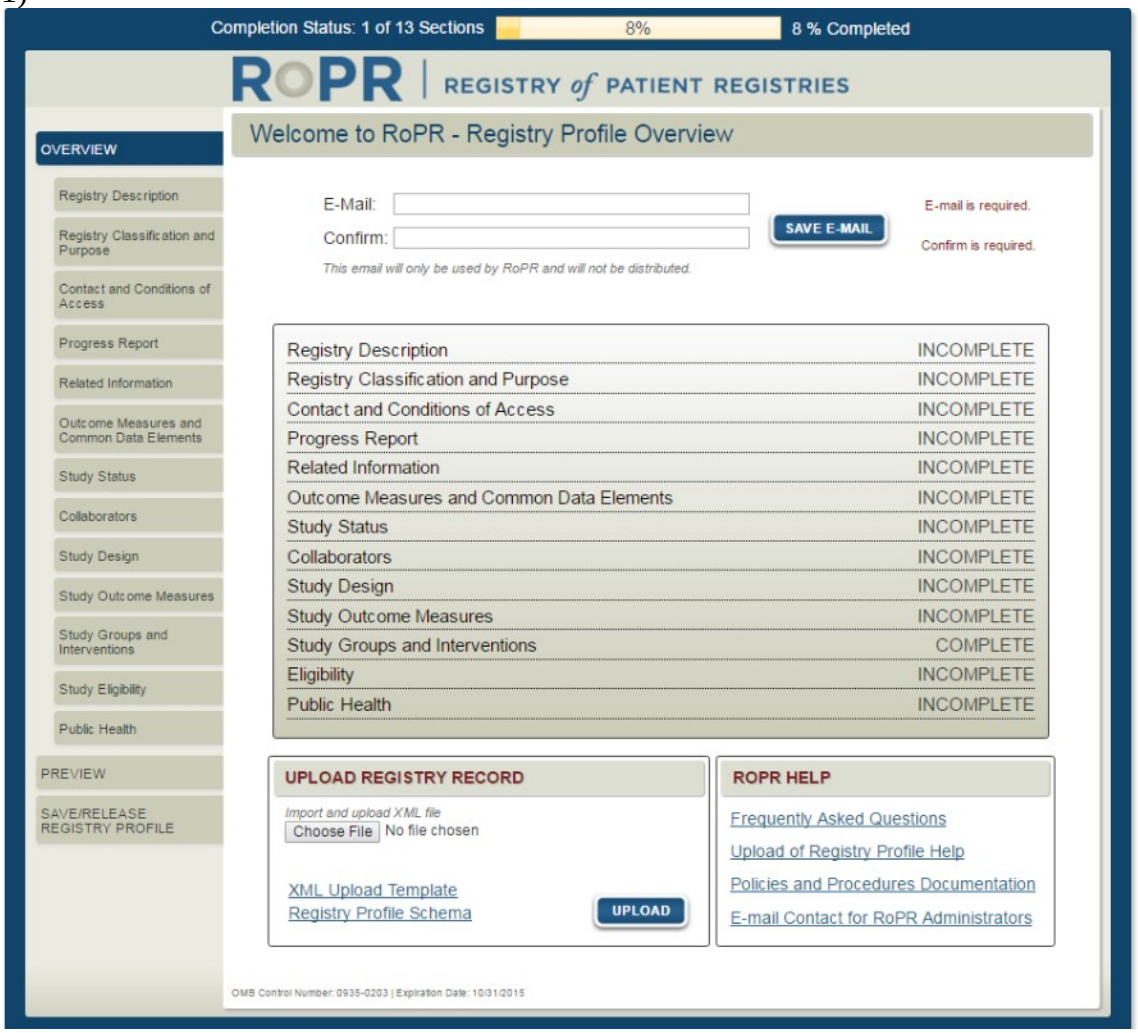
Form Approved
OMB No. 0935-XXXX
Exp. Date XX/XX/20XX

Attachment B: Questionnaires/Data Collection Instruments

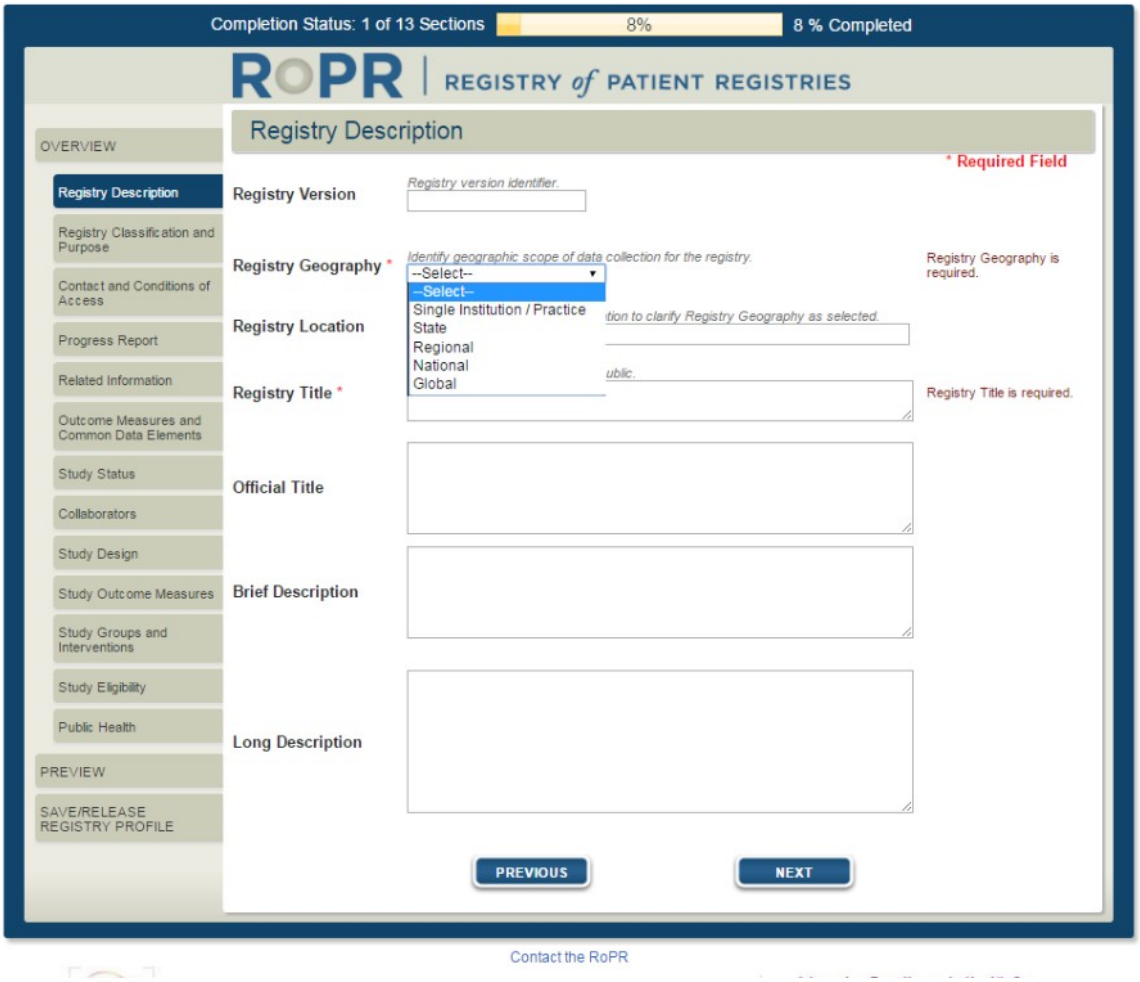
The RoPR data collection system is a web-based collection mechanism. The screenshots included in this document represent all sections that will be visible to users who enter information through the self-registration pathway. The online form has 20 sections.

Users who enter information through the ClinicalTrials.gov pathway (which already received OMB approval) will only see sections 1-8 and 20.

1)



2)


Completion Status: 1 of 13 Sections
8%
8 % Completed
RoPR | REGISTRY of PATIENT REGISTRIES
OVERVIEW
Registry Description
Registry Classification and Purpose
Contact and Conditions of Access
Progress Report
Related Information
Outcome Measures and Common Data Elements
Study Status
Collaborators
Study Design
Study Outcome Measures
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Study Eligibility
Public Health
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Registry Description
* Required Field
Registry Version
Registry version identifier.
Registry Geography *
Identify geographic scope of data collection for the registry.
--Select--
--Select--
Single Institution / Practice
State
Regional
National
Global
Registry Geography is required.
Registry Location
Registry Title *
Registry Title is required.
Official Title
Brief Description
Long Description
PREVIOUS
NEXT
Contact the RoPR

3a)


Completion Status: 1 of 13 Sections
8%
8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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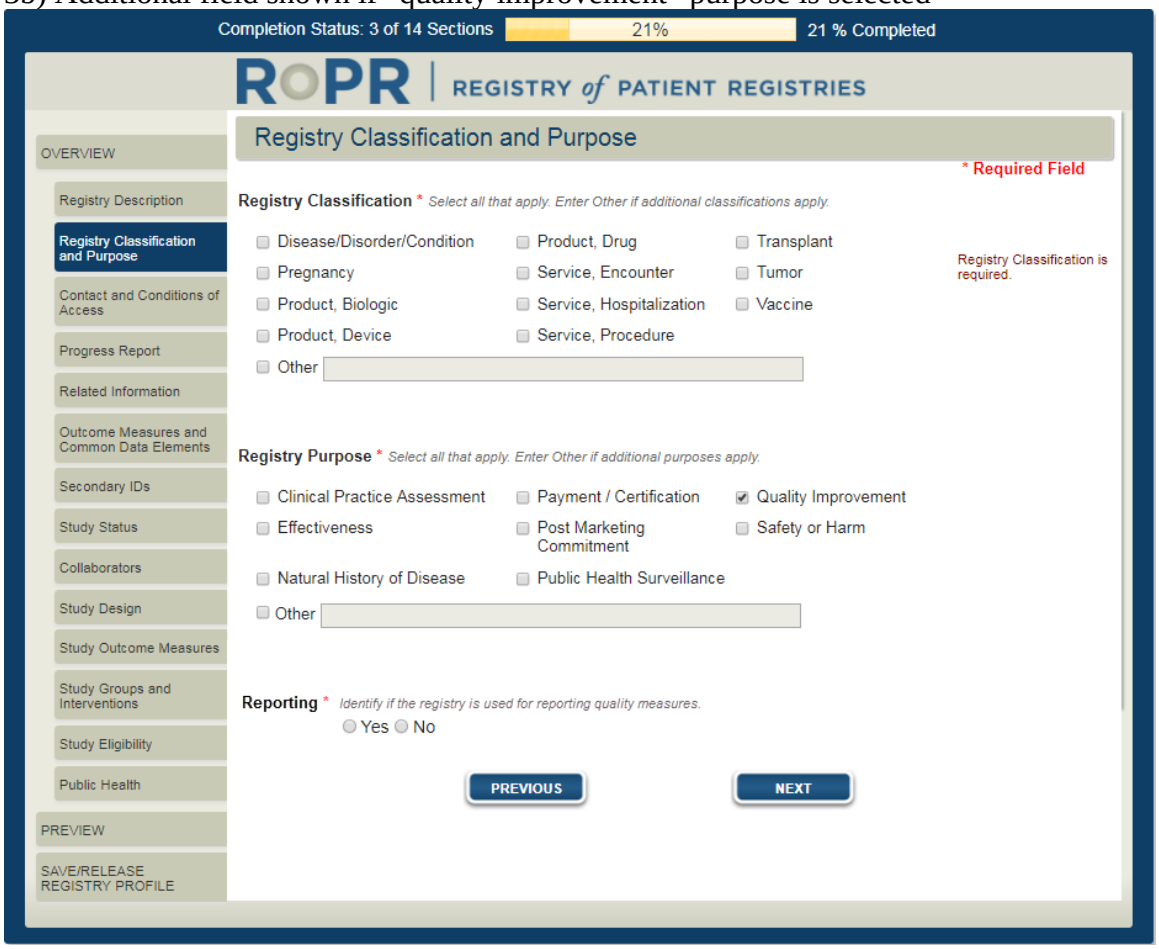
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Registry Classification and Purpose
* Required Field
Registry Classification * Select all that apply. Enter Other if additional classifications apply.
Disease/Disorder/Condition
Product, Drug
Transplant
Pregnancy
Service, Encounter
Tumor
Product, Biologic
Service, Hospitalization
Vaccine
Product, Device
Service, Procedure
Other
Registry Classification is required.
Registry Purpose * Select all that apply. Enter Other if additional purposes apply.
Clinical Practice Assessment
Payment / Certification
Quality Improvement
Effectiveness
Post Marketing Commitment
Safety or Harm
Natural History of Disease
Public Health Surveillance
Other
Registry Purpose is required.
PREVIOUS
NEXT

3b) Additional field shown if “quality improvement” purpose is selected



4)


Completion Status: 1 of 13 Sections
8%
8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
OVERVIEW
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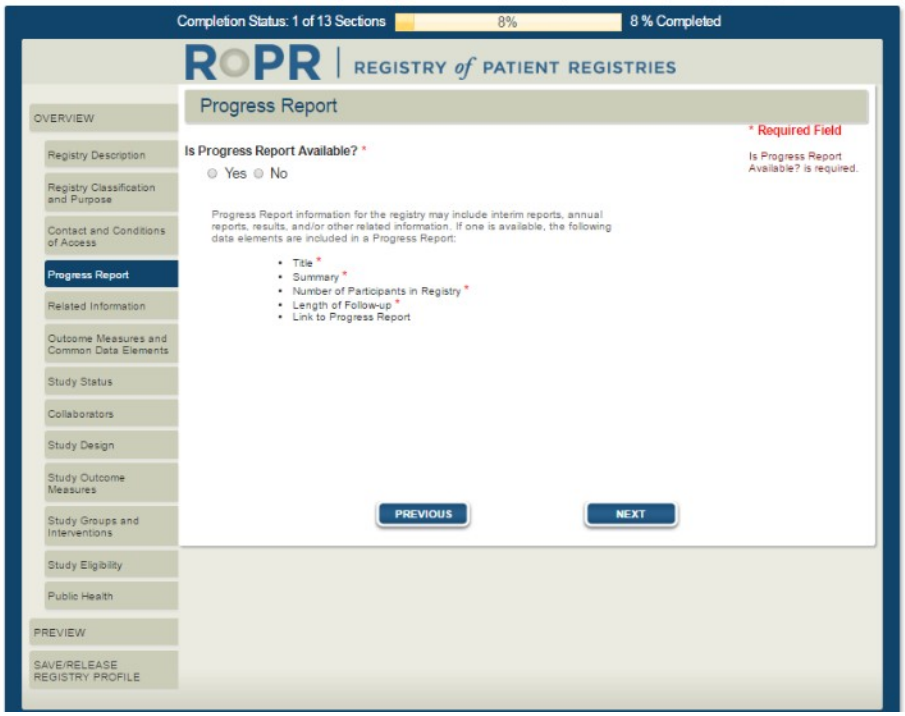
SAVE/RELEASE REGISTRY PROFILE
Contact and Conditions of Access
* Required Field
Interest in Being Contacted? is required.
Interest in Being Contacted? *
Identify if the sponsor is interested in being contacted for reasons listed below.
Yes No
Reasons for Being Contacted
Identify sponsor's reasons for being contacted. Enter Other if additional reasons apply.
Collaboration
Participation - Investigator
Data Access
Participation - Participant
More Information
Other
Organization
The primary contact organization.
First Name
The primary contact individual's first name.
Last Name
The primary contact individual's last name.
Title
The primary contact individual's title.
E-Mail
The primary contact email.
It is recommended that this e-mail be a department or distribution list so that if the contact person leaves the organization, the e-mail will still be delivered to a person within the department that can respond to the inquiry.
Phone
The primary contact phone number.
Ext.
Link to Organization or Registry Site
A link to the the organization or registry's Web site (including http:// or https://).
Link to Conditions of Access
A link to a Web site or document describing conditions of access required by sponsor (including http:// or https://).
Has Data Monitoring?
Yes No
PREVIOUS
NEXT

5)


Completion Status: 1 of 13 Sections
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8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Progress Report
* Required Field
Is Progress Report Available? *
Yes No
Is Progress Report Available? is required.
Progress Report information for the registry may include interim reports, annual reports, results, and/or other related information. If one is available, the following data elements are included in a Progress Report:
Title *
Summary *
Number of Participants in Registry *
Length of Follow-up *
Link to Progress Report
PREVIOUS
NEXT


Completion Status: 1 of 13 Sections
8%
8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Progress Report
* Required Field
Is Progress Report Available? *
Yes No
You must add at least one Progress Report.
ADD PROGRESS REPORT
New Progress Report
Title *
Title of the Progress Report.
Title is required.
Summary of all relevant progress report information. May include summary of interim reports, annual reports, and/or other related registry progress reports.
Summary *
Summary is required.
Number of Participants in Registry *
Progress data identifying the current number of participants in the registry.
Actual
Number of Participants in Registry is required.
Length of Follow-up *
Progress data identifying the length of follow-up data in years, as currently available within the registry.
Actual
Length of Follow-up is required.
Link to Progress Report
A link to the progress report (including http:// or https://).
SAVE
CANCEL
PREVIOUS
NEXT

6)


Completion Status: 1 of 13 Sections
8%
8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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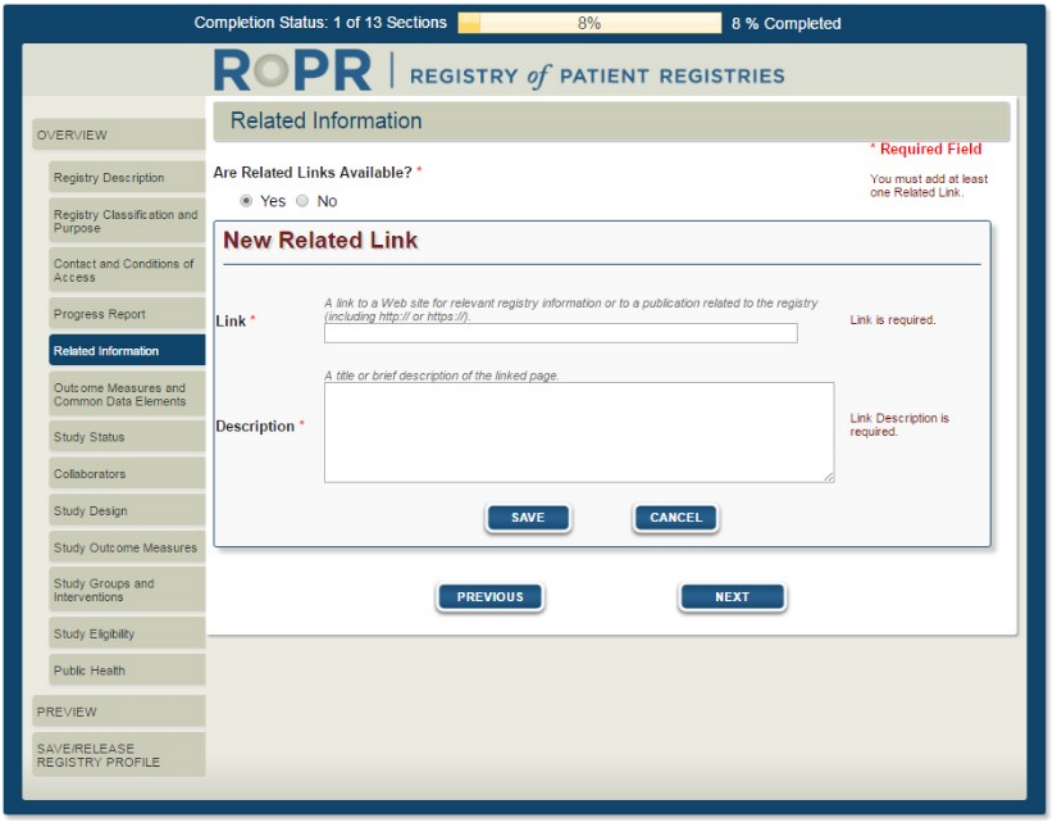
SAVE/RELEASE REGISTRY PROFILE
Related Information
* Required Field
Are Related Links Available? *
Yes No
Are Related Links Available? is required.
Indicate if references to other relevant information are available for this registry. If they are available, the following data elements are included for a Related Link:
Link *
Description *
PREVIEW
NEXT


Completion Status: 1 of 13 Sections
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8 % Completed
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SAVE/RELEASE REGISTRY PROFILE
Related Information
* Required Field
Are Related Links Available? *
Yes No
You must add at least one Related Link.
New Related Link
Link *
A link to a Web site for relevant registry information or to a publication related to the registry (including http:// or https://).
Link is required.
Description *
A title or brief description of the linked page.
Link Description is required.
SAVE
CANCEL
PREVIEW
NEXT

7)


Completion Status: 1 of 13 Sections
8%
8 % Completed
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SAVE/RELEASE REGISTRY PROFILE
Condition or Service of Interest for Registry
Condition
Category
Outcome Measures and Common Data Elements - Condition or Service of Interest *
* Required Field
Primary disease, condition or service being studied. Use the National Library of Medicine's Medical Subject Headings (MeSH). Select all that apply. Enter Other if additional Conditions apply.
Bacterial and Fungal Diseases
Behaviors and Mental Disorders
Blood and Lymph Conditions
Cancers and other Neoplasms
Digestive System Diseases
Diseases or Abnormalities at or before Birth
Ear, Nose, and Throat Diseases
Eye Diseases
Gland and Hormone Related Diseases
Heart and Blood Diseases
Immune System Diseases
Mouth and Tooth Diseases
Muscle, Bone, and Cartilage Diseases
Nervous System Diseases
Nutritional and Metabolic Diseases
Occupational Diseases
Parasitic Diseases
Respiratory Tract (Lung and Bronchial) Diseases
Skin and Connective Tissue Diseases
Substance Related Disorders
Symptoms and General Pathology
Urinary Tract, Sexual Organs, and Pregnancy Conditions
Viral Diseases
Wounds and Injuries
Other
At least one Condition is required.
PREVIOUS
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8)


Completion Status: 1 of 13 Sections
8%
8 % Completed
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Category of Interest for Registry
Condition
Category
Outcome Measures and Common Data Elements - Categories *
Select all that apply. Enter Other if additional Categories apply.
* Required Field
Clinical Assessments
Demographics
Devices
Diagnosis
Disease Response
Events of Interest
Genetic Information
Medications
Other
Patient Reported Outcomes
Procedures
Risk Factors
Staging Systems
Survival Outcomes
Treatments
Vitals
At least one Category is required.
PREVIOUS
NEXT

9)


Completion Status: 1 of 13 Sections
8%
8 % Completed
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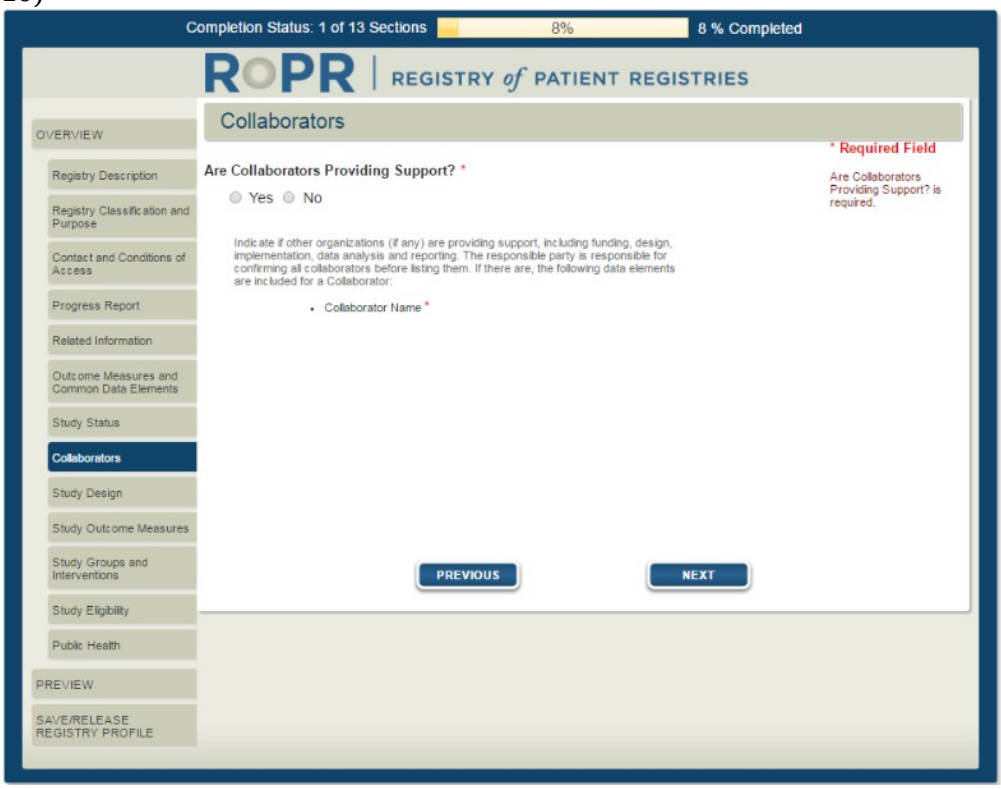
Study Status
* Required Field
Record Verification Date*
The date on which the responsible party last verified the clinical study information in the entire RoPR record for the clinical study, even if no additional or updated information is being submitted.
--Select-- Year 2017
A Verification Date Must be provided
Overall Recruitment Status*
The recruitment status for the clinical study as a whole, based upon the status of the individual sites.
--Select--
A Recuitment Status must be selected
Study Start Date
The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.
--Select-- Year
Continuous Enrollment
Yes No
Primary Completion Date
The date on which data collection is completed for all of the primary outcomes.
--Select-- Year Type --Select--
Study Completion Date
The date on which data collection is completed for all of the primary and secondary outcomes.
--Select-- Year Type --Select--
PREVIOUS
NEXT

10)


Completion Status: 1 of 13 Sections
8%
8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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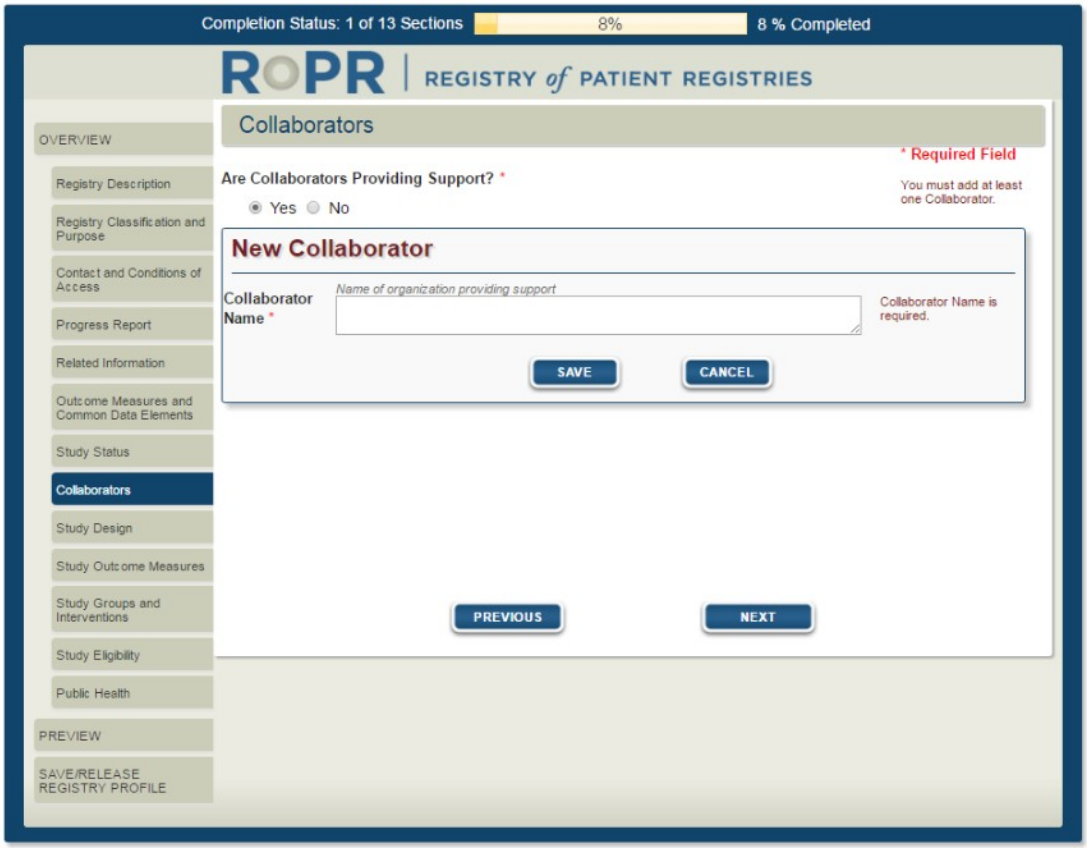
Collaborators
* Required Field
Are Collaborators Providing Support? *
Yes No
Are Collaborators Providing Support? is required.
Indicate if other organizations (if any) are providing support, including funding, design, implementation, data analysis and reporting. The responsible party is responsible for confirming all collaborators before listing them. If there are, the following data elements are included for a Collaborator:
Collaborator Name *
PREVIOUS
NEXT


Completion Status: 1 of 13 Sections
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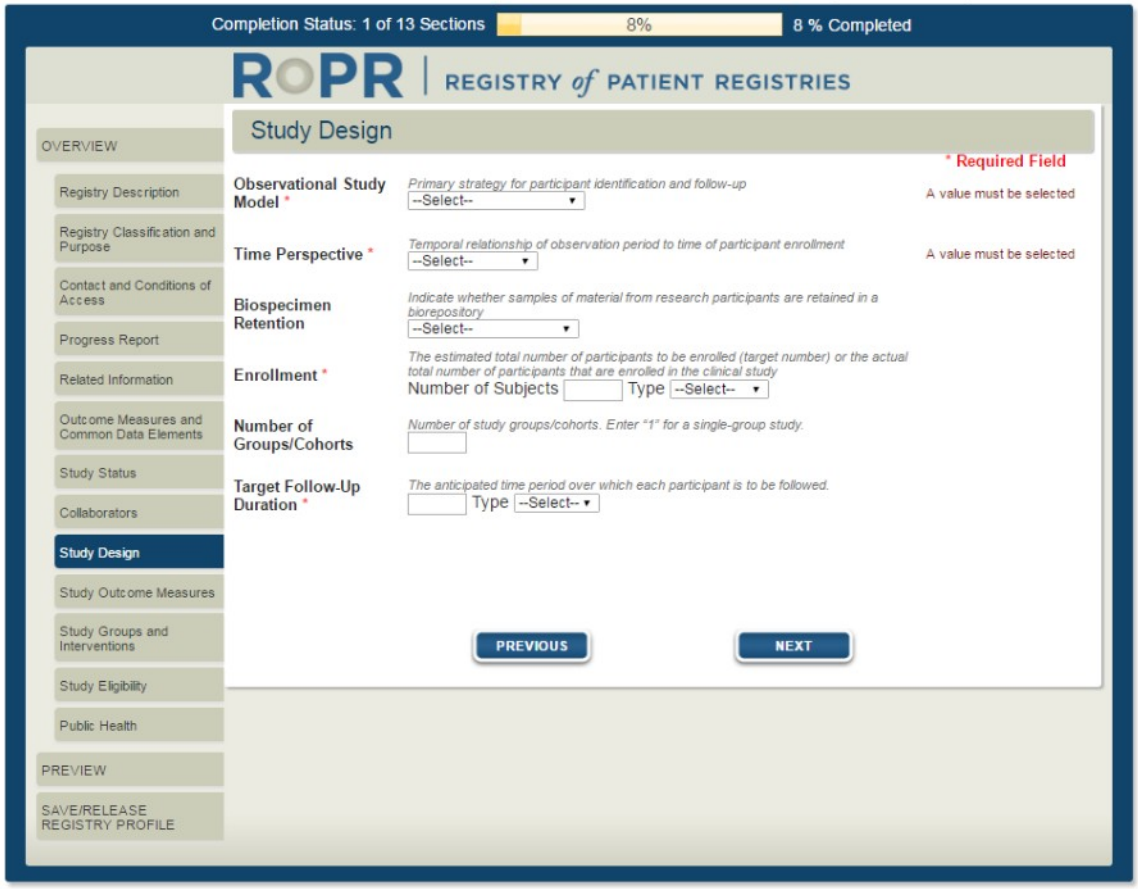
Collaborators
* Required Field
Are Collaborators Providing Support? *
Yes No
You must add at least one Collaborator.
New Collaborator
Collaborator Name *
Name of organization providing support
Collaborator Name is required.
SAVE
CANCEL
PREVIOUS
NEXT

11)


Completion Status: 1 of 13 Sections
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8 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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SAVE/RELEASE REGISTRY PROFILE
Study Design
* Required Field
Observational Study Model *
Primary strategy for participant identification and follow-up
--Select--
A value must be selected
Time Perspective *
Temporal relationship of observation period to time of participant enrollment
--Select--
A value must be selected
Biospecimen Retention
Indicate whether samples of material from research participants are retained in a biorepository
--Select--
Enrollment *
The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study
Number of Subjects
Type
--Select--
Number of Groups/Cohorts
Number of study groups/cohorts. Enter "1" for a single-group study.
Target Follow-Up Duration *
The anticipated time period over which each participant is to be followed.
Type
--Select--
PREVIOUS
NEXT

12)


Completion Status: 1 of 13 Sections
8%
8 % Completed
RoPR | REGISTRY of PATIENT REGISTRIES
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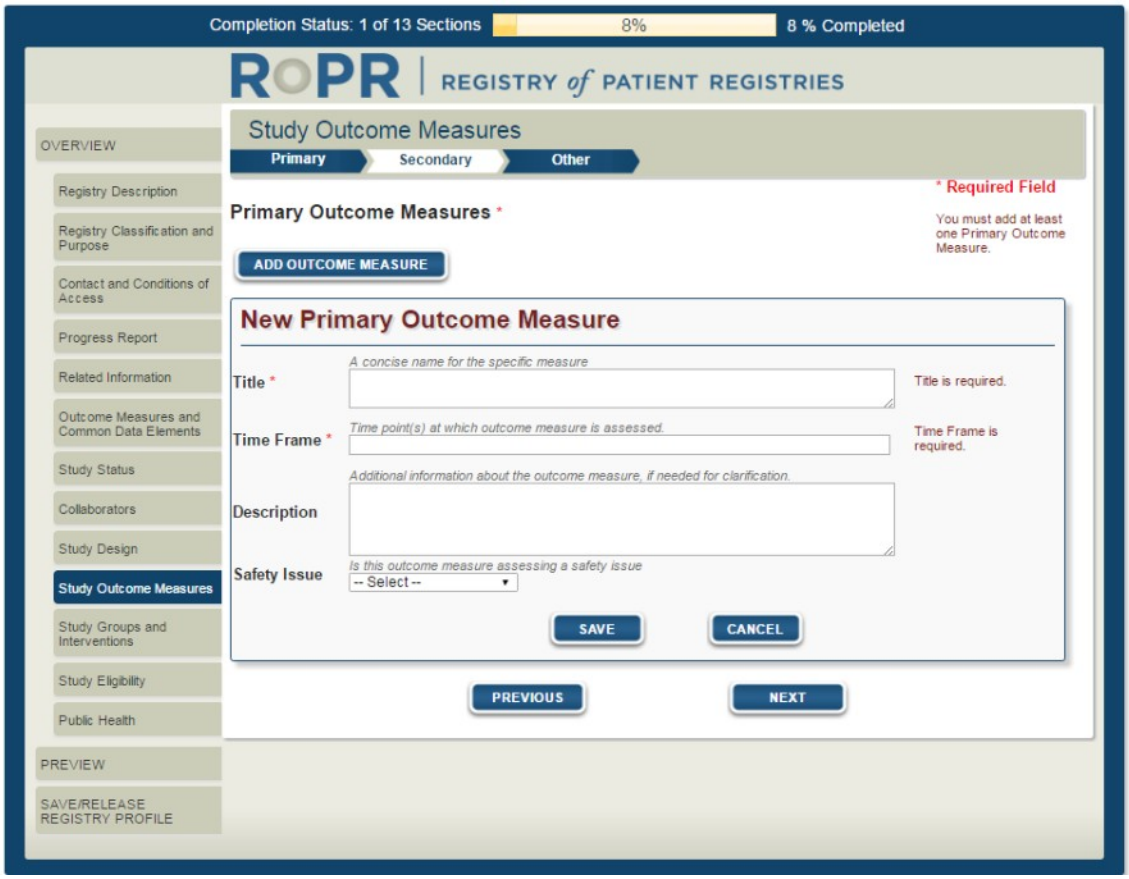
Study Outcome Measures
Primary
Secondary
Other
* Required Field
Primary Outcome Measures *
You must add at least one Primary Outcome Measure.
ADD OUTCOME MEASURE
PREVIOUS
NEXT


Completion Status: 1 of 13 Sections
8%
8 % Completed
RoPR | REGISTRY of PATIENT REGISTRIES
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Study Outcome Measures
Primary
Secondary
Other
* Required Field
Primary Outcome Measures *
You must add at least one Primary Outcome Measure.
ADD OUTCOME MEASURE
New Primary Outcome Measure
Title *
A concise name for the specific measure
Title is required.
Time Frame *
Time point(s) at which outcome measure is assessed.
Time Frame is required.
Description
Additional information about the outcome measure, if needed for clarification.
Safety Issue
Is this outcome measure assessing a safety issue
-- Select --
SAVE
CANCEL
PREVIOUS
NEXT

13)


Completion Status: 2 of 13 Sections
15%
15 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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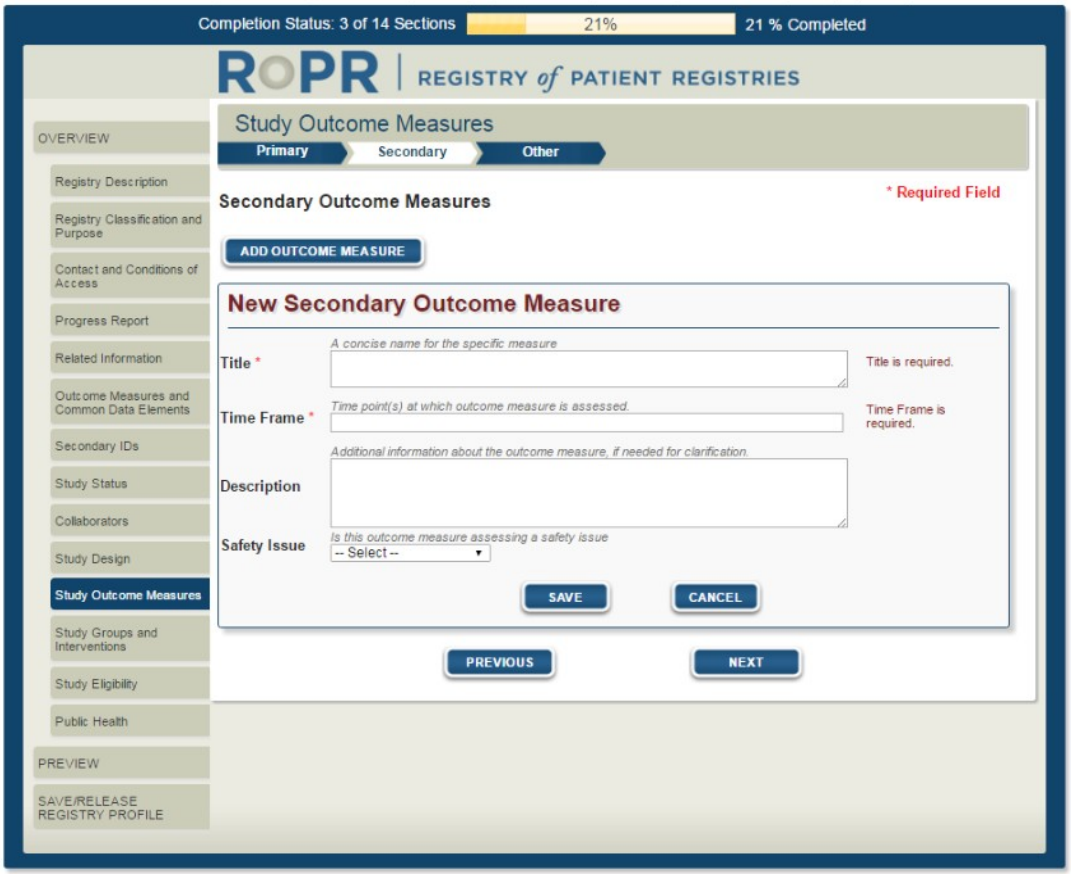
Primary
Secondary
Other
Secondary Outcome Measures
* Required Field
ADD OUTCOME MEASURE
PREVIOUS
NEXT


Completion Status: 3 of 14 Sections
21%
21 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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Study Outcome Measures
Primary
Secondary
Other
Secondary Outcome Measures
* Required Field
ADD OUTCOME MEASURE
New Secondary Outcome Measure
A concise name for the specific measure
Title *
Title is required.
Time point(s) at which outcome measure is assessed.
Time Frame *
Time Frame is required.
Additional information about the outcome measure, if needed for clarification.
Description
Is this outcome measure assessing a safety issue
Safety Issue
-- Select --
SAVE
CANCEL
PREVIOUS
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14)


Completion Status: 2 of 13 Sections
15%
15 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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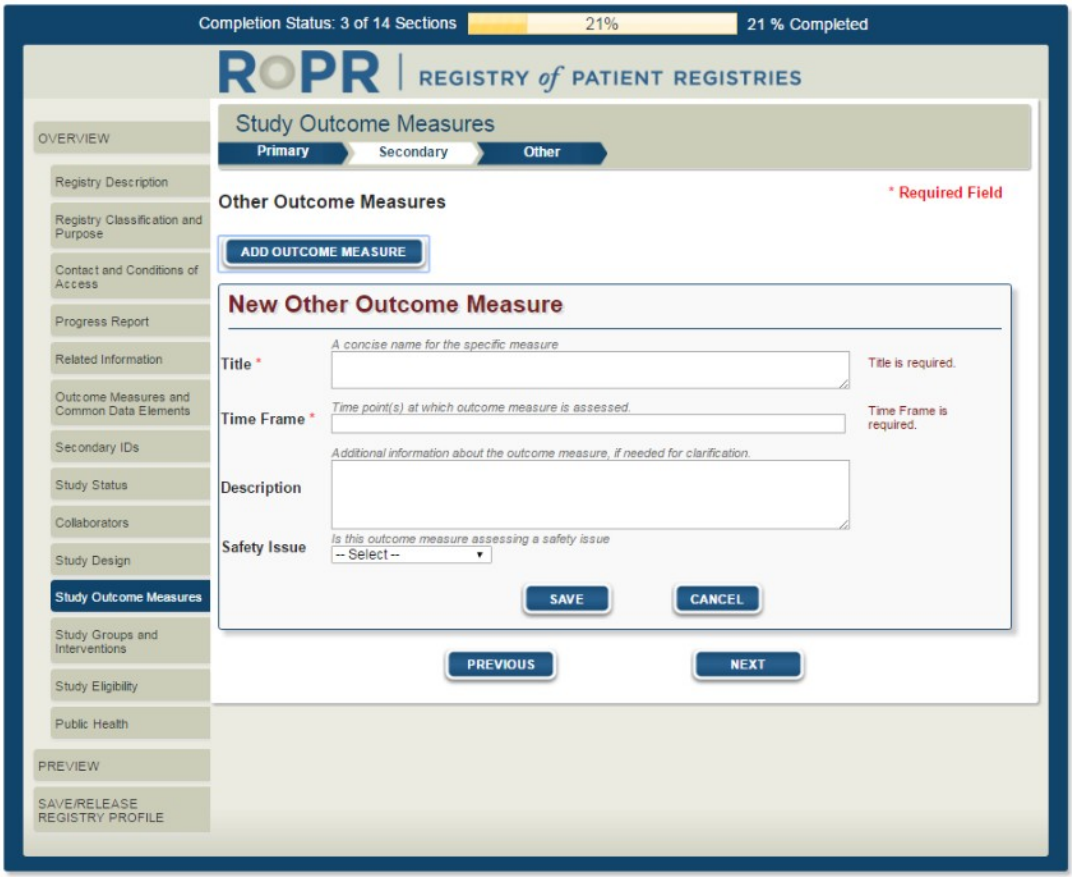
Study Outcome Measures
Primary
Secondary
Other
Other Outcome Measures
* Required Field
ADD OUTCOME MEASURE
PREVIOUS
NEXT


Completion Status: 3 of 14 Sections
21%
21 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
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Study Outcome Measures
Primary
Secondary
Other
Other Outcome Measures
* Required Field
ADD OUTCOME MEASURE
New Other Outcome Measure
A concise name for the specific measure
Title *
Title is required.
Time point(s) at which outcome measure is assessed.
Time Frame *
Time Frame is required.
Additional information about the outcome measure, if needed for clarification.
Description
Is this outcome measure assessing a safety issue
Safety Issue
-- Select --
SAVE
CANCEL
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Completion Status: 2 of 13 Sections
15%
15 % Completed
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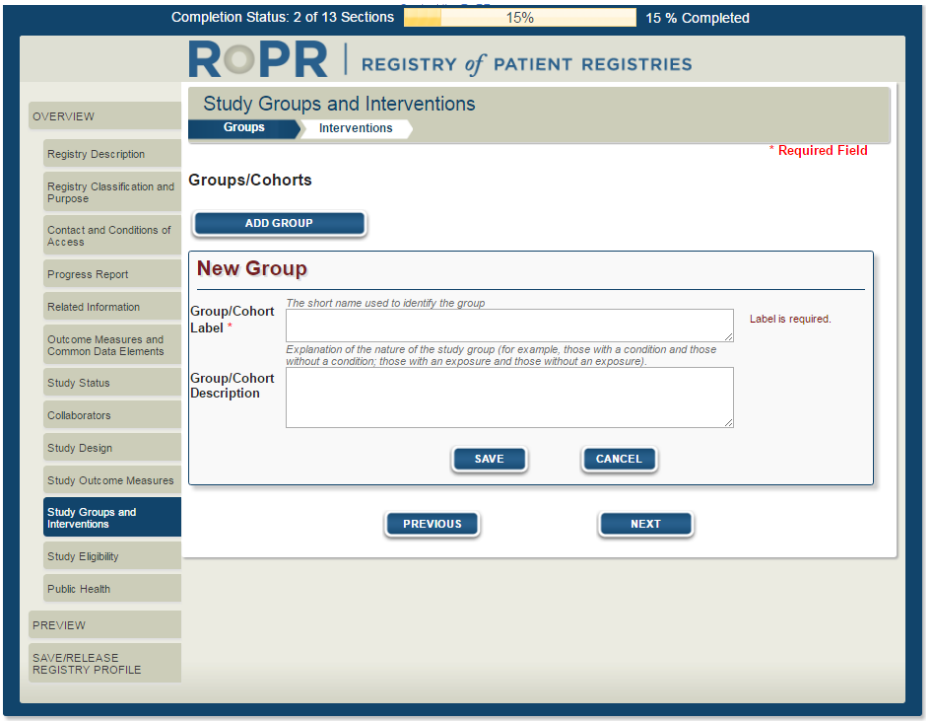
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Study Groups and Interventions
Groups
Interventions
* Required Field
Groups/Cohorts
ADD GROUP
PREVIOUS
NEXT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15 % Completed
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Study Groups and Interventions
Groups
Interventions
* Required Field
Groups/Cohorts
ADD GROUP
New Group
Group/Cohort Label *
The short name used to identify the group
Label is required.
Group/Cohort Description
Explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure).
SAVE
CANCEL
PREVIOUS
NEXT

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Completion Status: 2 of 13 Sections
15%
15 % Completed
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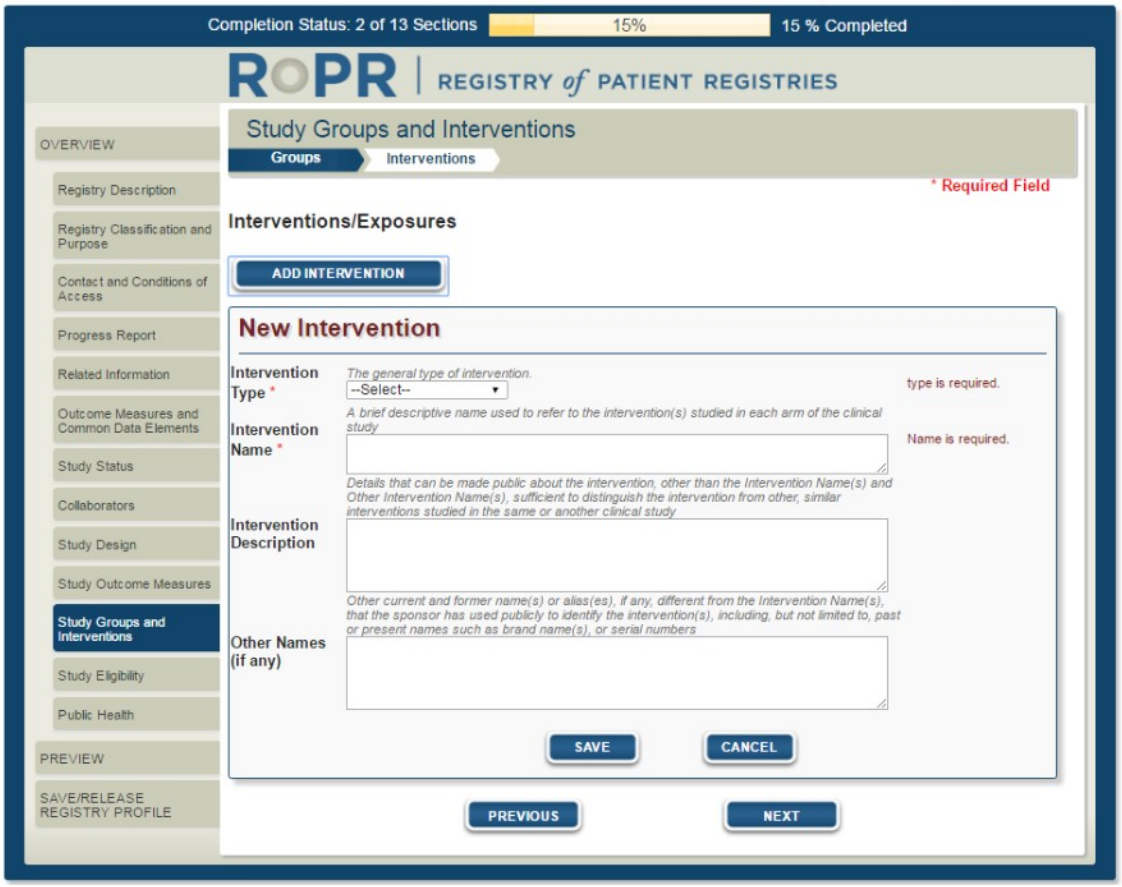
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Study Groups and Interventions
Groups
Interventions
* Required Field
Interventions/Exposures
ADD INTERVENTION
PREVIOUS
NEXT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15 % Completed
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Groups
Interventions
* Required Field
Interventions/Exposures
ADD INTERVENTION
New Intervention
Intervention Type *
The general type of intervention.
--Select--
type is required.
Intervention Name *
A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study
Name is required.
Intervention Description
Details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical study
Other Names (if any)
Other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers
SAVE
CANCEL
PREVIOUS
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17)


Completion Status: 0 of 13 Sections
0%
0 % Completed
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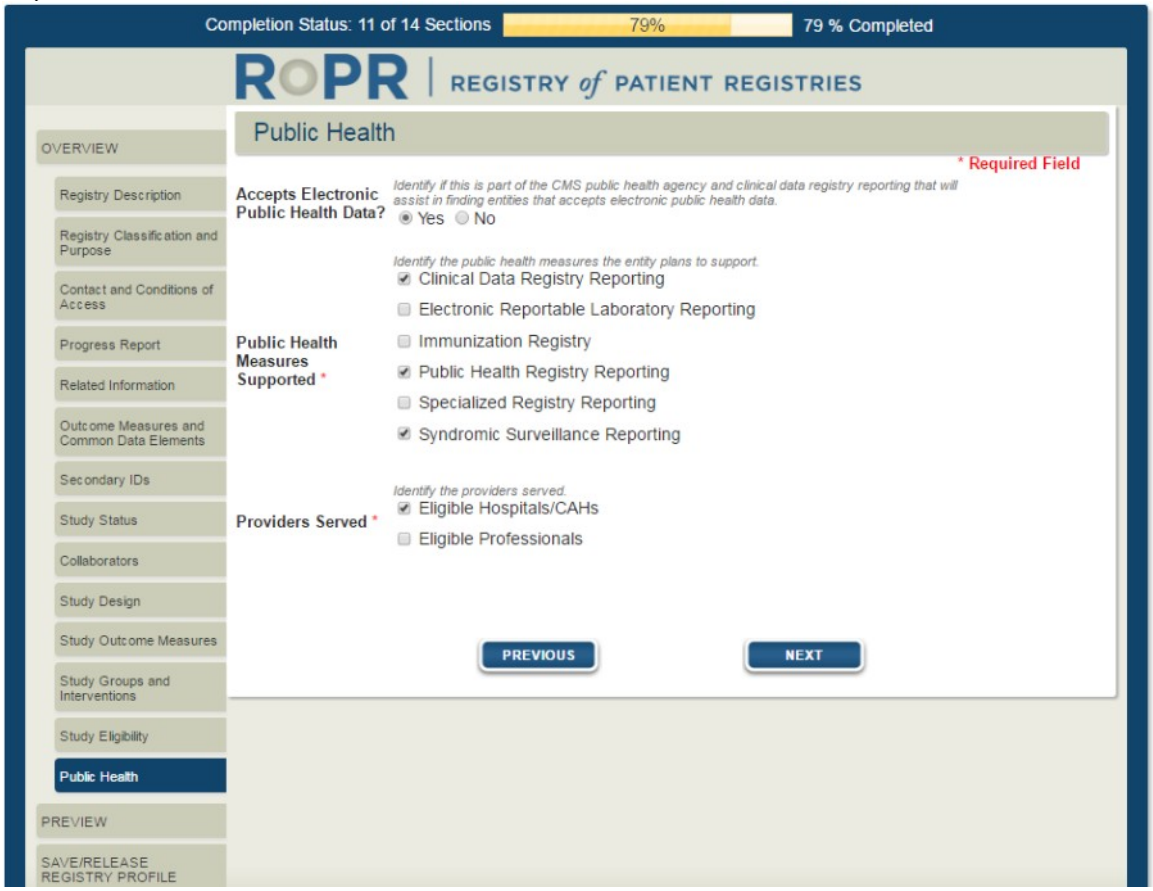
Study Groups and Interventions
Study Eligibility
Public Health
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Study Eligibility
* Required Field
A description of the population from which the groups or cohorts will be selected
Study Population Description *
Population Description is required.
Sampling Method *
Select one
--Select--
A Sampling Method must be selected.
Gender
Physical gender of individuals who may participate in the protocol
--Select--
Age Limits
Age of participants
Unit of Time
Minimum
--Select--
Maximum
--Select--
Accepts Healthy Volunteers?
Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study.
--Select--
Summary criteria for participant selection.
Eligibility Criteria
Inclusion Criteria:
-
Exclusion Criteria:
-
PREVIOUS
NEXT

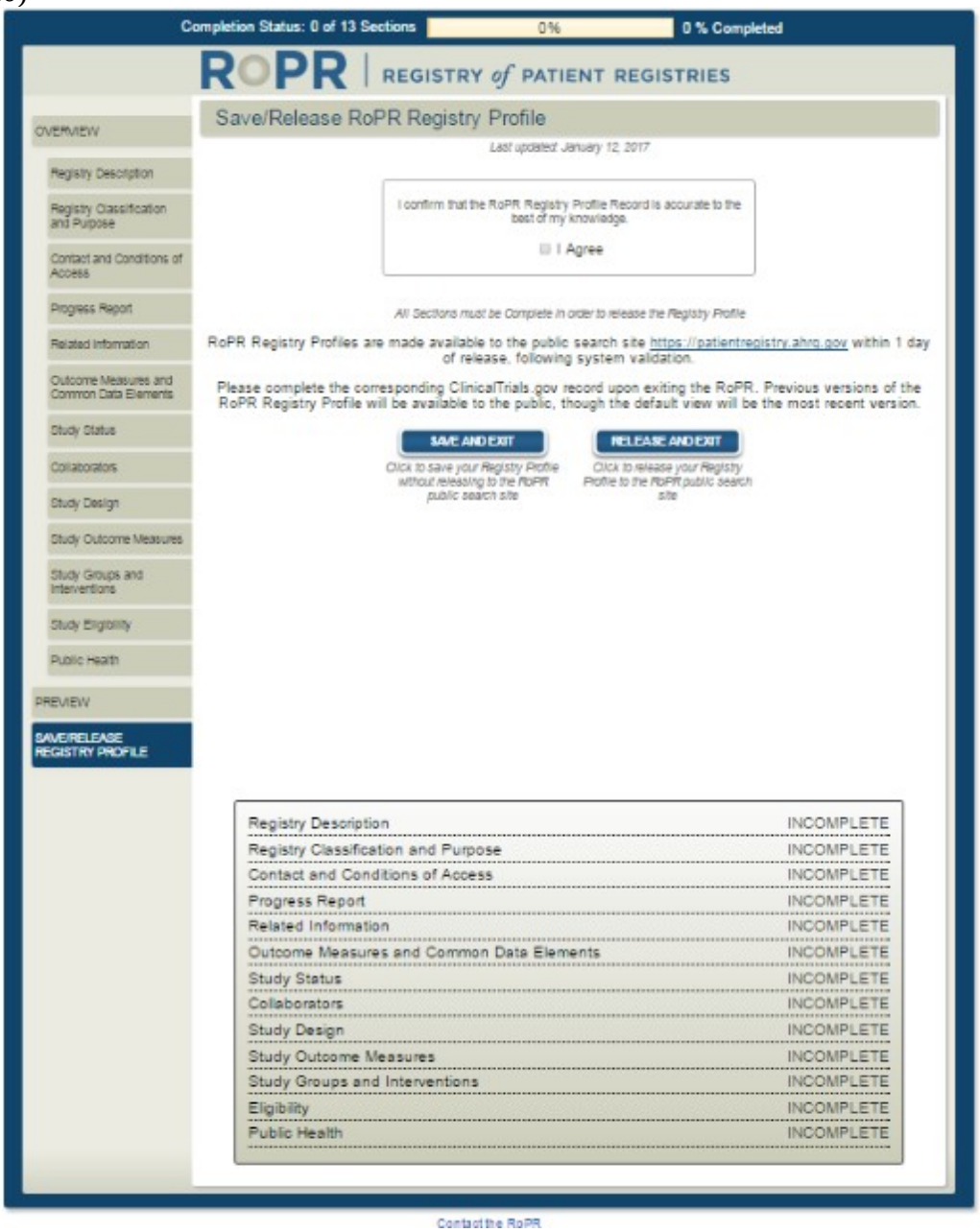
18)


Completion Status: 11 of 14 Sections
79%
79 % Completed
ROPR | REGISTRY of PATIENT REGISTRIES
OVERVIEW
Registry Description
Registry Classification and Purpose
Contact and Conditions of Access
Progress Report
Related Information
Outcome Measures and Common Data Elements
Secondary IDs
Study Status
Collaborators
Study Design
Study Outcome Measures
Study Groups and Interventions
Study Eligibility
Public Health
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Public Health
* Required Field
Accepts Electronic Public Health Data?
Identify if this is part of the CMS public health agency and clinical data registry reporting that will assist in finding entities that accepts electronic public health data.
Yes
No
Public Health Measures Supported *
Identify the public health measures the entity plans to support.
Clinical Data Registry Reporting
Electronic Reportable Laboratory Reporting
Immunization Registry
Public Health Registry Reporting
Specialized Registry Reporting
Syndromic Surveillance Reporting
Providers Served *
Identify the providers served.
Eligible Hospitals/CAHs
Eligible Professionals
PREVIOUS
NEXT

19)


Completion Status: 0 of 13 Sections
0%
0 % Completed
RoPR | REGISTRY of PATIENT REGISTRIES
OVERVIEW
Registry Description
Registry Classification and Purpose
Contact and Conditions of Access
Progress Report
Related Information
Outcome Measures and Common Data Elements
Study Status
Collaborators
Study Design
Study Outcome Measures
Study Groups and Interventions
Study Eligibility
Public Health
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Registry Profile Preview
RoPR ID: 21635
NCT ID - Pending Release to ClinicalTrials.gov
(Click the NCT ID to view the ClinicalTrials.gov details for this record)
Use the Edit Icon to navigate to the specific section.
REGISTRY DESCRIPTION
Registry Title
Version
Official Title
Last Updated On
January 12, 2017
First Received On
January 12, 2017
Brief Description
Long Description
Geography and Location
REGISTRY CLASSIFICATION AND PURPOSE
Registry Classification
Registry Purpose
CONTACT AND CONDITIONS OF ACCESS
Interested in Being Contacted
Organization
Contact

20)


Completion Status: 0 of 13 Sections
0%
0 % Completed
RoPR | REGISTRY of PATIENT REGISTRIES
OVERVIEW
Registry Description
Registry Classification and Purpose
Contact and Conditions of Access
Progress Report
Related Information
Outcome Measures and Common Data Elements
Study Status
Collaborators
Study Design
Study Outcome Measures
Study Groups and Interventions
Study Eligibility
Public Health
PREVIEW
SAVE/RELEASE REGISTRY PROFILE
Save/Release RoPR Registry Profile
Last updated: January 12, 2017
I confirm that the RoPR Registry Profile Record is accurate to the best of my knowledge.
I Agree
All Sections must be Complete in order to release the Registry Profile
RoPR Registry Profiles are made available to the public search site https://patientregistry.ahrq.gov within 1 day of release, following system validation.
Please complete the corresponding ClinicalTrials.gov record upon exiting the RoPR. Previous versions of the RoPR Registry Profile will be available to the public, though the default view will be the most recent version.
SAVE AND EXIT
Click to save your Registry Profile without releasing to the RoPR public search site
RELEASE AND EXIT
Click to release your Registry Profile to the RoPR public search site
Registry Description INCOMPLETE
Registry Classification and Purpose INCOMPLETE
Contact and Conditions of Access INCOMPLETE
Progress Report INCOMPLETE
Related Information INCOMPLETE
Outcome Measures and Common Data Elements INCOMPLETE
Study Status INCOMPLETE
Collaborators INCOMPLETE
Study Design INCOMPLETE
Study Outcome Measures INCOMPLETE
Study Groups and Interventions INCOMPLETE
Eligibility INCOMPLETE
Public Health INCOMPLETE
Contact the RoPR