## 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.

	ROPR   REGISTRY of PATH	
	ROPR   REGISTRY OF PATH	ENT REGISTRIES
RVIEW	Welcome to RoPR - Registry Profile Ov	verview
egistry Description	E-Mail:	E-mail is required.
egistry Classification and urpose	Confirm:	SAVE E-MAIL Confirm is required.
contact and Conditions of ccess	This email will only be used by RoPR and will not be distrib	unea.
rogress Report	Registry Description	INCOMPLETE
elated Information	Registry Classification and Purpose	INCOMPLETE
	Contact and Conditions of Access	INCOMPLETE
outcome Measures and common Data Elements	Progress Report	INCOMPLETE
tudy Status	Related Information	INCOMPLETE
•	Outcome Measures and Common Data Elemen	ts INCOMPLETE
ollaborators	Study Status	INCOMPLETE
tudy Design	Collaborators	INCOMPLETE
tudy Outcome Measures	Study Design	INCOMPLETE
	Study Outcome Measures	INCOMPLETE
tudy Groups and nterventions	Study Groups and Interventions	COMPLETE
tudy Eligibility	Eligibility	INCOMPLETE
ublic Health	Public Health	INCOMPLETE
VIEW	UPLOAD REGISTRY RECORD	ROPR HELP
	Import and upload XML file	
E/RELEASE BISTRY PROFILE	Choose File No file chosen	Frequently Asked Questions
		Upload of Registry Profile Help
	XML Upload Template	Policies and Procedures Documentation
	Registry Profile Schema	E-mail Contact for RoPR Administrators

Public reporting burden for this collection of information is estimated to average 55 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 5600 Fishers Lane, # 07W41A, Rockville, MD 20857.

c	ompletion Status: 1 of 1	13 Sections	8%	8 % Completed	
	ROPR	REGISTRY of	PATIENT REGI	STRIES	
OVERVIEW	Registry Desci	ription			
OVERVIEW					* Required Field
Registry Description	Registry Version	Registry version identifier.			
Registry Classification and Purpose	Registry Geography *	Identify geographic scope of da	ta collection for the registry.		Registry Geography is
Contact and Conditions of Access	Registry Geography	Select Select Single Institution / Practice			required.
Progress Report	Registry Location	State Regional	tion to clarify Registry Geog	rapny as selected.	
Related Information	Registry Title *	National Global	ublic.		Registry Title is required.
Outcome Measures and Common Data Elements	Regiouy rite			1.	region y nuclo required.
Study Status	Official Title				
Collaborators				4	
Study Design					
Study Outcome Measures	Brief Description				
Study Groups and Interventions				h	
Study Eligibility					
Public Health	Long Description				
PREVIEW					
SAVE/RELEASE REGISTRY PROFILE				h	
		PREVIOUS		NEXT	
		Contact the F			

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3a)

	Completion Status: 1 of 13 Sections		8 % Completed	«
OVERVIEW	Registry Classification	and Purpose		
Registry Description	Registry Classification * Select all the	at apply. Enter Other if additional clas	sifications apply.	* Required Field
Registry Classification and Purpose Contact and Conditions of Access	<ul> <li>Disease/Disorder/Condition</li> <li>Pregnancy</li> <li>Product, Biologic</li> </ul>	<ul> <li>Product, Drug</li> <li>Service, Encounter</li> <li>Service, Hospitalization</li> </ul>		Registry Classification is required.
Progress Report	<ul> <li>Product, Device</li> <li>Other</li> </ul>	Service, Procedure		
Outcome Measures and Common Data Elements Study Status Collaborators	Registry Purpose * Select all that apply Clinical Practice Assessment Effectiveness		apply. Quality Improvement Safety or Harm	Registry Purpose is required.
Study Design Study Outcome Measures Study Groups and Interventions	Natural History of Disease     Other	Public Health Surveillanc	e NEXT	
Study Elicibility				
Study Eligibility Public Health				

## 3b) Additional field shown if "quality improvement" purpose is selected

C	Completion Status: 3 of 14 Sections	21%	21 % Completed	
		ISTRY of PATIENT	REGISTRIES	
OVERVIEW	Registry Classification	and Purpose		
OVERVIEW				* Required Field
Registry Description	Registry Classification * Select all the	at apply. Enter Other if additional cla	assifications apply.	
Registry Classification and Purpose	Disease/Disorder/Condition	Product, Drug	Transplant	
and Purpose	Pregnancy	Service, Encounter	Tumor	Registry Classification is required.
Contact and Conditions of Access	Product, Biologic	Service, Hospitalization	Vaccine	
Progress Report	Product, Device	Service, Procedure		
Related Information	Other			
Outcome Measures and Common Data Elements	Registry Purpose * Select all that app	ly. Enter Other if additional purposes	s apply.	
Secondary IDs	Clinical Practice Assessment	Payment / Certification	Quality Improvement	
Study Status	Effectiveness	Post Marketing Commitment	Safety or Harm	
Collaborators	Natural History of Disease	Public Health Surveillance	e	
Study Design	Other			
Study Outcome Measures				
Study Groups and Interventions	Reporting * Identify if the registry is us	ed for reporting quality measures.		
Study Eligibility	Yes No			
Public Health		PREVIOUS	NEXT	
PREVIEW				
SAVE/RELEASE REGISTRY PROFILE				

	RODE	REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Contact and	Conditions of Access	1Decimetral
Registry Description	Interest in Being Contacted?*	Identify if the sponsor is interested in being contacted for reasons listed below. © Yes © No	* Required Field Interest in Being Contacted? Is required
Registry Classification and Purpose		Identify sponsor's reasons for being contacted. Enter Other If additional reasons apply.	
Contact and Conditions of Access	Reasons for Being Contacted	Data Access     Participation - Participant     More Information	
Progress Report		Other	
Related information Outcome Measures and	Organization	The primary contact organization.	
Common Data Elements Study Status	First Name	The primary contact individual's first name.	
Collaborators	Last Name	The primary contact individual's last name.	
Study Design Study Outcome Measures	Title	The primary contact individual's title.	
Study Groups and Interventions		The primary contact email.	
Study Eligibility Public Health	E-Mail	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.	
PREVIEW	Phone	The primary contact phone number.	
SA/E/RELEASE	Phone	Ext	
REGISTRY PROFILE	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 obcurrent describing conditions of access required by sponsor (including http:// or https://).	
	Has Data Monitoring?	© Yes ◎ No	

	Completion Status: 1 of 13 Sections 8% 8 % Completed	
	<b>ROPR</b>   REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Progress Report	* Required Field
Registry Description	Is Progress Report Available? *	Is Progress Report Available? is required.
Registry Classification and Purpose	Progress Report information for the registry may include interim reports, annual	
Contact and Conditions of Access	reports, results, and/or other related information. If one is available, the following data elements are included in a Progress Report:	
Progress Report	<ul> <li>Title</li> <li>Summary</li> <li>Number of Participants in Registry</li> </ul>	
Related Information	<ul> <li>Length of Follow-up*</li> <li>Link to Progress Report</li> </ul>	
Common Data Elements		
Collaborators		
Study Design		
Study Outcome Measures		
Study Groups and Interventions	PREVIOUS	
Study Eligibility		
Public Health PREVIEW		
SAVE/RELEASE REGISTRY PROFILE		

	Completion Stat	us: 1 of 13 Sections	8%	8 % Completed	
	ROP		of PATIENT R	EGISTRIES	
OVERVIEW	Progress	Report			* Required Field
Registry Description	ls Progress Rep ⊛ Yes ⊚ I	port Available? *			You must add at least one Progress Report.
Registry Classification and Purpose	ADD PROGR				
Contact and Conditions of Access					
Progress Report	New Pro	gress Report			
Related Information	Title *	Title of the Progress Report.			Title is required.
Outcome Measures and Common Data Elements		Summary of all relevant progress reports, annual reports, and/or ot			
Study Status	Summary *				Summary is required.
Collaborators					
Study Design	Number of Participants in	Progress data identifying the curr		n the registry.	Number of Participants in
Study Outcome Measures	Registry *	Actual	•		Registry is required.
Study Groups and Interventions	Length of Follow-up *	Progress data identifying the leng the registry.	th of follow-up data in year	s, as currently available withi	n Length of Follow-up is required.
Study Eligibility					
Public Health	Link to Progress	A link to the progress report (inclu	ding http:// or https://).		
PREVIEW	Report				
SAVE/RELEASE REGISTRY PROFILE		Į	SAVE	CANCEL	
		PREVIOU	s	NEXT	

5)		
с	ompletion Status: 1 of 13 Sections 8% 8% Completed	
	<b>ROPR</b>   REGISTRY <i>of</i> PATIENT REGISTRIES	
OVERVIEW	Related Information	
	Are Related Links Available? *	* Required Field
Registry Description	Ves No	Are Related Links Available? is required.
Registry Classification and Purpose		
Contact and Conditions of	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:	
Access	• Link *	
Progress Report	Description*	
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		

OVERVIEW       Related Information       * Required Field         Registry Description       Are Related Links Available?*       You must add at least one Related Link.         Progress Report       New Related Link       New Related Link.         New Related 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.         A title or brief description of the linked page.       A title or brief description of the linked page.       Link is required.	c	Completion Statu	s: 1 of 13 Sections	8%	8 % Completed	
OVERVIEW       * Required Field         Registry Description       Are Related Links Available? *       You must add at least one Related Link.         Registry Classification and Purpose       • Yes • No       No         Contact and Conditions of Access       • New Related Link       New Related Link         Progress Report       Link *       A link to a Web sile for relevant registry information or to a publication related to the registry         Link *       A link to a Web sile for relevant registry information or to a publication related to the registry       Link is required.         Outcome Measures and       A title or brief description of the linked page.       Link is required.		ROP		Y of PATIENT F	REGISTRIES	
Registry Description       Are Related Links Available? *       You must add at least one Related Link.         Registry Classification and Purpose       • Yes • No       No         Contact and Conditions of Access       New Related Link.       New Related Link.         Progress Report       Link *       A link to a Web sile for relevant registry information or to a publication related to the registry Link is required.         Related Information       A title or brief description of the linked page.       Link is required.	OVERVIEW	Related I	nformation			
Registry Classification and Purpose       No         Purpose       No         Contact and Conditions of Access       New Related Link         Progress Report       Link *         Link *       A link to a Web site for relevant registry information or to a publication related to the registry (including http:// or https://).         Outcome Measures and       A tile or brief description of the linked page.	Registry Description	Are Related Lin	ks Available? *			You must add at least
Contact and Conditions of Access       A link to a Web site for relevant registry information or to a publication related to the registry (including http:// or https://).         Related information       A tile or brief description of the linked page.						one Related Link.
Progress Report       Link *       (including http:// or https://).       Link is required.         Related Information       A tille or brief description of the linked page.       A tille or brief description of the linked page.		New Rela	ated LINK			
A tille or brief description of the linked page.	Progress Report	Link *	A link to a Web site for relevant re (including http:// or https://).	gistry information or to a publi	ication related to the registry	Link is required.
Outcome Measures and	Related Information	1				
Link Description is			A title or brief description of the lin	kea page.		Link Description is
Study Status Description *	Study Status	Description *				
Collaborators	Collaborators				10	
Study Design SAVE CANCEL	Study Design			SAVE	NCEL	
Study Outcome Measures	Study Outcome Measures	L				
Study Groups and Interventions PREVIOUS NEXT			PREVIO	us	NEXT	
Study Eligibility	Study Eligibility					
Public Health	Public Health					
PREVIEW	PREVIEW					
SAVE/RELEASE REGISTRY PROFILE						

	Completion Status: 1 of 13 Sections	8%	8 % Completed	
		RY of PATIENT RE	GISTRIES	
OVERVIEW	Condition or Service of Inte	rest for Registry		
Registry Description	Outcome Measures and Common Data E			* Required Field
Registry Classification a	(MeSH). Select all that apply. Enter Other if addition		e s medical Subject rieadings	
Purpose	Bacterial and Fungal Diseases	Muscle, Bone, and Car	rtilage Diseases	
Contact and Conditions	of Behaviors and Mental Disorders	Nervous System Disea	ases	At least one Condition i required.
Access	Blood and Lymph Conditions	Nutritional and Metabo	lic Diseases	
Progress Report	Cancers and other Neoplasms	Occupational Diseases	3	
Related Information	Digestive System Diseases	Parasitic Diseases		
Outcome Measures and Common Data Elements	<ul> <li>Diseases or Abnormalities at or before Birth</li> </ul>	<ul> <li>Respiratory Tract (Lung Diseases</li> </ul>	g and Bronchial)	
Study Status	Ear, Nose, and Throat Diseases	Skin and Connective T	issue Diseases	
Study Status	Eye Diseases	Substance Related Dis	sorders	
Collaborators	Gland and Hormone Related	Symptoms and Generation	al Pathology	
Study Design	Diseases <ul> <li>Heart and Blood Diseases</li> </ul>	Urinary Tract, Sexual O Pregnancy Conditions	Organs, and	
Study Outcome Measur	Immune System Diseases	Viral Diseases		
Study Groups and	Mouth and Tooth Diseases	Wounds and Injuries		
Interventions	Other			
Study Eligibility				
Public Health	PREV	ious	NEXT	
PREVIEW				
SAVE/RELEASE REGISTRY PROFILE				

		ISTRY of PATIENT REGISTRIE	ES
OVERVIEW	Category of Interest for Condition Category	Registry	
Registry Description	Outcome Measures and Common E Select all that apply. Enter Other if additional	Data Elements - Categories * Categories apply.	* Required Field
Registry Classification and Purpose	Clinical Assessments	Patient Reported Outcomes	
Contact and Conditions of Access	<ul> <li>Demographics</li> <li>Devices</li> </ul>	<ul> <li>Procedures</li> <li>Risk Factors</li> </ul>	At least one Category i required.
Progress Report	Diagnosis	Staging Systems	
Related Information	<ul> <li>Disease Response</li> <li>Events of Interest</li> </ul>	<ul> <li>Survival Outcomes</li> <li>Treatments</li> </ul>	
Outcome Measures and Common Data Elements	Genetic Information	Vitals	
Study Status	Medications     Other		
Collaborators			
Study Design			
Study Outcome Measures			
Study Groups and Interventions		NEXT	
Study Eligibility			
Public Health			
PREVIEW			
SAVE/RELEASE REGISTRY PROFILE			

	ROPR	REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Study Status		
Registry Description	Record Verification	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.	* Required Field A Verification Date Must be provided
Registry Classification and Purpose	Overall Recruitment	Select-  • Year 2017 The recruitment status for the clinical study as a whole, based upon the status of the individual sites.	A Recuitment Status must b selected
Contact and Conditions of Access	Study Start Date	Select- 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.	3000100
Progress Report	Study Start Date	Select- • Year	
Related Information	Continuous Enrollment	◎ Yes ◎ No	
Outcome Measures and Common Data Elements	Primary Completion Date	The date on which data collection is completed for all of the primary outcomes. Select-  V  Type -Select-  V	
Study Status	Study Completion	The date on which data collection is completed for all of the primary and secondary	
Collaborators	Date	Select • Year TypeSelect •	
Study Design			
Study Outcome Measures			
Study Groups and Interventions		PREVIOUS	
Study Eligibility			
Public Health			
PREVIEW			
SAVE/RELEASE REGISTRY PROFILE			

c	Completion Status: 1 of 13 Sections 8% 8% Completed	
	<b>ROPR</b>   REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Collaborators	
Registry Description	* Required Field Are Collaborators Providing Support? * Are Collaborators Providing Support?	
Registry Classification and Purpose	Yes      No     required.	
Contact and Conditions of Access	Indicate if other organizations (if any) are providing support, including funding, design, implementation, data analysis and reporting. The responsible party is responsible for confirming al collaborators before listing them. If there are, the following data elements are included for a Collaborator:	
Progress Report	Collaborator Name	
Related Information		
Outcome Measures and Common Data Elements		
Study Status		
Collaborators		
Study Design		
Study Outcome Measures		
Study Groups and Interventions	PREVIOUS	
Study Eligibility		-
Public Health		
PREVIEW		
SAVE/RELEASE REGISTRY PROFILE		

c	ompletion Statu	s: 1 of 13 Sections	8%	8 % Completed	1
	ROP		RY of PATIENT	REGISTRIES	
OVERVIEW	Collabora	ators			
	Are Cellaborate	ors Providing Support? *			* Required Field
Registry Description	Yes				You must add at least one Collaborator.
Registry Classification and Purpose					
Contact and Conditions of	New Col	laborator			
Access	Collaborator	Name of organization providing	support		Collaborator Name is
Progress Report	Name *				required.
Related Information			SAVE	CANCEL	
Outcome Measures and Common Data Elements	Ļ				
Study Status					
Collaborators					
Study Design					
Study Outcome Measures					
Study Groups and Interventions		PREVI	ous	NEXT	
Study Eligibility					
Public Health					
PREVIEW					
SAVE/RELEASE REGISTRY PROFILE					

c	ompletion Status: 1 of	13 Sections	8%	8 % Com	pleted
	ROPR	REGIST	RY of PATIENT	REGISTRIES	
VERVIEW	Study Design				
					* Required Field
Registry Description	Observational Study Model *	Primary strategy for p Select	articipant identification and t	ollow-up	A value must be selected
Registry Classification and Purpose	Time Perspective *	Temporal relationship	of observation period to time	e of participant enrollment	A value must be selected
Contact and Conditions of Access	Biospecimen	biorepository		ch participants are retained i	n a
Progress Report	Retention	Select	•		
Related Information	Enrollment *		pants that are enrolled in the		e actual
Outcome Measures and Common Data Elements	Number of Groups/Cohorts	Number of study grou	os/cohorts. Enter "1" for a s	ingle-group study.	
Study Status		The ordering of the order		in a star to the fail to and	
Collaborators	Target Follow-Up Duration *	TypeS	eriod over which each partie elect •	npant is to be rollowed.	
Study Design					
Study Outcome Measures					
Study Groups and Interventions		PREVI	ous	NEXT	
Study Eligibility					
Public Health					
PREVIEW					
SAVE/RELEASE REGISTRY PROFILE					

	letion Status: 1 of 13	Sections	8%	8 % Completed		
F	<b>PR</b>	REGISTRY of	PATIENT REC	SISTRIES		
OVERVIEW	Study Outcome Primary Se	Measures condary Other				
Registry Description	30	Condury			* Required Field	
	mary Outcome M	easures *			You must add at least one Primary Outcome Measure.	
Contact and Conditions of Access	ADD OUTCOME MEASUF	RE				
Progress Report						
Related Information						
Outcome Measures and Common Data Elements						
Study Status						
Collaborators						
Study Design						
Study Outcome Measures						
Study Groups and Interventions		PREVIOUS		NEXT		
Study Eligibility						
Public Health						
PREVIEW						
SAVE/RELEASE REGISTRY PROFILE						
	Completion Statu	s: 1 of 13 Sections		8%	8 % Completed	10
			STRY OF PA	TIENT REG	ISTRIES	
				TIENT REG	ISTRIES	
OVERVIEW	Study Ou	Itcome Measure	es	TIENT REG	ISTRIES	1
				TIENT REG	ISTRIES	* Required Field
Registry Description	Study Ou Primary Primary Out	Itcome Measure	Conter	ATIENT REG	ISTRIES	* Required Field You must add at least one Primary Outcome
Registry Description Registry Classification and Purpose	Study Ou Primary Primary Out	secondary	Conter	ATIENT REG	ISTRIES	
Registry Description	Study Ou Primary Primary Out	Itcome Measure Secondary come Measures	Other	ATIENT REG	ISTRIES	You must add at least one Primary Outcome
Registry Description Registry Classification and Purpose Contact and Conditions of	Study Ou Primary Primary Out	Itcome Measure Secondary	es Other	ATIENT REG	ISTRIES	You must add at least one Primary Outcome
Registry Description Registry Classification an Purpose Contact and Conditions of Access	Study Ou Primary Primary Out	Itcome Measure Secondary come Measures	es Other	ATIENT REG	ISTRIES	You must add at least one Primary Outcome
Registry Description Registry Classification and Purpose Contact and Conditions of Access Progress Report	Study Ou Primary Primary Out ADD OUTCOM	Itcome Measure Secondary	es Other e Measure	•	ISTRIES	You must add at least one Primary Outcome Measure. Title is required. Title is required.
Registry Description Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and	Study Ou Primary Primary Out ADD OUTCON New Prin Title *	A concise name for the sp	e Measure	essed.		You must add at least one Primary Outcome Measure.
Registry Description Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and Common Data Elements	Study Ou Primary Primary Out ADD OUTCON New Prin Title *	A concise name for the sp Time point(s) at which out	e Measure	essed.		You must add at least one Primary Outcome Measure. Title is required. Title is required.
Registry Description Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and Common Data Elements Study Status	Study Ou Primary Primary Out ADD OUTCON New Prin Title * Time Frame * Description	A concise name for the sp Time point(s) at which out Additional information aboo	e Measure come measure is ass ut the outcome meas	essed. rre, if needed for clarific		You must add at least one Primary Outcome Measure. Title is required. Title is required.
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 Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	It come Measure Secondary COME Measures MEMEASURE Mary Outcome A concise name for the sp Time point(s) at which out Additional information abou	e Measure come measure is ass ut the outcome meas	essed. rre, if needed for clarific		You must add at least one Primary Outcome Measure. Title is required. Title is required.
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 Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	A concise name for the sp Time point(s) at which out Additional information aboo	e Measure e Measure come measure is ass ut the outcome meas	essed. rre, if needed for clarific	ation.	You must add at least one Primary Outcome Measure. Title is required. Title is required.
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	Study Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	It come Measure Secondary	e Measure e Measure ecolic measure come measure is ass ut the outcome meas assessing a safety is SAVE	essed. .re, if needed for clarific	ation.	You must add at least one Primary Outcome Measure. Title is required. Title is required.
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 Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	It come Measure Secondary	e Measure becific measure come measure is ass ut the outcome meas assessing a safety is	essed. .re, if needed for clarific	ation.	You must add at least one Primary Outcome Measure. Title is required. Title is required.
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 Outcome Measures Study Groups and Interventions	Study Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	It come Measure Secondary	e Measure e Measure ecolic measure come measure is ass ut the outcome meas assessing a safety is SAVE	essed. .re, if needed for clarific	ation.	You must add at least one Primary Outcome Measure. Title is required. Title is required.
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	Study Ou Primary Primary Out ADD OUTCOM New Prin Title * Time Frame * Description Safety Issue	It come Measure Secondary	e Measure e Measure ecolic measure come measure is ass ut the outcome meas assessing a safety is SAVE	essed. .re, if needed for clarific	ation.	You must add at least one Primary Outcome Measure. Title is required. Title is required.

C	ompletion Status: 2 of 13 Sections 15% 15 % Completed	
	<b>ROPR</b>   REGISTRY <i>of</i> PATIENT REGISTRIES	
OVERVIEW	Study Outcome Measures Primary Secondary Other	
Registry Description	Secondary Outcome Measures	* Required Field
Purpose Contact and Conditions of	ADD OUTCOME MEASURE	
Access Progress Report		
Related Information		
Outcome Measures and Common Data Elements		
Study Status		
Collaborators		
Study Design		
Study Outcome Measures		
Study Groups and Interventions	PREVIOUS	
Study Eligibility		
Public Health		
PREVIEW		
SAVE/RELEASE REGISTRY PROFILE		_

Comp	etion Status	3: 3 of 14 Sections 21% 21% Complete	ed
F	<b>Sob</b>	R REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Study Ou Primary	secondary Other	
Registry Description Se Registry Classification and Purpose	condary (	Dutcome Measures	* Required Field
Contact and Conditions of Access			
Progress Report	lew Sec	ondary Outcome Measure	
Related Information Titl	ie *	A concise name for the specific measure	Title is required.
Outcome Measures and Common Data Elements	ne Frame *	Time point(s) at which outcome measure is assessed.	Time Frame is required.
Secondary IDs		Additional information about the outcome measure, if needed for clarification.	
Study Status Des	scription		
Collaborators Study Design	fety Issue	Is this outcome measure assessing a safety issue	
Study Outcome Measures		SAVE	
Study Groups and Interventions			
Study Eligibility		PREVIOUS	
Public Health			
PREVIEW			
SAVE/RELEASE REGISTRY PROFILE			

с	ompletion Status: 2 of 13 Sections
	<b>ROPR</b>   REGISTRY of PATIENT REGISTRIES
OVERVIEW	Study Outcome Measures Primary Secondary Other
Registry Description	Other Outcome Measures * Required Field
Registry Classification and Purpose	
Contact and Conditions of Access	ADD OUTCOME MEASURE
Progress Report	
Related Information	
Outcome Measures and Common Data Elements	
Study Status	
Collaborators	
Study Design	
Study Outcome Measures	
Study Groups and Interventions	PREVIOUS
Study Eligibility	
Public Health	
PREVIEW	
SAVE/RELEASE REGISTRY PROFILE	

c	ompletion Statu	s: 3 of 14 Sections	21%	21 % Comple	ted
	ROF		Y of PATIENT	REGISTRIES	
OVERVIEW	Study Ou Primary	utcome Measures	Other		
Registry Description	Other Outco	ome Measures			* Required Field
Purpose Contact and Conditions of Access	ADD OUTCOM				
Progress Report	New Oth	er Outcome Meas	sure		
Related Information	Title *	A concise name for the specific m	neasure		Title is required.
Outcome Measures and Common Data Elements	Time Frame *	Time point(s) at which outcome m	easure is assessed.		Time Frame is required.
Secondary IDs		Additional information about the ou	utcome measure, if needed fo	or clarification.	
Study Status Collaborators	Description				
Study Design	Safety Issue	Is this outcome measure assessi Select •	ng a safety issue	,	20
Study Outcome Measures			SAVE	CANCEL	
Study Groups and Interventions		PREVIO	us	NEXT	
Study Eligibility					
Public Health					
PREVIEW					
SAVE/RELEASE REGISTRY PROFILE					

OVERVIEW         Study Groups and Interventions           Registry Description         Interventions           Beautry Oligatification and         Groups/Cohorts	
Registry Description	
Comme 10 a baseta	
Groups/Coborts	* Required Field
Registry Classification and Groups/Conorts Purpose	
Contact and Conditions of ADD GROUP	
Progress Report	
Related Information	
Outcome Measures and Common Data Elements	
Study Status	
Collaborators	
Study Design	
Study Outcome Measures	
Study Groups and Interventions NEXT	
Study Eligibility	
Public Health	
PREVIEW	
SAVE/RELEASE REGISTRY PROFILE	
Completion Status: 2 of 13 Sections 15% 15 % Completion	eted
<b>ROPR</b>   REGISTRY of PATIENT REGISTRIES	
Study Groups and Interventions	
OVERVIEW Groups Interventions	* Required Field
OVERVIEW         Groups         Interventions           Registry Description         Groups/Cohorts         Groups/Cohorts	* Required Field
OVERVIEW         Groups         Interventions           Registry Description         Converse (Converse)         Converse (Converse)	* Required Field
OVERVIEW         Groups         Interventions           Registry Description         Groups/Cohorts         Groups/Cohorts           Purpose         ADD GROUP         ADD GROUP	* Required Field
Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Contact and Conditions of Access     New Groups       Progress Report     New Group       Related Information     The short name used to identify the group	
Begistry Description     Groups     Interventions       Registry Classification and Purpose     Groups/Cohorts       Contact and Conditions of Access     ADD GROUP       Progress Report     New Group       Group/Cohort     The short name used to identify the group       Group/Cohort     The short name used to identify the group       Outcome Measures and Common Data Elements     Explanation of the nature of the study group (for example, those with a condition and those	* Required Field
OVERVIEW     Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Contact and Conditions of Access     ADD GROUP       Related Information     Group/Cohort       Related Information     The short name used to identify the group       Group/Cohort     The short name used to identify the group       Common Data Elements     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).	
Overview     Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Access     ADD GROUP       Access     Mew Group       Progress Report     New Group       Group/Cohort     The short name used to identify the group       Outcome Measures and Common Data Elements     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).	
Overview     Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Contact and Conditions of Access     ADD GROUP       Progress Report     New Group       Related Information     The short name used to identify the group       Outcome Measures and Common Data Elements     The short name used to identify the group       Study Status     Group/Cohort Bescription     The short name used to identify the group       Study Status     Group/Cohort Bescription     The short name used to identify the group (for example, those with a condition and those without a condition, those with an exposure and those without an exposure).	
Overview     Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Access     ADD GROUP       Access     New Group       Progress Report     New Group       Group/Cohort     The short name used to identify the group       Outcome Measures and Common Data Elements     The short name used to identify the group       Study Status     Group/Cohort Description     The short name used to identify the group       Study Status     Group/Cohort Description     The short name used to identify the group	
Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Access     ADD GROUP       Progress Report     New Group       Related information     Group/Cohort       Outcome Measures and Common Data Elements     The short name used to identify the group       Study Status     Group/Cohort       Study Status     Group/Cohort       Study Design     SAVE	
Overview     Groups     Interventions       Registry Description     Groups/Cohorts       Purpose     ADD GROUP       Access     ADD GROUP       Access     Contact and Conditions of Access       Progress Report     New Groups       Outcome Measures and Common Data Elements     The short name used to identify the group Coup/Cohort Label *       Study Status     Group/Cohort Description       Study Design     Study Outcome Measures       Study Outcome Measures     Study Outcome Measures	
Groups       Interventions         Registry Description       Groups/Cohorts         Purpose       ADD GROUP         Access       ADD GROUP         Progress Report       New Group         Group/Cohort       The short name used to identify the group         Contact and Conditions of Access       Froup/Cohort         Study Status       Group/Cohort         Coleborators       Study Design         Study Design       Study Outcome Measures         Study Outcome Measures       Study Conges and Interventions         Study Conges and Interventions       Image: Conges and Interventions	
Groups       Interventions         Registry Description       Groups/Cohorts         Propress       ADD GROUP         Access       ADD GROUP         Progress Report       New Groups         Outcome Measures and Common Data Elements       The short name used to identify the group Label*         Study Status       Group/Cohort Bescription       The short name used to identify the group Label*         Study Status       Group/Cohort Description       The short name used to identify the group whout a condition 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).         Study Design       Study Outcome Measures         Study Circops and Interventions       Previous         Study Eligbility       NEXT	

С	Completion Status: 2 of 13 Sections 15% 15% Completed	
	<b>ROPR</b>   REGISTRY of PATIENT REGISTRIES	
OVERVIEW	Study Groups and Interventions	
Registry Description	* Required Field	
Registry Classification and Purpose	Interventions/Exposures	
Contact and Conditions of Access	ADD INTERVENTION	
Progress Report		
Related Information		
Outcome Measures and Common Data Elements		
Study Status		
Collaborators		
Study Design		
Study Outcome Measures		
Study Groups and Interventions	PREVIOUS	
Study Eligibility		_
Public Health		
PREVIEW		
SAVE/RELEASE REGISTRY PROFILE		

C	ompletion Statu	is: 2 of 13 Sections 15% Complete	d
	ROF	<b>PR</b>   REGISTRY <i>of</i> PATIENT REGISTRIES	
OVERVIEW	Study Groups	roups and Interventions	
Registry Description			* Required Field
Registry Classification and Purpose	Intervention	ns/Exposures	
Contact and Conditions of Access	ADD INTE	RVENTION	
Progress Report	New Inte	ervention	
Related Information	Intervention Type *	The general type of interventionSelect-	type is required.
Outcome Measures and Common Data Elements	Intervention	A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study	Name is required.
Study Status	Name *	1.	Name is required.
Collaborators		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	
Study Design	Intervention Description		
Study Outcome Measures			
Study Groups and Interventions	Other Names	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, pas or present names such as brand name(s), or serial numbers	t
Study Eligibility	(if any)		
Public Health		//	
PREVIEW		SAVE	
SAVE/RELEASE REGISTRY PROFILE		PREVIOUS NEXT	

С	ompletion Status: 0 of	13 Sections	0	%	0 % Completed	
	ROPR		SISTRY of PA	TIENT REG	ISTRIES	
OVERVIEW	Study Eligibili	ty				
Registry Description Registry Classification and Purpose	Study Population Description *	A description	of the population from whi	ch the groups or coho	rts will be selected	* Required Field Population Description is required.
Contact and Conditions of Access	Sampling Method *	Select one Select	Ŧ		10	A Sampling Method must be selected.
Progress Report	Gender	Physical gend Select	der of individuals who may	participate in the prot	ocol	
Related Information	Age Limits	Minimum	Age of participants		•	
Outcome Measures and Common Data Elements		Maximum Indicate if pers	sons who have not had th	e condition(s) being s	determine tudied or otherwise related	1
Study Status	Accepts Healthy Volunteers?	study.	symptoms, as specified in	the eligibility requirem	ients, may participate in tr	ne
Collaborators		Summary crit	eria for participant selectic Criteria:	n.		
Study Design		- Exclusion	Criteria			
Study Outcome Measures	Eligibility Criteria	-				
Study Groups and Interventions						
Study Eligibility					1.	
Public Health			PREVIOUS		NEXT	
PREVIEW						
SAVE/RELEASE REGISTRY PROFILE						
Sec. 1						

	ROPF	REGISTRY of PATIENT REGISTRIES
VERVIEW	Public Health	
Registry Description	Accepts Electronic Public Health Data?	
Registry Classification and Purpose		Identify the public health measures the entity plans to support.
Contact and Conditions of Access		Electronic Reportable Laboratory Reporting
Progress Report	Public Health Measures	Immunization Registry
Related Information	Supported *	Public Health Registry Reporting
Outcome Measures and Common Data Elements		<ul> <li>Specialized Registry Reporting</li> <li>Syndromic Surveillance Reporting</li> </ul>
Secondary IDs		Identify the providers served.
Study Status	Providers Served *	Eligible Hospitals/CAHs     Eligible Brofessionals
Collaborators		Eligible Professionals
Study Design		
Study Outcome Measures		PREVIOUS
Study Groups and Interventions		
Study Eligibility		
Public Health		
REVIEW		
AVE/RELEASE EGISTRY PROFILE		

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

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	ROPR   REGISTRY of PATIENT REGISTRI	ES		
VERVIEW	Save/Release RoPR Registry Profile			
	Last updated January 12, 2017			
Registry Description				
Registry Classification and Purpose	I confirm that the RoPR Registry Profile Record is accurate best of my knowledge.	e to the		
Contact and Conditions of Access	I Agree			
Progress Report	All Sections must be Complete In order to release the Registry	y Pafle		
Related Information	RoPR Registry Profiles are made available to the public search site <a href="https://pointerase.following">https://pointerase.following</a> system validation.	atientregistry.ahrg.gov within 1 da		
Outcome Measures and Common Data Elements	Please complete the corresponding ClinicalTrials.gov record upon exiting th RoPR Registry Profile will be available to the public, though the default view	e RoPR. Previous versions of the w will be the most recent version.		
Study Status	SAVE AND EXIT RELEASE AND E	ит		
Collaborators	Click to save your Registry Profile Click to release your without releasing to the RoPit Profile to the RoPit public	Registry		
Study Design	public search site site	ic search		
Study Outcome Measures				
Study Groups and				
Interventions.				
Interventions Study Englority				
Interventions				
Interventions Study Englosity Public Health				
Interventions Study Englowity				
Interventions Study Eligibility Public Health REVIEW AVERIELEASE				
Interventions Study Eligibility Public Health REVIEW AVERIELEASE				
Interventions Study Eligibility Public Health REVIEW AVERIELEASE				
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Description	INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Description Registry Classification and Purpose	INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE				
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose	INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose Contact and Conditions of Access	INCOMPLETE INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information	INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and Common Data Elements	INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and Common Data Elements Study Status	INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE		
Interventions Study Eligibility Public Health REVIEW AVERIELEASE	Registry Classification and Purpose Contact and Conditions of Access Progress Report Related Information Outcome Measures and Common Data Elements Study Status Collaborators	INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE		
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Interventions Study Eligibility Public Health REVIEW AVERIELEASE	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 Dutcome Measures Study Groups and Interventions	INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE INCOMPLETE		
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Contact the RoPR