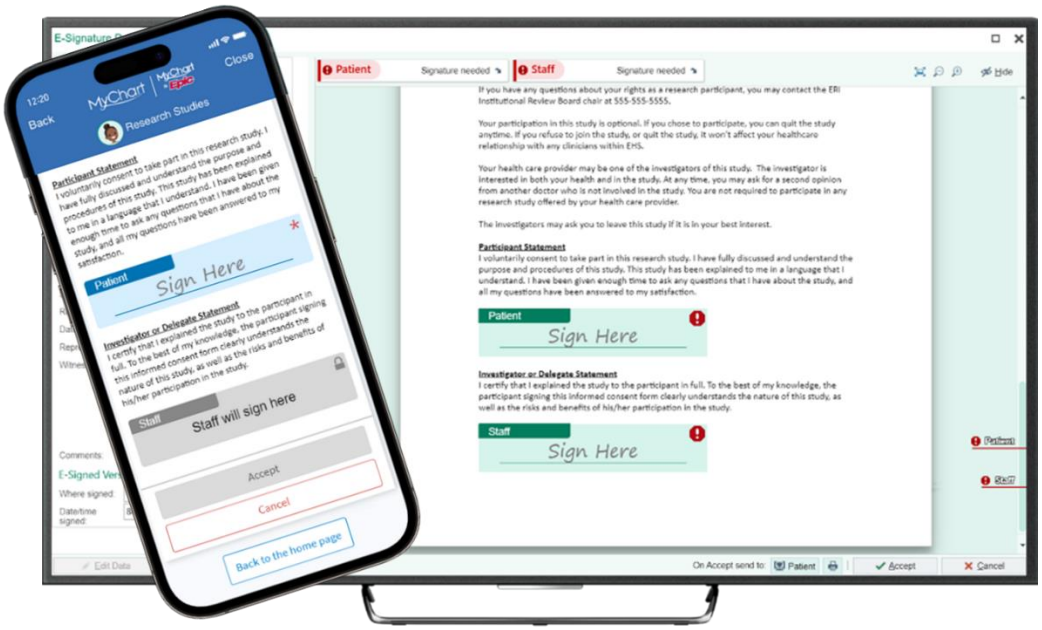
Studies that utilise pre-existing questionnaires (such as a PHQ-9) do not need to pilot this feature—this feature is for questionnaires specific to an individual study.

# E-Consents

*This tool is currently not in scope for Tranche A; this guide is provided for awareness ahead of its future implementation.*

## Description

Research study users can electronically add consent forms to confirm that a patient has consented to participate in a particular research study. These consent forms can then be automatically linked to a study. Electronic consents can be captured in SDPR directly, using tablets, or E-Signature pads, or within the patient portal, enabling patients to give consent in the office or at home.




*Consent forms can be signed using MyNSWHealth (left) or SDPR (right).*

## Use Considerations

Studies with more basic consent forms are preferred candidates to pilot this feature. If a study is expecting a high volume of amendments, this feature requires more updates and maintenance. There are legal and regulatory requirements on e-signature devices, please consider whether study team will have access to appropriate devices.

## Additional Benefits

If e-consents are amended, study teams can use a Reporting Workbench report to find all patients needing reconsent and assign a task to their next visit to have the study team acquire the new

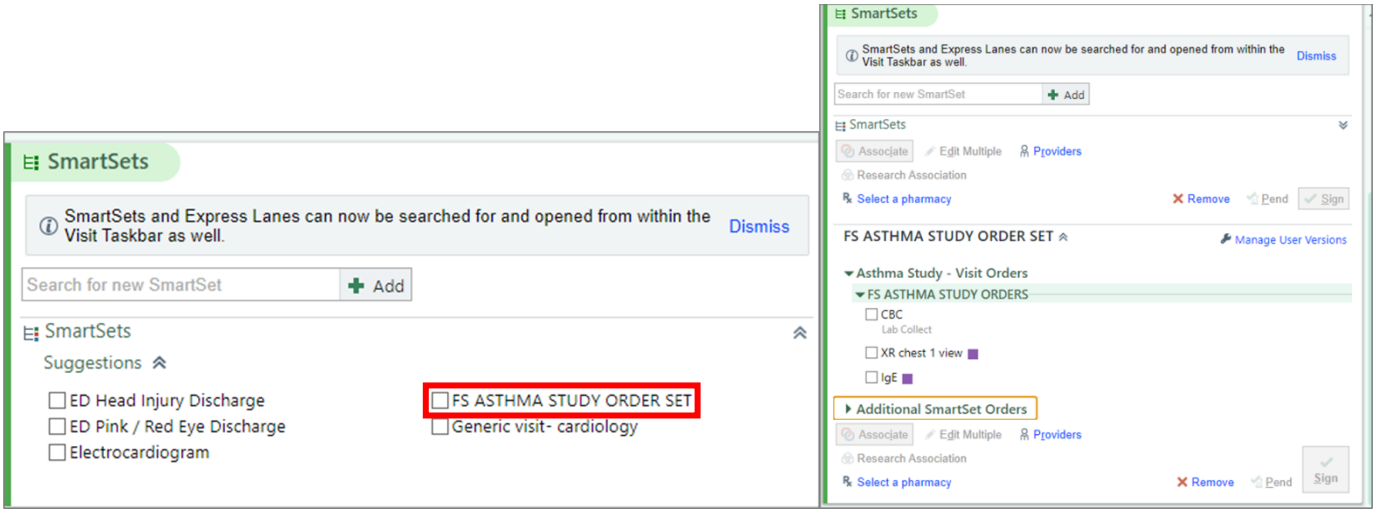
consent. Consent forms can also be tailored by changing the language for certain studies or patients, and the language is determined based on the patient's primary language.

# Research Ordering Tools (SmartSets and Order Sets)

## Description

SmartSets and Order Sets are ordering tools that can make finding and executing orders more convenient. These are created and maintained by the SDPR team grouping orders, notes, and diagnosis codes together. Orders placed through this tool for research participants are automatically linked to the research study, simplifying accurate identification of research-related orders.

SmartSets and Order Sets function similarly, but SmartSets are configured for outpatient settings while Order Sets are built for hospital settings.




*Linked Sets are suggested to the provider for research participants.*

## Use Considerations

High-enrolling studies with well-established clinical guidelines or protocols to design the ordering tool will benefit the most from this tool.

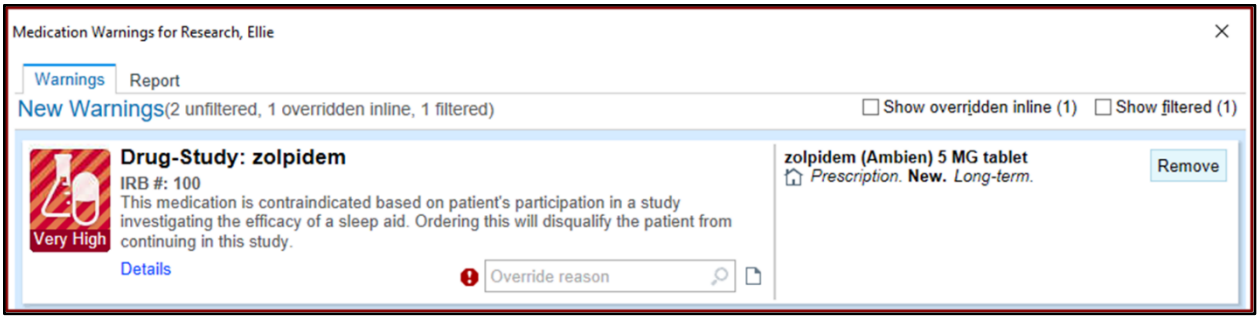
## Additional Features

You can create multiple ordering tools and restrict them to certain users for individual studies to limit use to correct combination of patient, study, and clinician.

# Contraindicated Medications

## Description

When a patient is enrolled in a research study, you can warn clinicians when the patient is at risk of taking a medication that might jeopardise their participation in the study. It is important that all ordering users are notified if a medication they prescribe to a study participant may harm them, disqualify them from a clinical trial, cause an interaction with an investigational medication, or risk compromising an investigational medication's effectiveness. You can configure a contraindicated medication warning to appear to ordering users in SDPR for specific research studies.




*Clinicians are warned that the medication is contraindicated to the study and that they must provide an override reason if they want to proceed with the order.*

## Use Considerations

Studies are a good fit for this tool if there are designated medications that would put the patient's safety at risk or put them at risk of being disqualified from the study. Studies that have contraindicated medications for a period of time aside from the duration of the study (e.g., if a medication is contraindicated for a study X days after a patient is enrolled), or studies for which the restriction is only for certain dose levels, might not be a good fit.

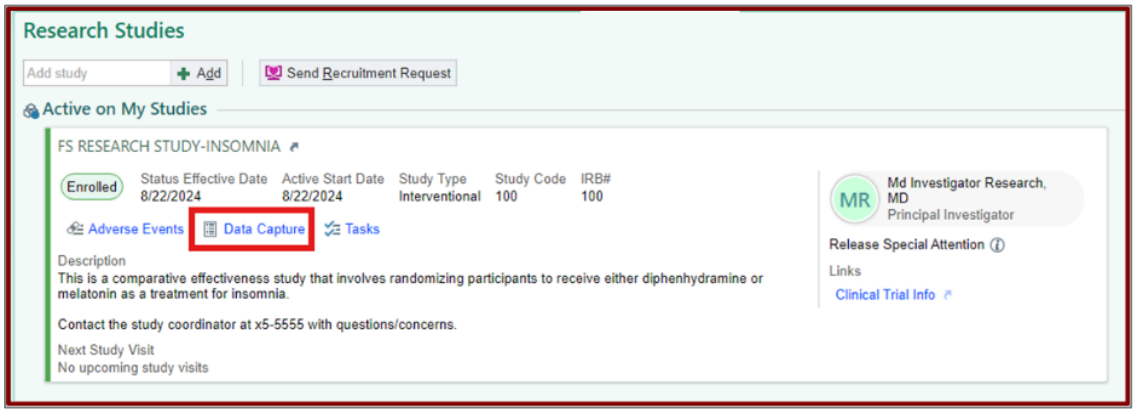
## Additional Features

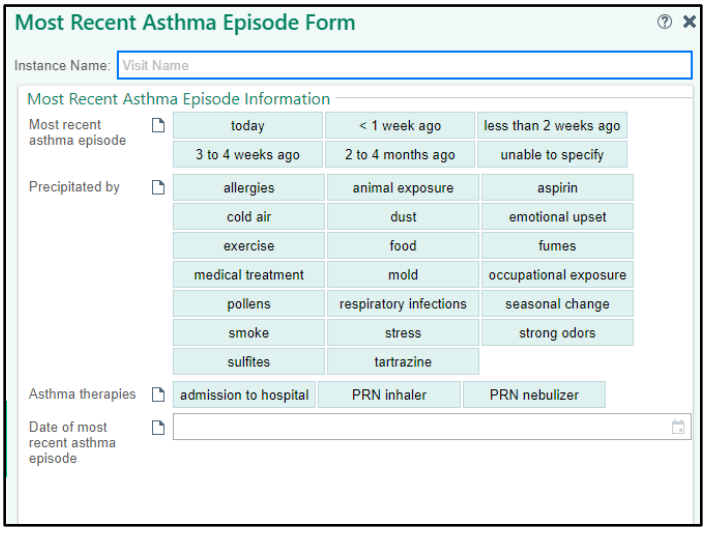
Occasionally, research users need to find all study patients who are taking contraindicated medication. For example, if research users add a new contraindicated medication to a study or a patient was taking a contraindicated medication before joining the study, they might want to follow up with study patients who are already taking the medication. Study teams can run reports in SDPR to identify and follow up with these patients.

# SmartForms for Research Data Capture

## Description

The Research Data Capture activity allows for standardised, discrete documentation in Epic. Data capture forms can be linked to the study so that study users can view all forms that have been completed or are in progress in the Data Capture activity.




*Research Data Capture Forms are linked to the study and can be accessed by study staff.*

## Use Considerations

Studies that currently use physical documents for data collection and could benefit from collecting and storing data electronically in SDPR are a good fit for this tool. Studies with regular set of assessment questions are a good fit for this tool.

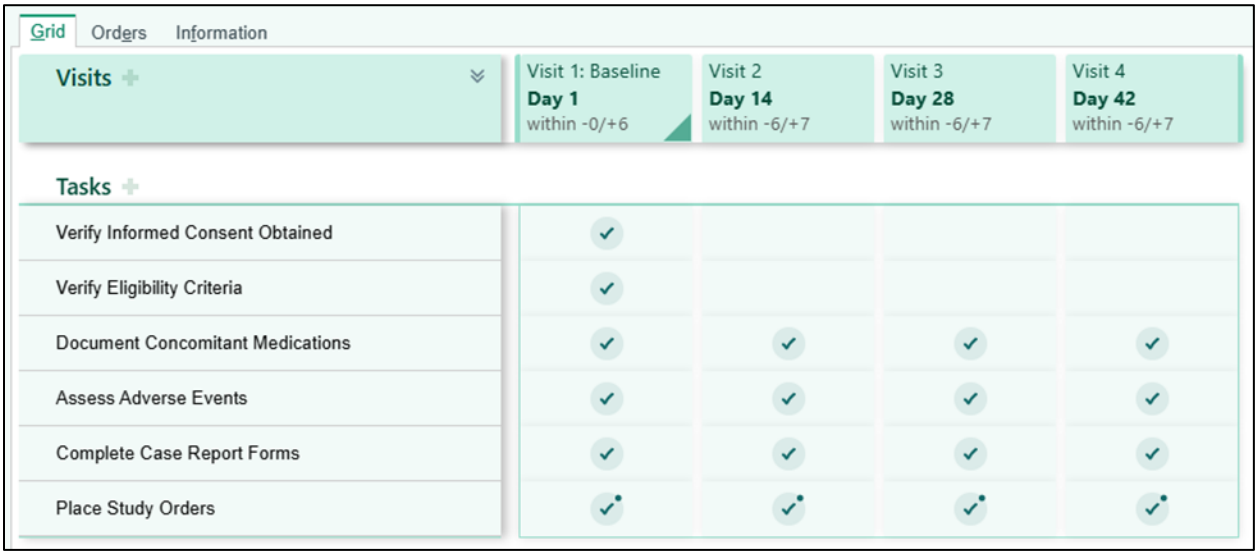
## Additional Benefits

Research Data Capture collects discrete data so that your team can run reports from the forms and access those reports from the reporting dashboard.

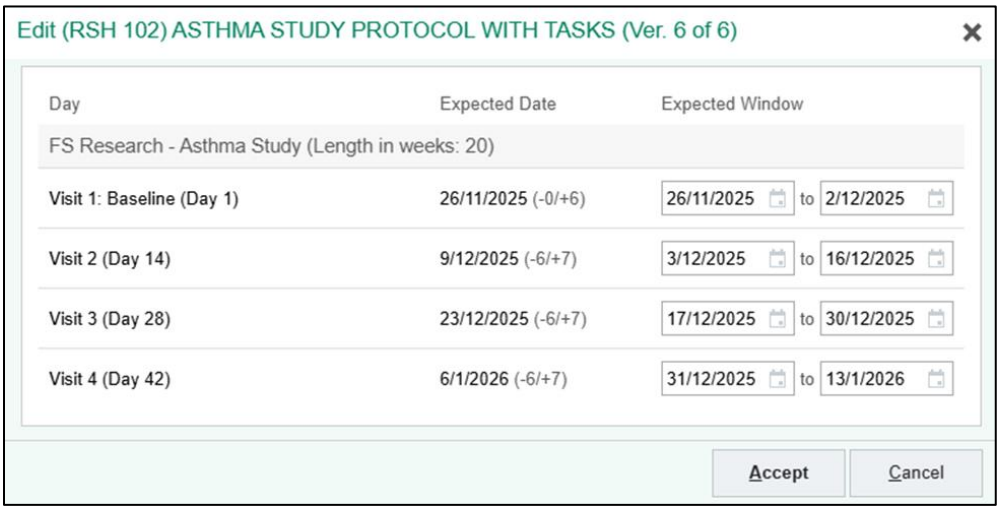
# Research Schedule of Activities with Tasks

## Description

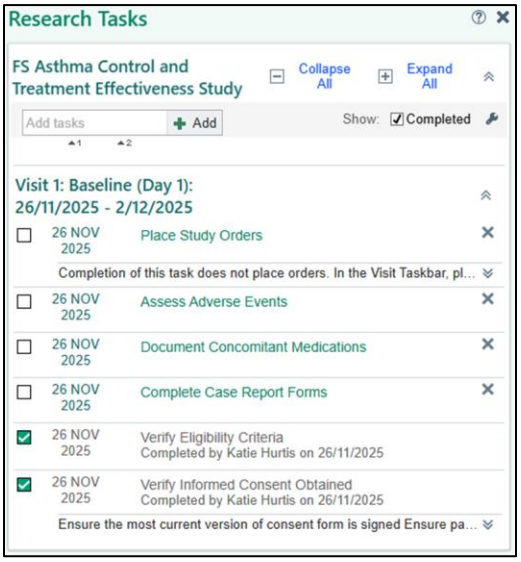
Research tasks remind study teams of the tasks they need to complete for patients participating in a research study. When a member of the study team completes a task, such as obtaining the patient's consent document or completing case report forms, they should check off the task to track that it has been done. By including tasks in a study-level schedule of activities and using this to create a patient-specific schedule for each participant, study teams are automatically reminded to complete the appropriate tasks during the designated visit.




*Assigned visit tasks are indicated within specific study visits*




*One a timeline is applied to a patient, and the first expected visit is indicated, dates for expected future visits are automatically defined based on the schedule of activities.*




*Tasks that need to be completed during this visit are based on the tasks defined in the schedule of activities.*

## Use Considerations

Research studies with multiple study visits and a moderate list of tasks to complete per visit will be good candidates to pilot this feature. Epic strongly recommends piloting with study teams capable of reliably applying and maintaining timelines for all participants.

## Additional Features

Separate schedules of activities can be applied to different branches or arms of a study if the tasks to be performed should differ between them.

Study teams can use out-of-the box reports to monitor tasks that have an upcoming due date or are overdue.