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Shaking the Myth of Real-World Evidence: Updates From the RWE Transparency Initiative

Presented by ISPOR in collaboration with ISPE, Duke Margolis and NPC

December 17, 2020

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Shaking the Myth of Real-World Evidence: Updates From the RWE Transparency Initiative

Presented by ISPOR in collaboration with ISPE, Duke Margolis and NPC

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Speakers

- Lucinda Orsini, DPM, MPH
  - Associate Chief Science Officer ISPOR
  - Head of Health Science and Health Policy Initiatives, ISPOR
- Shirley V. Wang, PhD
  - Assistant Professor, Department of Medicine, BWH and Harvard Medical School
  - Lead of Transparency and Reproducibility Subgroup, ISPE RWE Task Force
- David Mellor, PhD
  - Director of Policy Initiatives, Centers for Open Science

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Agenda

- Introduction – *Lucinda*
  - Reminder of what the RWE Transparency Initiative and the focus
  - Update on what we have done in the last 24 months
  - Recommendations for moving forward:
    - Study Registration Site and
    - Joint Task Force
- Introduce the Joint Task Force Rationale and Related Efforts – *Shirley*
- RWE Study Registration Site and the Centers for Open Science – *David*
  - Overview of the RWE Registration Site 1.0
  - How this efforts fits with the broader push for Transparency in Science

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Introduct

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ISPOR/ISPE Joint Special Task Force on Real-World Evidence in Healthcare Decision Making


Available online at www.sciencedirect.com
ScienceDirect
journal homepage: www.elsevier.com/locate/jval
ELSEVIER

Original Report

Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making

Marc L. Berger[1,*], Harold Sox[2], Richard J. Willke[3], Diana L. Brixner[4], Hans-Georg Eichler[5], Wim Goettsch[6], David Madigan[7], Amr Makady[6], Sebastian Schneeweiss[8], Rosanna Tarricone[9], Shirley V. Wang[8], John Watkins[10], C. Daniel Mullins[11]

Transparency of Study Processes


PDS Pharmacoepidemiology & Drug Safety
ORIGINAL REPORT

Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0

Shirley V. Wang[1,2] | Sebastian Schneeweiss[1,2] | Marc L. Berger[3] | Jeffrey Brown[4] | Frank de Vries[5] | Ian Douglas[6] | Joshua J. Gagne[1,2] | Rosa Gini[7] | Olaf Klungel[8] | C. Daniel Mullins[9] | Michael D. Nguyen[10] | Jeremy A. Rassen[11] | Liam Smeeth[6] | Miriam Sturkenboom[12] |
on behalf of the joint ISPE-ISPOR Special Task Force on Real World Evidence in Health Care Decision Making

Reproducibility of Study Implementation

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Real-World Evidence Transparency Partnership

ispe International Society for Pharmacoepidemiology
ISPOR
Duke MARGOLIS CENTER for Health Policy
National Pharmaceutical Council
U.S. National Library of Medicine ClinicalTrials.gov
INAHTA
EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
FDA
CADTH
AHRQ Agency for Healthcare Research and Quality Advancing Excellence in Health Care
NATIONAL HEALTH COUNCIL
Zorginstituut Nederland
AMCP Academy of Managed Care Pharmacy
Representatives from 7 pharma companies
Anthem
Syneos Health
flatiron
OPTUM Labs
NICE National Institute for Health and Care Excellence
patientslikeme

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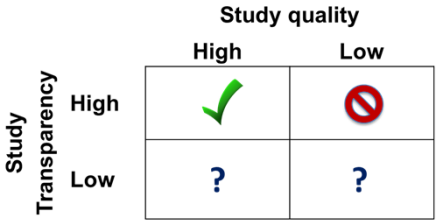
Transparency versus Quality

- End goal = decisions based on high quality evidence
- Registration process increases transparency of study process/methods



- Encouraging a culture of transparency can lead to…
  - higher quality evidence generated and used for decision making
  - confidence in this type of research

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Focus is on Secondary Data Use Studies

Challenges include:

- Underlying data quality
- Perceptions of Data dredging/p-hacking/cherry picking
- Lack of transparency of
  - research questions/objectives, data set choice, and a priori analysis plans
- Lack of results reporting
  - Decreases visibility into the universe of studies conducted and associated results
  - RWE studies NOT published at same rate as clinical trial evidence,
  - Creates a particular 'blind-spot' for assessing comparative effectiveness

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Focus on HETE Studies

- Hypothesis Evaluating Treatment Effect (HETE) studies
  - Intended for regulatory, payer, other decision-making, or peer-reviewed publication
  - Evaluates the presence or absence of a pre-specified treatment effect and/or its magnitude
  - Tests a specific hypothesis in a specific data set
  - In conjunction with other evidence, may lead to treatment recommendations

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RWE Transparency Initiative

Received: 22 April 2020 | Revised: 12 June 2020 | Accepted: 23 June 2020
DOI: 10.1002/pds.5079

COMMENTARY

WILEY

Improving transparency to build trust in real-world secondary data studies for hypothesis test recommendations and a road m evidence transparency initiative

Lucinda S. Orsini[1] | Brigitta Monz[2] | C. D
Gregory Daniel[5] | Hans-Georg Eichler[6] |
Marc Berger[1] | Nirosha M. Lederer[5] | Pal
Shirley V. Wang[9] | William Crown[10] | V

VALUE HEALTH. 2020; 23(9):1128–1136

ScienceDirect

Contents lists available at sciencedirect.com
Journal homepage: www.elsevier.com/locate/jval

ISPOR Report

Improving Transparency to Build Trust in Real-World Secondary Data Studies for Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative

Lucinda S. Orsini, DPM, MPH,* Marc Berger, MD, William Crown, PhD, Gregory Daniel, PhD, MPH, Hans-Georg Eichler, MD, Wim Goettsch, PhD, Jennifer Graff, PharmD, John Guerino, MHS, Pall Jonsson, PhD, Nirosha Mahendraratnam Lederer, PhD, Brigitta Monz, MD, MPH, MA, C. Daniel Mullins, PhD, Sebastian Schneeweiss, MD, ScD, David Van Brunt, PhD, Shirley V. Wang, PhD, ScM, Richard J. Willke, PhD

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Recommendations

Table 3. Recommendations for the RWE Transparency Initiative.

	Recommendation	Timeframe	Action	Considerations
1	Identify site to register HETE studies that use secondary data	Short term	• Actively encourage registration on existing sites (eg, EU-PAS, Clintrials.gov, and COS.io) • Initiate discussion with current study registry hosts (eg, NLM, ENCePP, and EMA)[a] • Consider hosting a test site with the Center for Open Science	• Current sites are "good enough" for some form of registration • Focus on HETE RWE studies whose purpose is to support decision-making (eg, about regulations or coverage).
2	Determine the characteristics of a "good" registration process to fit the purpose (starts in parallel with short term recommendations)	Medium term	Create multijurisdictional taskforces to do the following: 1. Survey potential users (investigators who register their studies and users of the results) about their needs for feasibility, transparency, and confidentiality 2. Design core requirements for registration and for study protocols based on those developed for other initiatives 3. Determine timing for release of study information 4. Pilot-test updates to registry and use the results to update partner registry or new registry, if required	• Feasibility of registering studies based on researcher and reviewer workload • Core elements to report in study registry, including fields and associated documents (eg, protocol, statistical methods, results) to upload • Balance between transparency and confidentiality (e.g., might establish a "lock box" that provides different access levels to different users) • Time-stamping of all data submitted to registry, including data looks and audit trail of changes made to any of this information
3	Provide incentives for routine registration of HETE studies	Long term	• Collaborate with key stakeholders to encourage implementation of registration requirements. • Encourage publication of findings from registered studies in peer-reviewed journals, just as the investigators of registered clinical trials are encouraged to publish their findings • Issue registry use reports (eg, quarterly reports with key information on registered studies) on the registry website; from time to time published	• Encouragement of registration of HETE RWE studies by funders, journals, regulators, payers, and those who assess health technologies

1. Identify a site to register secondary data use HETE studies
2. Determine the characteristics of a 'good' registration process for HETE studies
3. Provide incentives for routine registration of HETE studies

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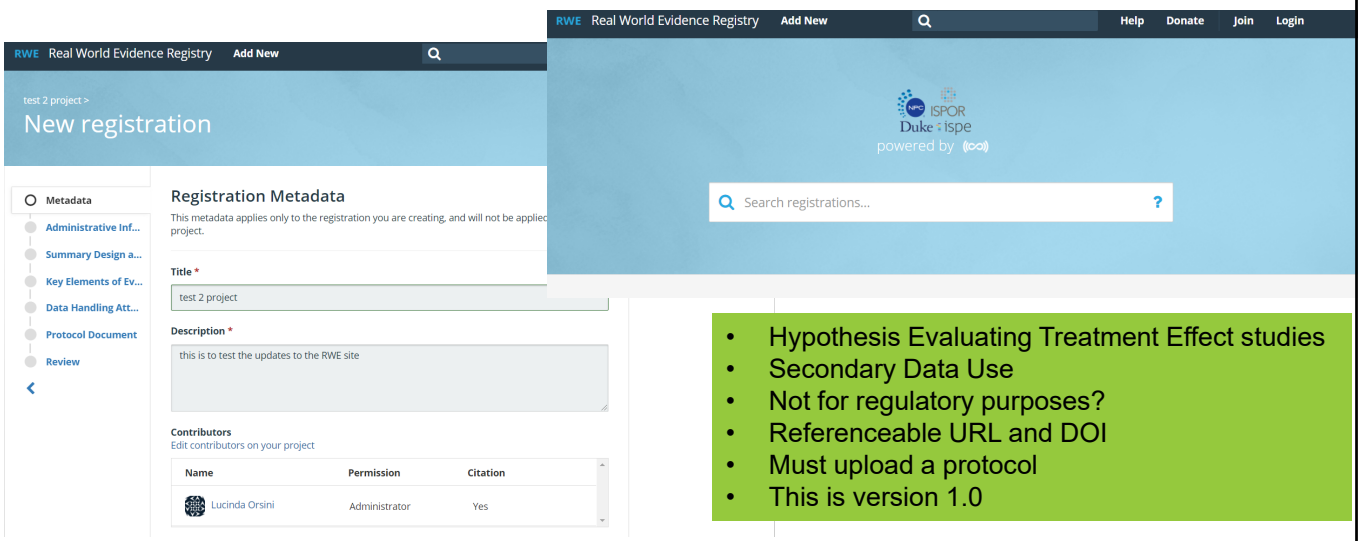
Real World Evidence Registry

https://osf.io/registries/rwe/discover



- Hypothesis Evaluating Treatment Effect studies
- Secondary Data Use
- Not for regulatory purposes?
- Referenceable URL and DOI
- Must upload a protocol
- This is version 1.0

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https://www.ispor.org/strategic-initiatives/real-world-evidence/real-world-evidence-transparency-initiative

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Harmonized RWE [illegible] Elements – Joint Task Force

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BWH

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Joint Task Force

Toward Rigorous Transparency - Harmonization of Protocol Templates for Design and Registration of Observational Hypothesis Evaluating Treatment Effectiveness (HETE) Studies

Shirley V Wang PhD, MSc

Division of Pharmacoepidemiology and Pharmacoeconomics,

Department of Medicine, Brigham and Women's Hospital, Harvard Medical School

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Aims

- Portfolio of activities on transparency and reproducibility
- Momentum

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Disclosures

- Dr. Wang has received salary support from Boehringer Ingelheim, Novartis, and Johnson & Johnson as PI on investigator-initiated grants to Brigham and Women's Hospital

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Activities

1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Activities

1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Jointly published in PDS and ViH 2017

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transparency in process for database studies (e.g. "what did you plan to do?")

WILEY

ORIGINAL REPORT

Good practices for real-world data studies of treatment and/or comparative effectiveness: Recommendations from the joint ISPOR-ISPE Special Task Force on real-world evidence in health care decision making

Marc L. Berger[1] | Harold Sox[2] | Richard J. Willke[3] | Diana L. Brixner[4] | Hans-Georg Eichler[5] | Wim Goettsch[6] | David Madigan[7] | Amr Makady[6] | Sebastian Schneeweiss[8] | Rosanna Tarricone[9] | Shirley V. Wang[8] | John Watkins[10] | C. Daniel Mullins[11]

ispe International Society for Pharmacoepidemiology

clarity of study execution
(e.g. "what did you actually do?)

WILEY

ORIGINAL REPORT

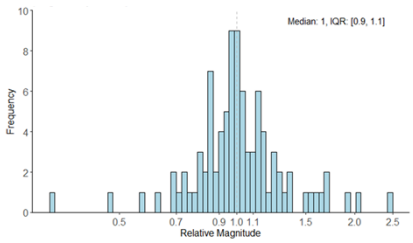
Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0

Shirley V. Wang[1,2] | Sebastian Schneeweiss[1,2] | Marc L. Berger[3] | Jeffrey Brown[4] | Frank de Vries[5] | Ian Douglas[6] | Joshua J. Gagne[1,2] | Rosa Gini[7] | Olaf Klungel[8] | C. Daniel Mullins[9] | Michael D. Nguyen[10] | Jeremy A. Rassen[11] | Liam Smeeth[6] | Miriam Sturkenboom[12] | on behalf of the joint ISPE-ISPOR Special Task Force on Real World Evidence in Health Care Decision Making

Activities

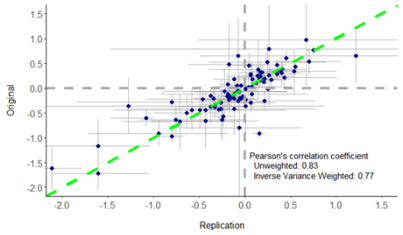
1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Relative magnitude of effect size (HR, RR, OR)
Publication/Reproduction



Median, IQR 1.0 [0.9, 1.1]
Range [0.3, 2.5]

Calibration plot
Publication effect size versus reproduction



Correlation coefficient: 0.8

Co-Led by Shirley V Wang and Sebastian Schneeweiss
Manuscript in preparation, target: *Science*
Multiple presentations at ICPE/ISPOR

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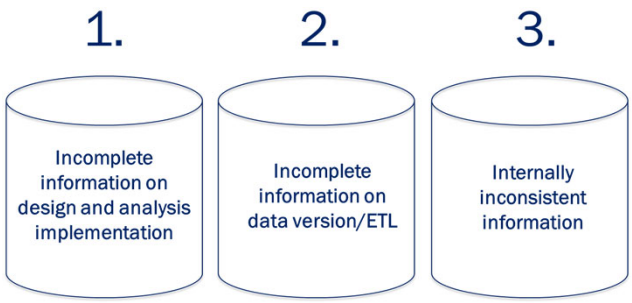
Activities

1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Why was it difficult to reproduce RWE studies?



Co-Led by Shirley V Wang and Sebastian Schneeweiss
Manuscript in preparation, target: *Science*
Multiple presentations at ICPE/ISPOR

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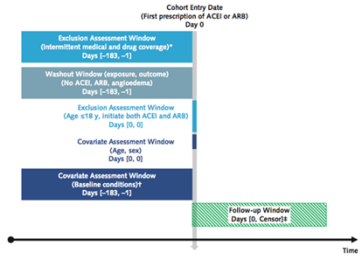
Activities

1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Collaboration between FDA and industry
Manuscript accepted at BMJ

Longitudinal design visualization



Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Graphical Depiction of Longitudinal Study Designs in Health Care Databases

Structured table of study design parameters

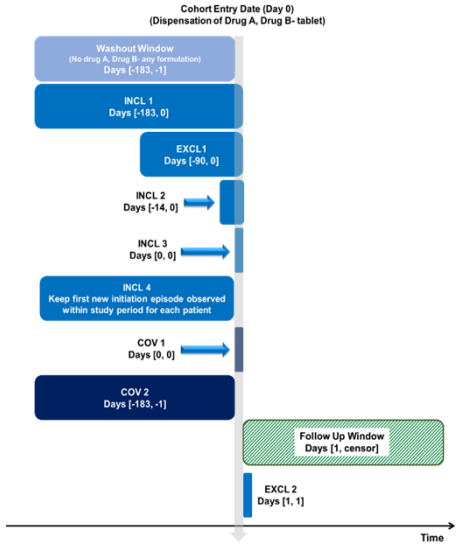
Wang et al, accepted at BMJ

START-RWE Table of Contents

- **Table 1.** Administrative Information
- **Table 2.** Version History
- **Figure 1.** Design Diagram
- **Table 3**. Summary of Study Population Parameters
- **Table 4.** Primary, Secondary, and Subgroup Analysis Specification
- **Table 5**. Sensitivity Analyses
- **Table 6.** Attrition Table
- **Table 7.** Power Calculation
- **Table 8.** Glossary of Terminology
- **Appendices**

Figure 1. Design Diagram

New initiator, active comparator cohort design evaluating risk of outcome Y for Drug A vs Drug B



INCL/EXCL = Inclusion/Exclusion Assessment Window

INCL1
Medical and Drug coverage (45 day gaps allowed)

INCL2
Community acquired pneumonia diagnosis and chest radiography

INCL3
Age between 18-65

INCL4
Keep first new initiator episode

EXCL1
Inpatient hospitalization

EXCL2
Censored on day follow up starts

Censoring
183 days
30-Sep-15
Discharged dead
Disenroll medical or drug coverage (45 day gaps allowed)

COV = Covariate Assessment Window

COV1
Age (continuous)
Gender

COV2
Metastatic cancer
Tumor
Arrhythmia
Congestive heart failure
Dementia
Renal failure
Weight loss
Hemiplegia
Alcohol abuse
Number of inpatient hospitalizations
Number of outpatient visits
Number of emergency department visits
Number of unique generics
Prior prescription of penicillins
Prior prescription of cephalosporins
Prior prescription of sulfonamides
Prior prescription of tetracyclines
Prior prescription of aminoglycosides
Pregnancy at time of initiation

Power point templates, R Shiny App (Developer: Lars Christian Lund)
https://www.repeatinitiative.org/projects.html

Table 3. Summary of Study Population Parameters

Instructions: Fill in the yellow highlighted sections. Example text included.

A. Meta-data about data source and software

This section records the calendar time range used to ascertain cohort entry (index date), as well as the calendar time range of data available for pre-index assessment windows and post-index follow up (study period). The data source name and version are identified, as well as any sampling criteria applied (for example, the data cut only includes patients with a diagnosis of diabetes). If there is data linkage involved, provide a citation or an appendix with description of the linkage (how, performance characteristics)

	Data Source 1	Data Source 2	Data Source 3	Data Source 4
Data Source(s):	XYZ database version 5.1.2	n/a	n/a	n/a
Study Period:	January 1, 2003 - September 30, 2015			
Eligible Cohort Entry Period:	January 1, 2003 - September 30, 2015			
Data Extraction Date/Version:	January 1, 2018			
Data sampling/extraction criteria:	All enrollees in data source between January, 2003 - September 30, 2015			
Type(s) of data:	Commercial claims			
Data linkage:	None			
Data conversion:	ABC Common Data Model version 7.0			
Software to create study population:	Statistical software version 9.4			

Table 3. Summary of Study Population Parameters

Instructions: Fill in the yellow highlighted sections. Example text included.

B. Index Date (day 0) defining criterion

The criterion that define the date of entry to the cohort(s) is specified in this section. There should be one row for each unique definition of study population entry. If the study is descriptive, there may only be one row filled out. An active comparator study may have 2 rows, one for the exposure of interest and one for the comparator.
Check the pre-specified box if the exclusion criterion was specified before beginning data analyses, check the varied for sensitivity box if it was modified as part of sensitivity analyses.

Study population(s)	Day 0 Description	Number of entries	Type of entry	Washout window	Incident with respect to…	Pre-specified	Varied for sensitivity
Exposure	Date of incident dispensation for Drug A (tablets only)	Single	Incident	[-183, 0]	Drug A or B (any formulation)	☐	☐
Comparator	Date of incident dispensation for Drug B (tablets only)	Single	Incident	[-183, 0]	Drug A or B (any formulation)	☐	☐

G. Outcome

Briefly define the outcome conceptually and whether it is the primary outcome of interest. Specify whether the type of outcome is incident (if so, there is a field to specify the washout window to define "incident" occurrences), prevalent or other. Specify whether there are restrictions on care setting or diagnosis position, and which groups or analyses the outcome is measured for. If there are performance characteristics for the algorithm (e.g. PPV) from publications, subsample validation or other sources, provide this information.

Check the pre-specified box if the outcome parameters were specified before beginning data analyses, check the varied for sensitivity box if the parameters were modified as part of sensitivity analyses.

Outcome name	Performance/Source of algorithm	Primary outcome?	Type	Washout window	Care Settings[1]	Primary Dx	Applied to study populations:	Pre-specified	Varied for sensitivity
Myocardial infarction	PPV 90%, Smith 2000 AJE	☒	Incident	[-183, 0]	IP, ED	n/a	Exposure, comparator	☒	☒
Stroke	PPV 85%, in sample of cohort	☐	Incident	[-183, 0]	IP	n/a	Exposure, comparator	☒	☐
Transient ischemic attack (TIA)	no validation	☐	Incident	[-183, 0]	IP, ED	n/a	Exposure, comparator	☒	☐
Major bleeding	Validation of all outcomes with chart review	☐	Incident	[-183, 0]	IP, ED	n/a	Exposure, comparator	☒	☐

H. Follow up

Specify when follow up begins relative to the index date and check the box for each censoring criterion that is applied.

	Day 1	
Begins		
Ends	**Check all that apply**	**Specify**
Outcome	☒	
Death	☒	
Disenrollment	☒	
Day X *(specify day)*	☒	183
End of study period *(specify date)*	☒	30-Sep-15
End of exposure *(specify stockpiling, grace)*	☐	**Stockpiling algorithm:** **Grace period:**
Add/switch exposure *(specify algorithm)*	☒	
Other *(specify)*	☐	

Appendices

Machine readable code algorithms in .csv or other form

A. Study population entry date defining criterion
B. Inclusion criteria
C. Exclusion criteria
D. Covariates
E. Outcome
F. Decisions made when converting to a Common Data Model
G. …

Exclusion criteria	Code	Code Category	Code Type	Description	Route	Strength
Drug A	00003016050	NDC	11	Awesome Drug	tablet	250mg
Drug B	00003016050	NDC	11	Really Cool Drug	tablet	250mg
Drug A	01003016050	NDC	11	Awesome Drug oral	oral suspension	5 ml
Drug B	00803016050	NDC	11	Really Cool Drug injectable	injectable	5 y injectable
Chest radiography	87.44	PX	09	Routine chest x-ray, so described		
Chest radiography	87.49	PX	09	Other chest x-ray		
Chest radiography	71010	PX	C4	Radiologic examination, chest; single view, frontal		
Chest radiography	71015	PX	C4	Radiologic examination, chest; stereo, frontal		

Activities

1. 1st ISPOR/ISPE Joint Task Force
2. REPEAT
3. STaRT-RWE
4. 2nd ISPE/ISPOR Joint Task Force

Develop a standardized RWE study protocol template by harmonizing existing protocol templates, reporting guidelines and checklists.

Co-Led by Shirley V Wang, Bill Crown, Anton Pottegard
Planning manuscript
Planning presentations at ICPE/ISPOR

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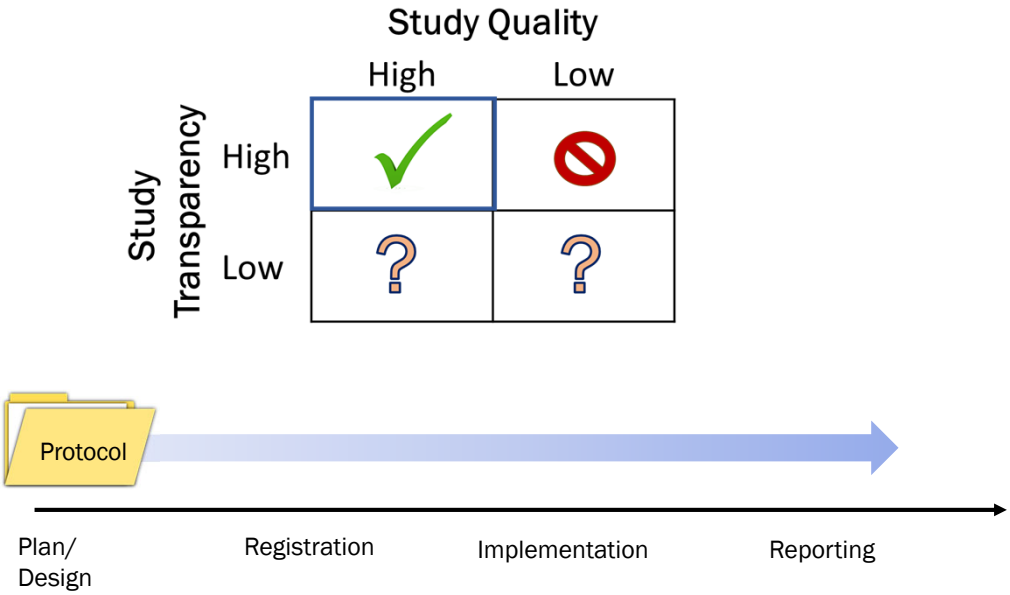
Study Transparency ≠ Study Quality



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2. Berger ML, Sox H, Willke RJ, Brixner DL, Eichler HG, Goettsch W, Madigan D, Makady A, Schneeweiss S, Tarricone R, Wang SV, Watkins J, Daniel Mullins C. **Good practices for real-world data studies of treatment and/or comparative effectiveness: Recommendations from the joint ISPOR-ISPE Special Task Force on real-world evidence in health care decision making.** Pharmacoepidemiol Drug Saf. 2017;26(9):1033-39. PMID: 28913966, PMCID: PMC5639372 (Jointly published in Value and Health PMID: 28964)
3. Schneeweiss S, Rassen JA, Brown JS, Rothman KJ, Happe L, Arlett P, Dal Pan G, Goettsch W, Murk W, Wang SV. **Graphical Depiction of Longitudinal Study Designs in Health Care Databases**. Ann Intern Med. 2019;170:398-406. PMID: 30856654
4. Orsini LS, Monz B, Mullins CD, Van Brunt D, Daniel G, Eichler HG, Graff J, Guerino J, Berger M, Mahendraratnam Lederer N, Jonsson P, Schneeweiss S, Wang SV, Crown W, Goettsch W, Willke R . **Improving Transparency to Build Trust in Real-World Secondary Data Studies for Hypothesis Testing—Why, What, and How: Recommendations and a Road Map from the Real-World Evidence Transparency Initiative.** Pharmacoepidemiol Drug Saf. 2020 [in press].
5. Wang SV, Pinheiro S, Hua W, Arlett P, Uyama Y, Berlin JA, Bartels D, Kahler K, Bessette LG, Schneeweiss S, 2020, "Manuscript: **STaRT-RWE: A structured template for planning and reporting on the implementation of real-world evidence studies**", https://doi.org/10.7910/DVN/6R1KCA, Harvard Dataverse, V2 (accepted BMJ)

Contact: swang1@bwh.harvard.edu

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RWE Study Registr[illegible]n [illegible] and the Centers for Open Science

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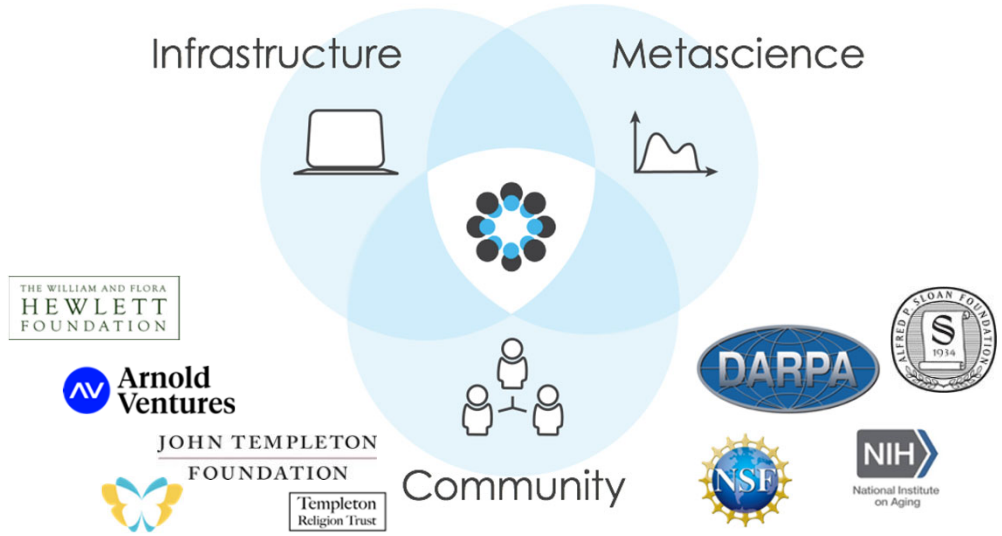
CENTER FOR OPEN SCIENCE

Our mission is to increase the openness, integrity, and reproducibility of research.



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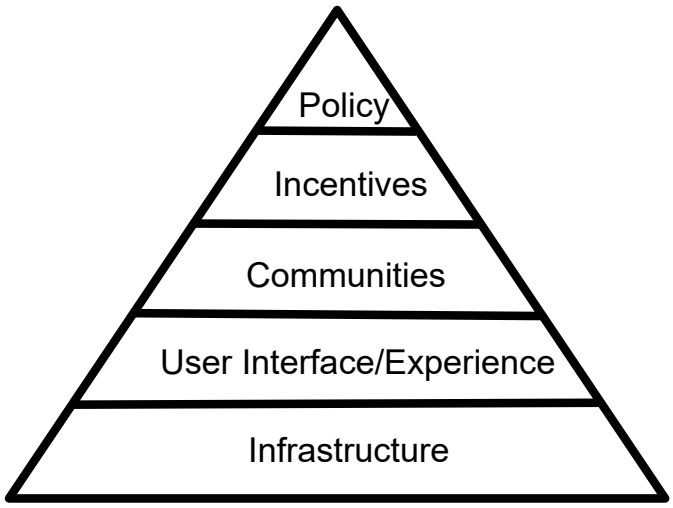
Changing a Research Culture



Make it required

Make it rewarding

Make it normative

Make it easy

Make it possible

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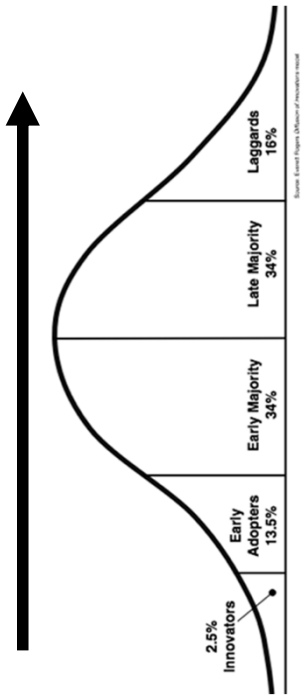

TOP GUIDELINES
TRANSPARENCY AND OPENNESS PROMOTION

Make it required

Make it rewarding

Make it normative

Make it easy

Make it possible

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Disambiguation

Clinical research, economics, psychology, and social sciences use different terminology:

- Preregistration
- Registration
- Prospective trial registration
- Pre-analysis plans

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Confirmatory versus exploratory analysis

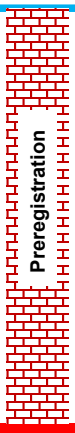
Context of confirmation

Traditional hypothesis testing

Results held to the highest standards of rigor

Goal is to minimize false positives

P-values interpretable



Context of discovery

Pushes knowledge into new areas

Generates: testable hypotheses, models, or theories

Goal is to minimize false negatives

P-values meaningless

Presenting exploratory results as confirmatory increases publishability at the expense of credibility

39

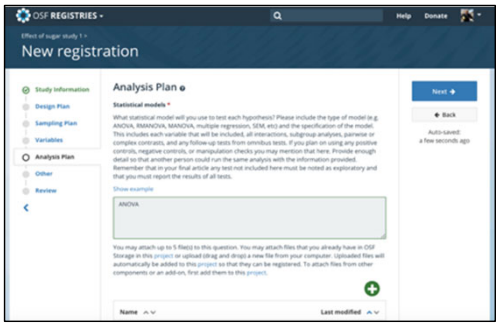
Culture Change: Preregistration

- **Make it possible**
- **Make it easy**
- **Make it normative**
- **Make it rewarded**
- **Make it required**

40

Culture Change: Preregistration

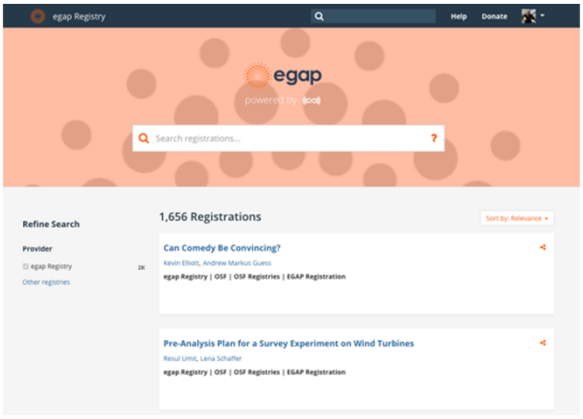
- Make it possible
- Make it easy
- Make it normative
- Make it rewarded
- Make it required



41

Culture Change: Preregistration

- Make it possible
- Make it easy
- Make it normative
- Make it rewarded
- Make it required

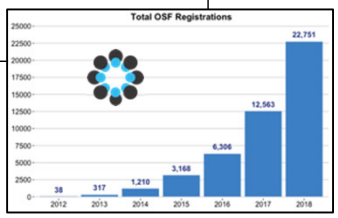


http://cos.io/registries

42

Culture Change: Preregistration

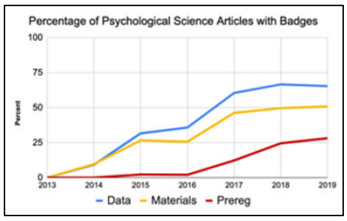
- Make it possible
- Make it easy
- Make it normative
- Make it rewarded
- Make it required



43

Culture Change: Preregistration

- Make it possible
- Make it easy
- Make it normative
- Make it rewarded
- Make it required



PREREGISTRATION CHALLENGE

44

Culture Change: Preregistration

- Make it possible
- Make it easy
- Make it normative
- ~~Make it rewarded~~
- Make it required

TOP GUIDELINES
TRANSPARENCY AND OPENNESS PROMOTION

Level 3 Requirements for Confirmatory or Inferential Research

BMJ Open Science

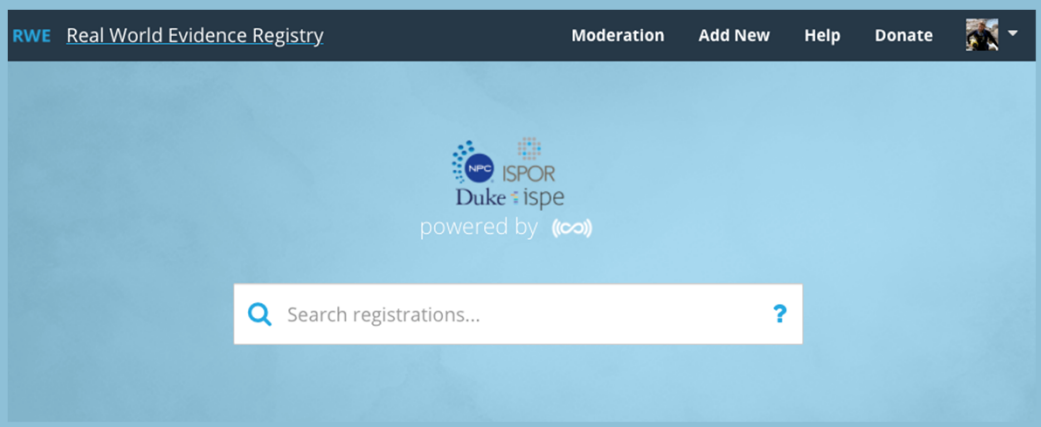
Arnold Ventures

ies INSTITUTE OF EDUCATION SCIENCES

Advances in Methods and Practices in Psychological Science

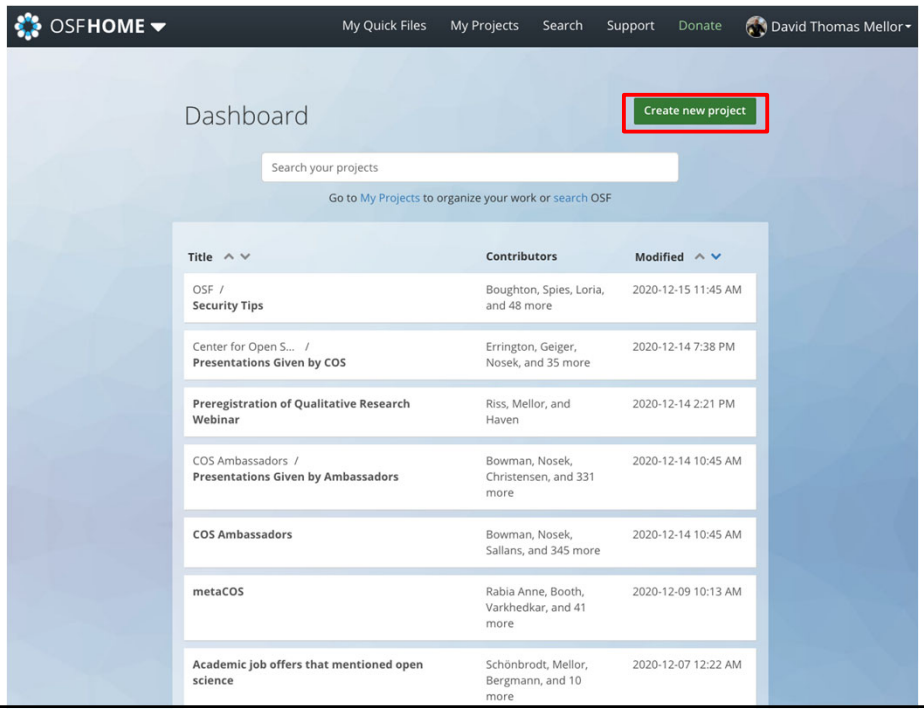
46

osf.io/registries/rwe/

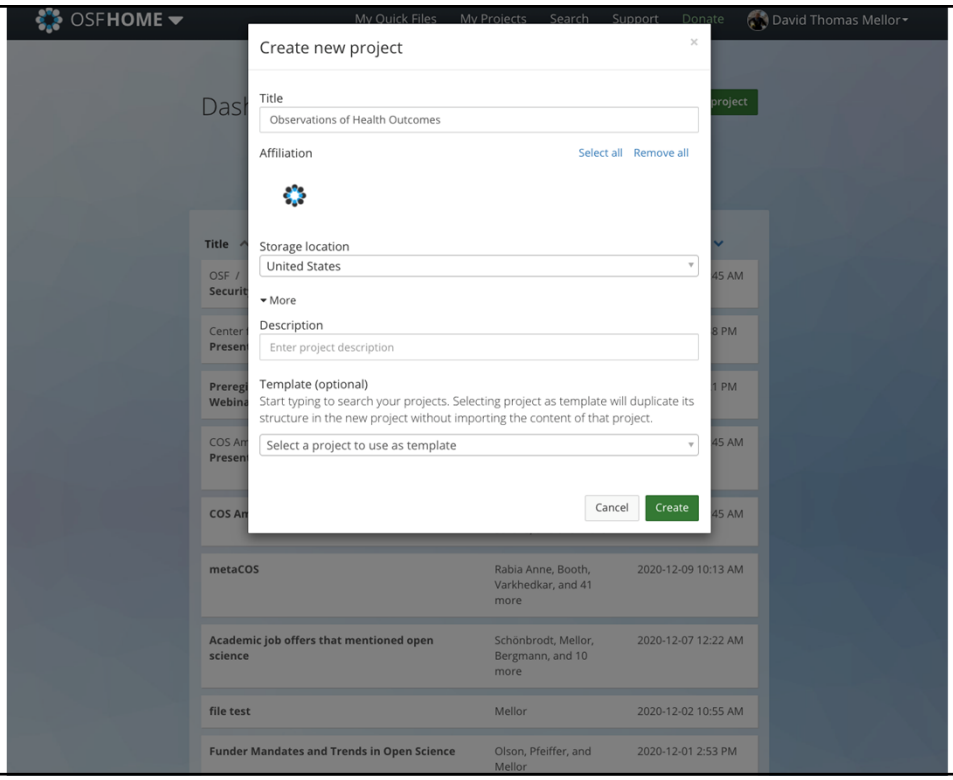


47

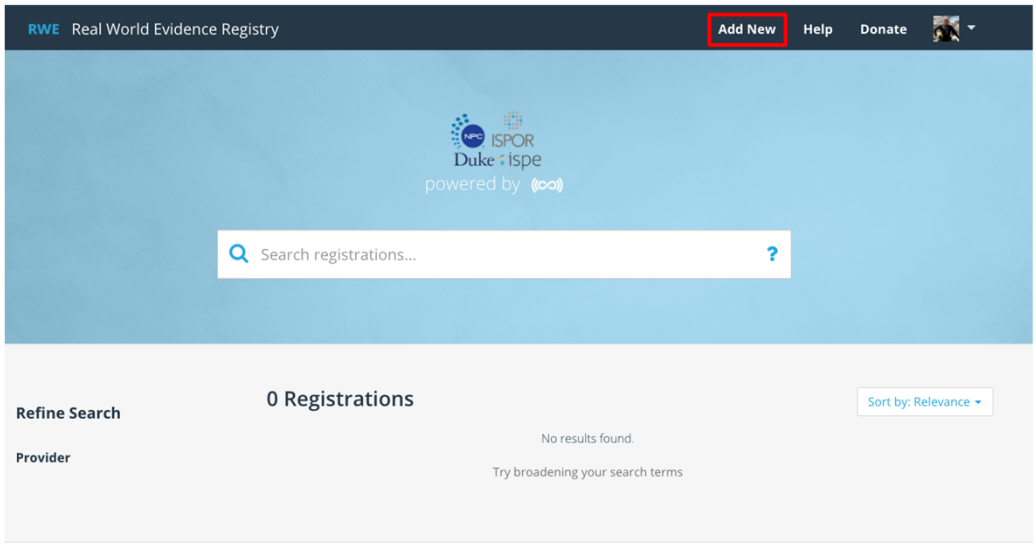
osf.io


OSF HOME
My Quick Files
My Projects
Search
Support
Donate
David Thomas Mellor
Dashboard
Create new project
Search your projects
Go to My Projects to organize your work or search OSF
Title
Contributors
Modified
OSF / Security Tips
Boughton, Spies, Loria, and 48 more
2020-12-15 11:45 AM
Center for Open S... / Presentations Given by COS
Errington, Geiger, Nosek, and 35 more
2020-12-14 7:38 PM
Preregistration of Qualitative Research Webinar
Riss, Mellor, and Haven
2020-12-14 2:21 PM
COS Ambassadors / Presentations Given by Ambassadors
Bowman, Nosek, Christensen, and 331 more
2020-12-14 10:45 AM
COS Ambassadors
Bowman, Nosek, Sallans, and 345 more
2020-12-14 10:45 AM
metaCOS
Rabia Anne, Booth, Varkhedkar, and 41 more
2020-12-09 10:13 AM
Academic job offers that mentioned open science
Schönbrodt, Mellor, Bergmann, and 10 more
2020-12-07 12:22 AM

48


Create new project
Title
Observations of Health Outcomes
Affiliation
Select all
Remove all
Storage location
United States
More
Description
Enter project description
Template (optional)
Start typing to search your projects. Selecting project as template will duplicate its structure in the new project without importing the content of that project.
Select a project to use as template
Cancel
Create

49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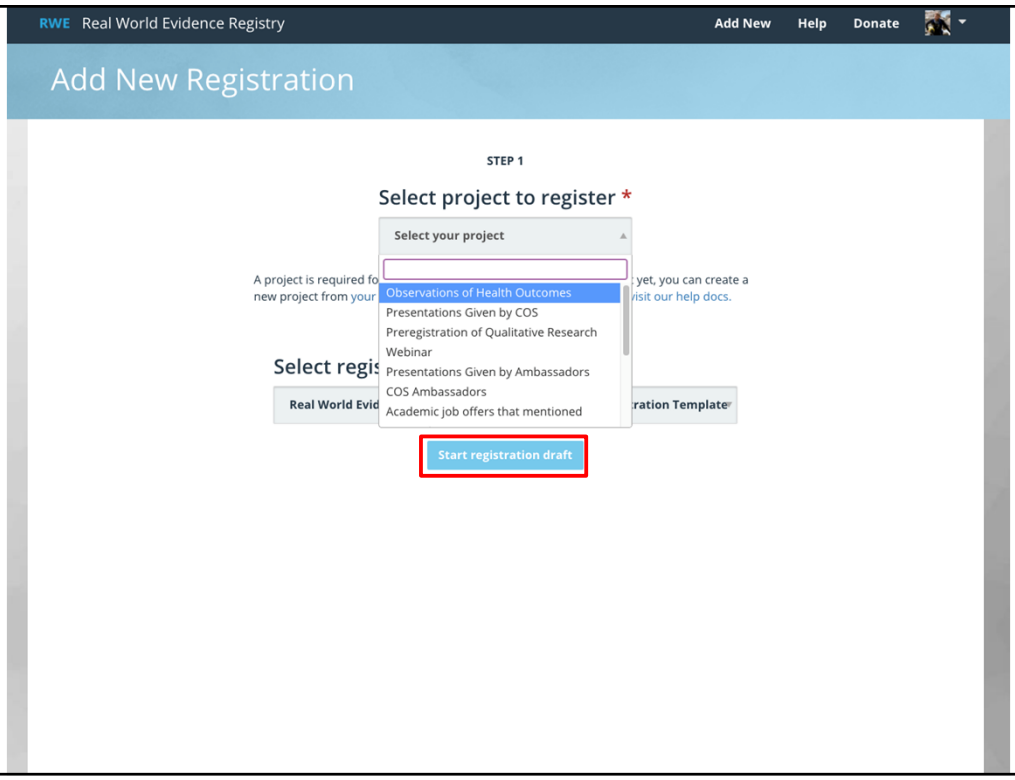
Duke ispe
powered by
Search registrations...
Refine Search
Provider
0 Registrations
Sort by: Relevance
No results found.
Try broadening your search terms

50


RWE Real World Evidence Registry
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Help
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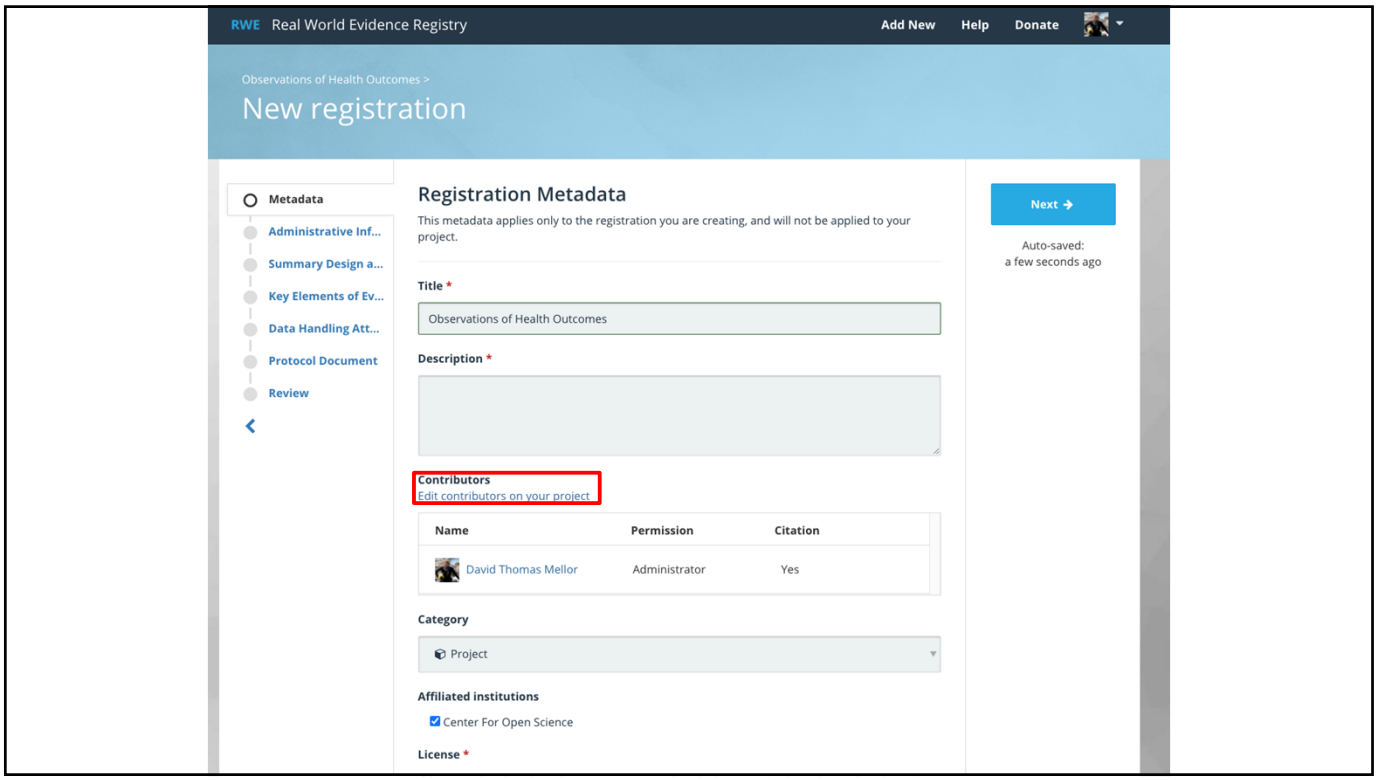
Add New Registration
STEP 1
Select project to register *
Select your project
Observations of Health Outcomes
Presentations Given by COS
Preregistration of Qualitative Research
Webinar
Presentations Given by Ambassadors
COS Ambassadors
Academic job offers that mentioned
Start registration draft

51


RWE Real World Evidence Registry
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Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Registration Metadata
This metadata applies only to the registration you are creating, and will not be applied to your project.
Title *
Observations of Health Outcomes
Description *
Contributors
Edit contributors on your project
Name
Permission
Citation
David Thomas Mellor
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Center For Open Science
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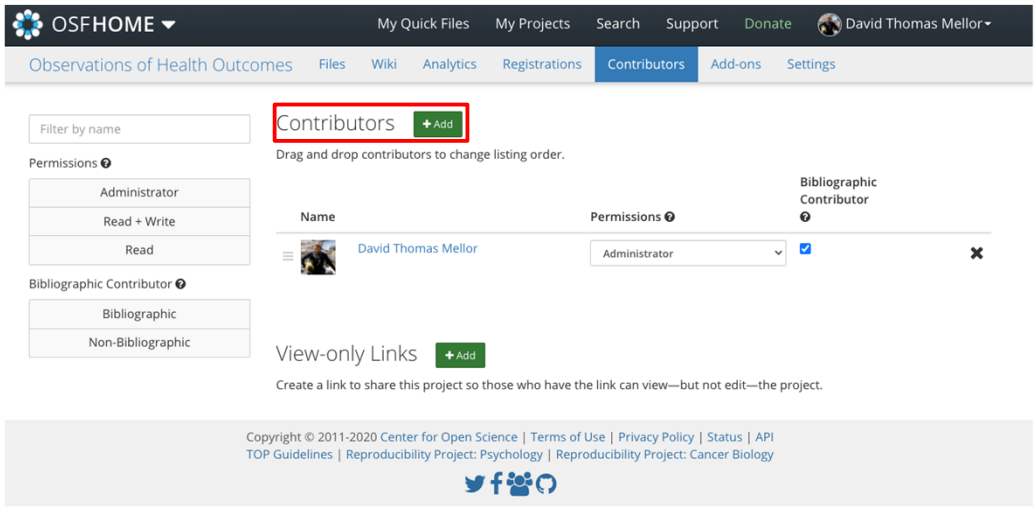
52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Wiki
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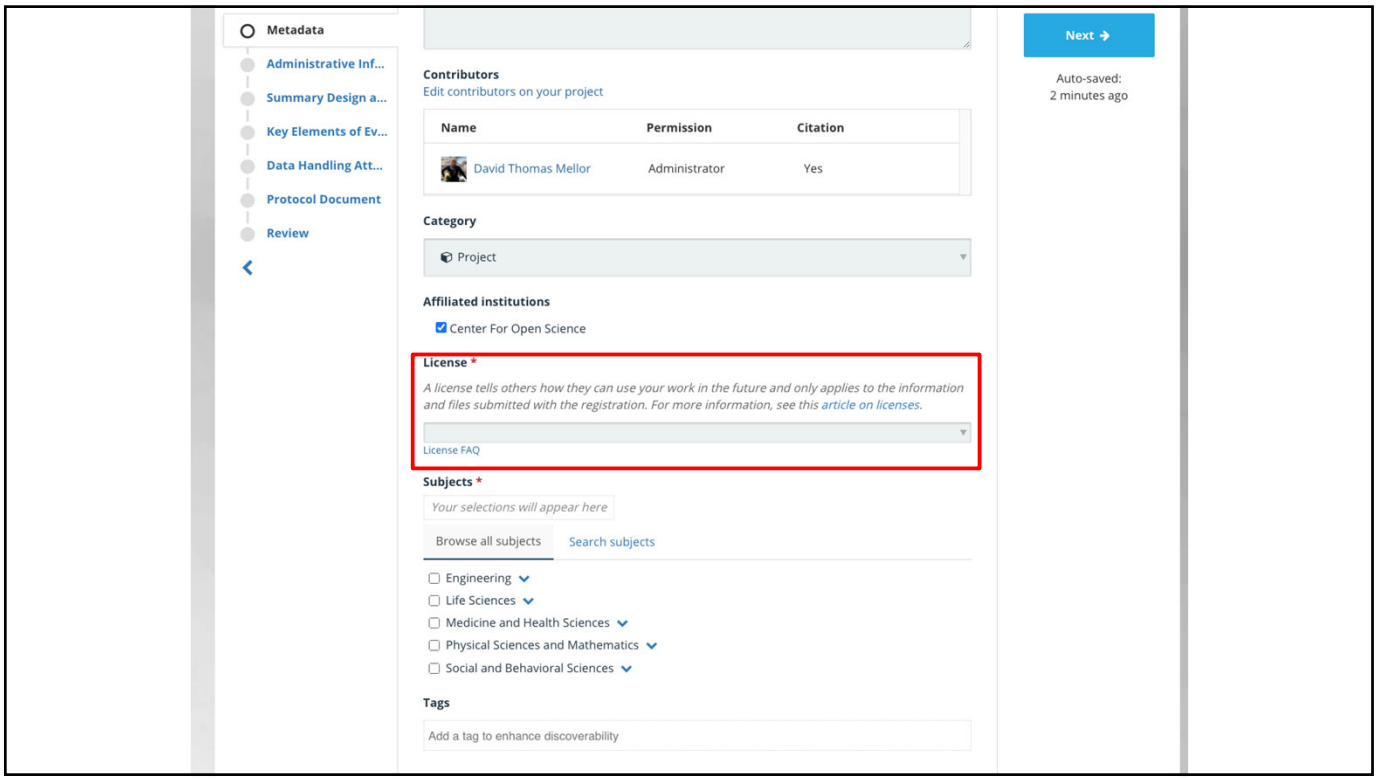
53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Key Elements of Ev...
Data Handling Att...
Protocol Document
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Life Sciences
Medicine and Health Sciences
Physical Sciences and Mathematics
Social and Behavioral Sciences
Tags
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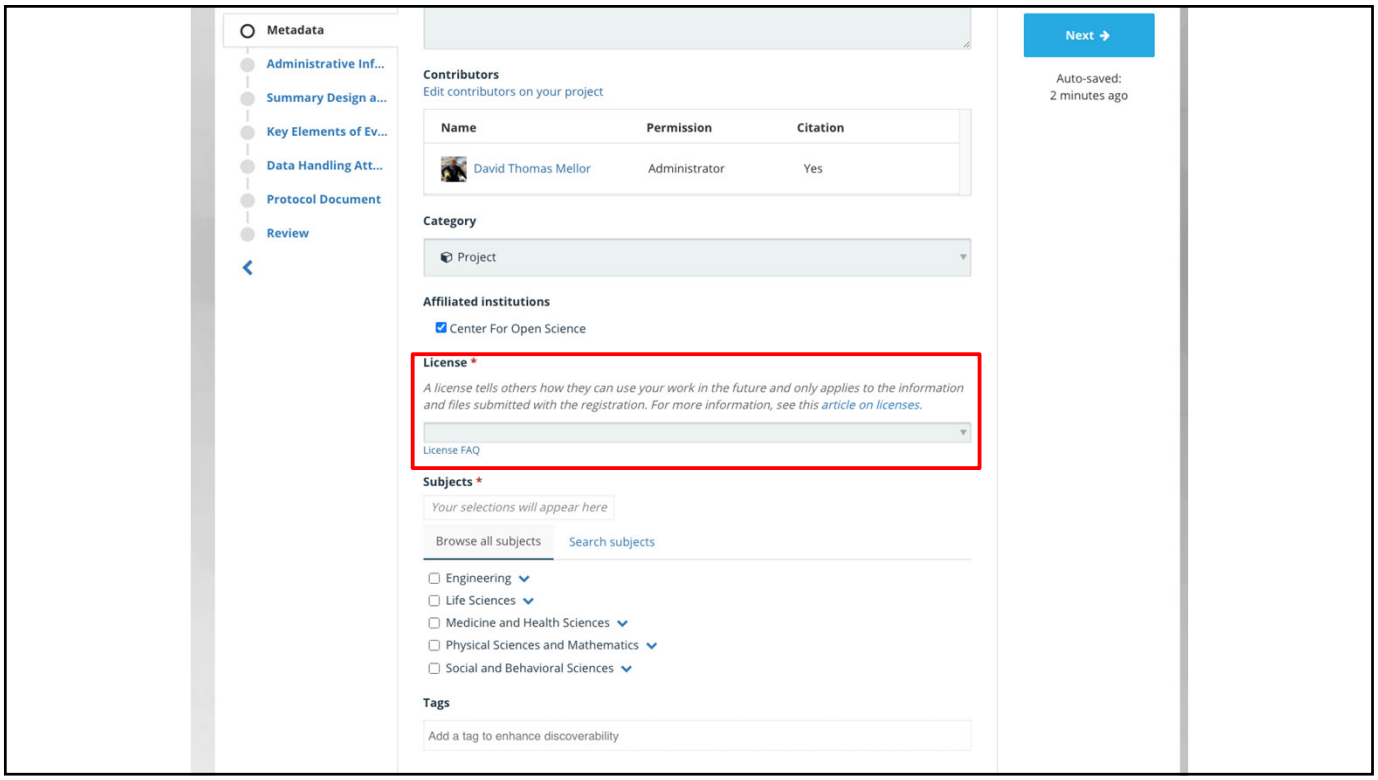
54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Key Elements of Ev...
Data Handling Att...
Protocol Document
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Social and Behavioral Sciences
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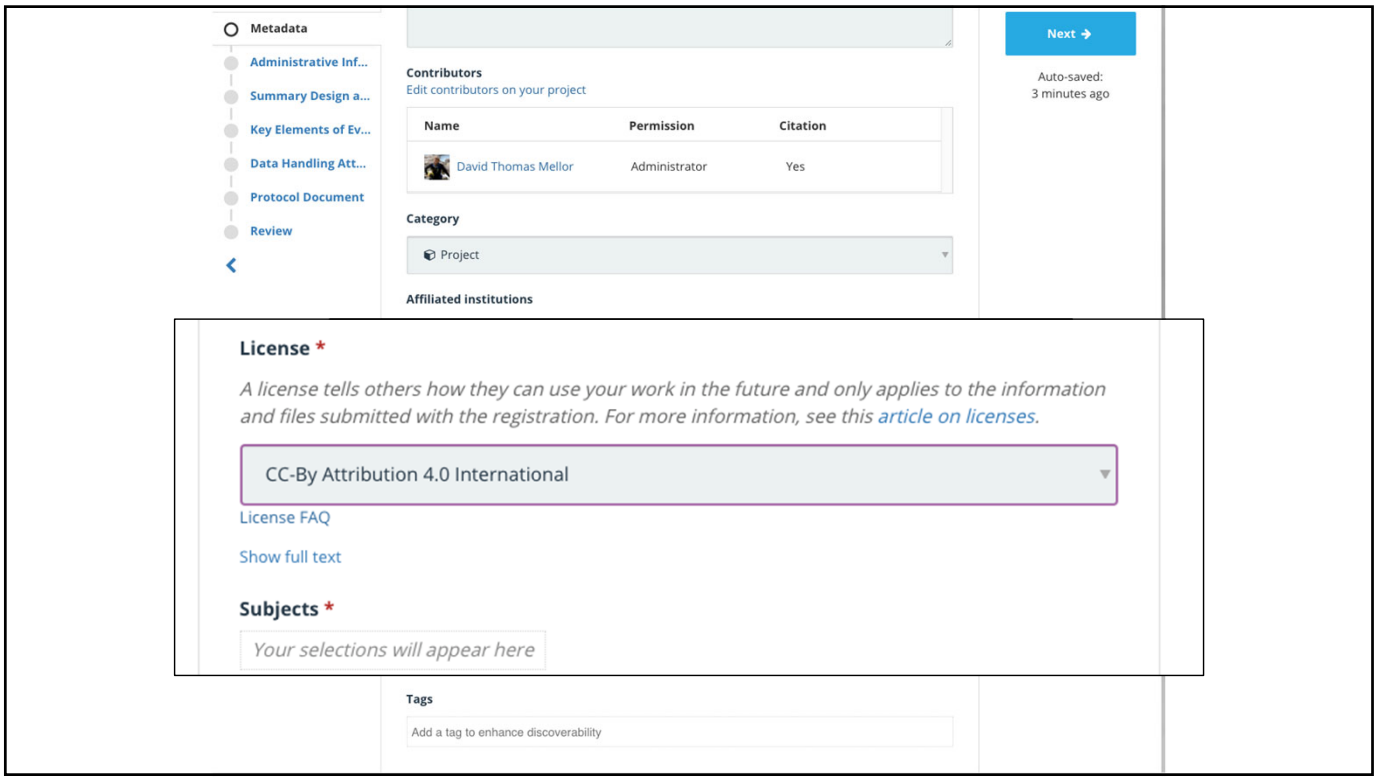
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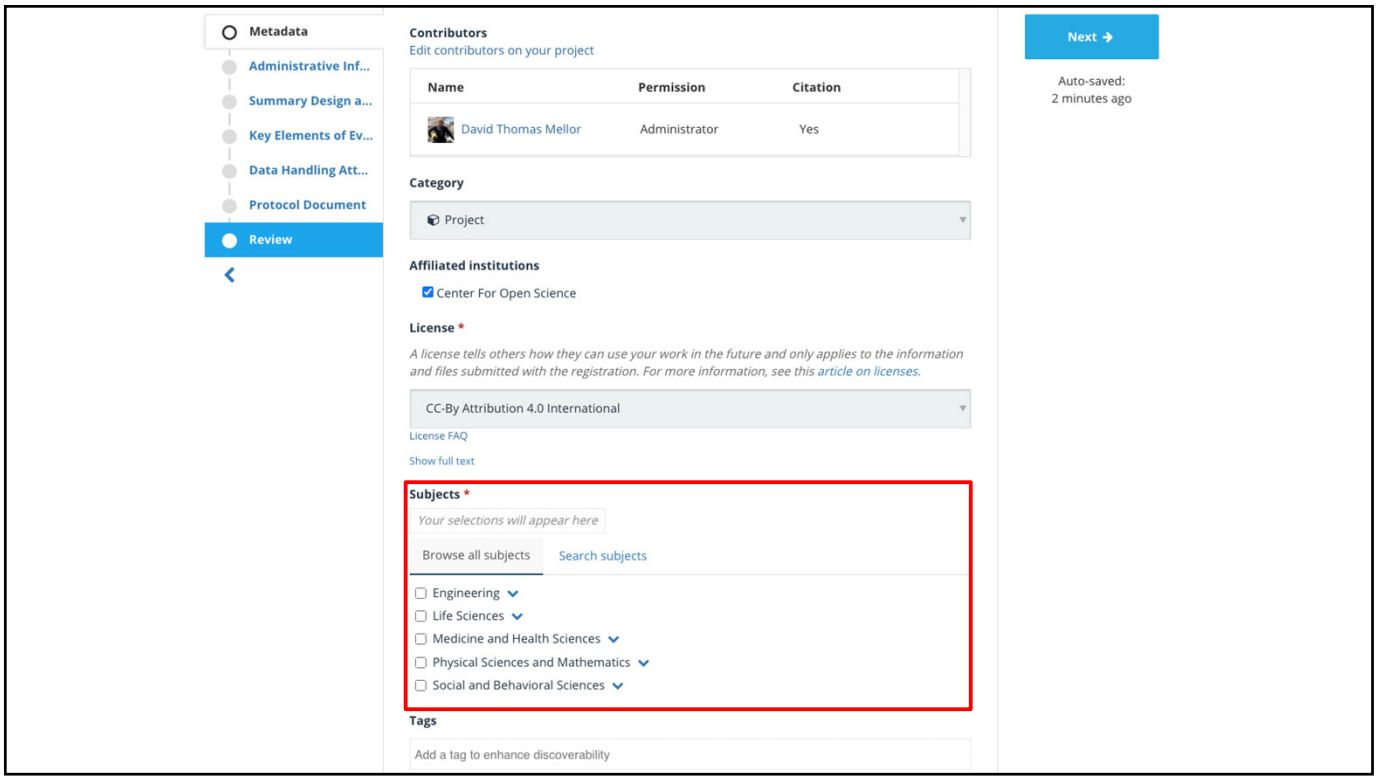
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Summary Design a...
Key Elements of Ev...
Data Handling Att...
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Medicine and Health Sciences
Physical Sciences and Mathematics
Social and Behavioral Sciences
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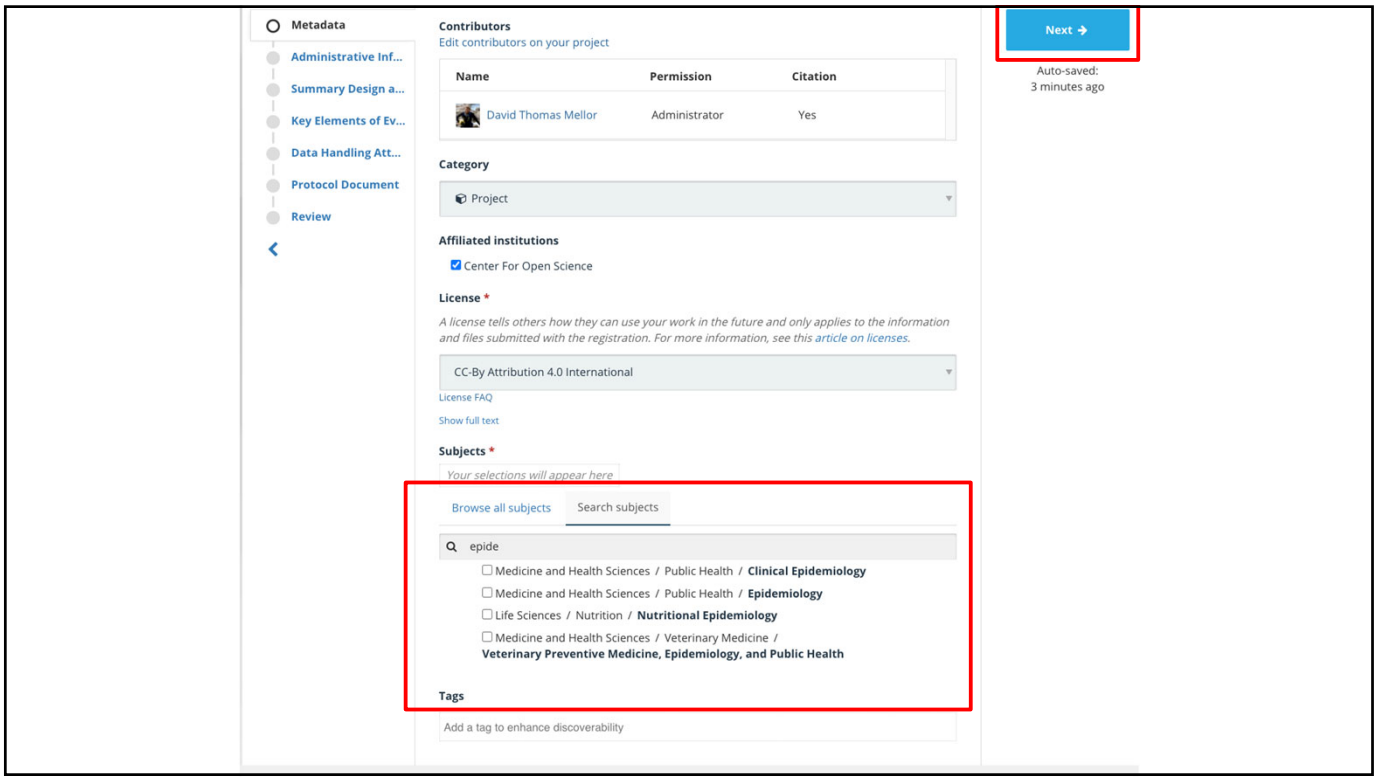
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Summary Design a...
Key Elements of Ev...
Data Handling Att...
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Life Sciences / Nutrition / Nutritional Epidemiology
Medicine and Health Sciences / Veterinary Medicine / Veterinary Preventive Medicine, Epidemiology, and Public Health
Tags
Add a tag to enhance discoverability
Next
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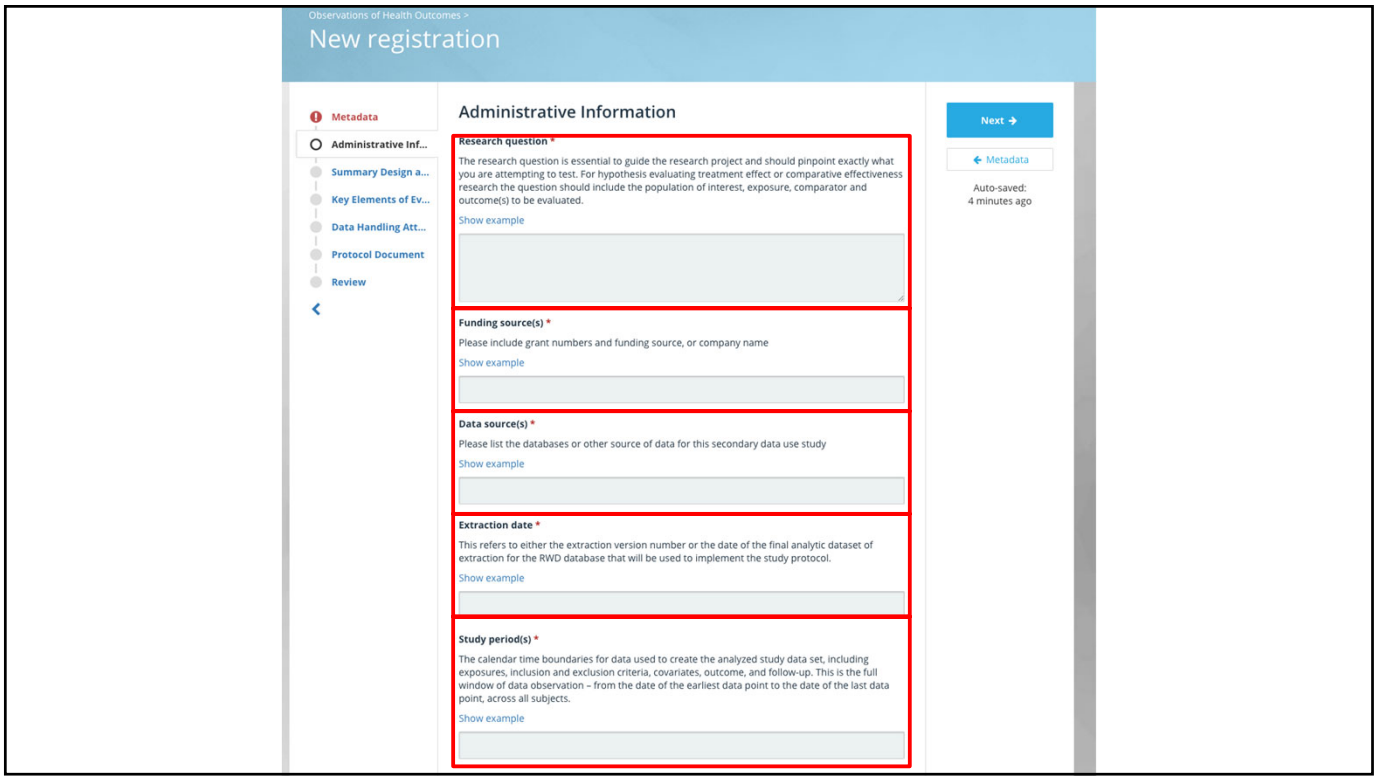
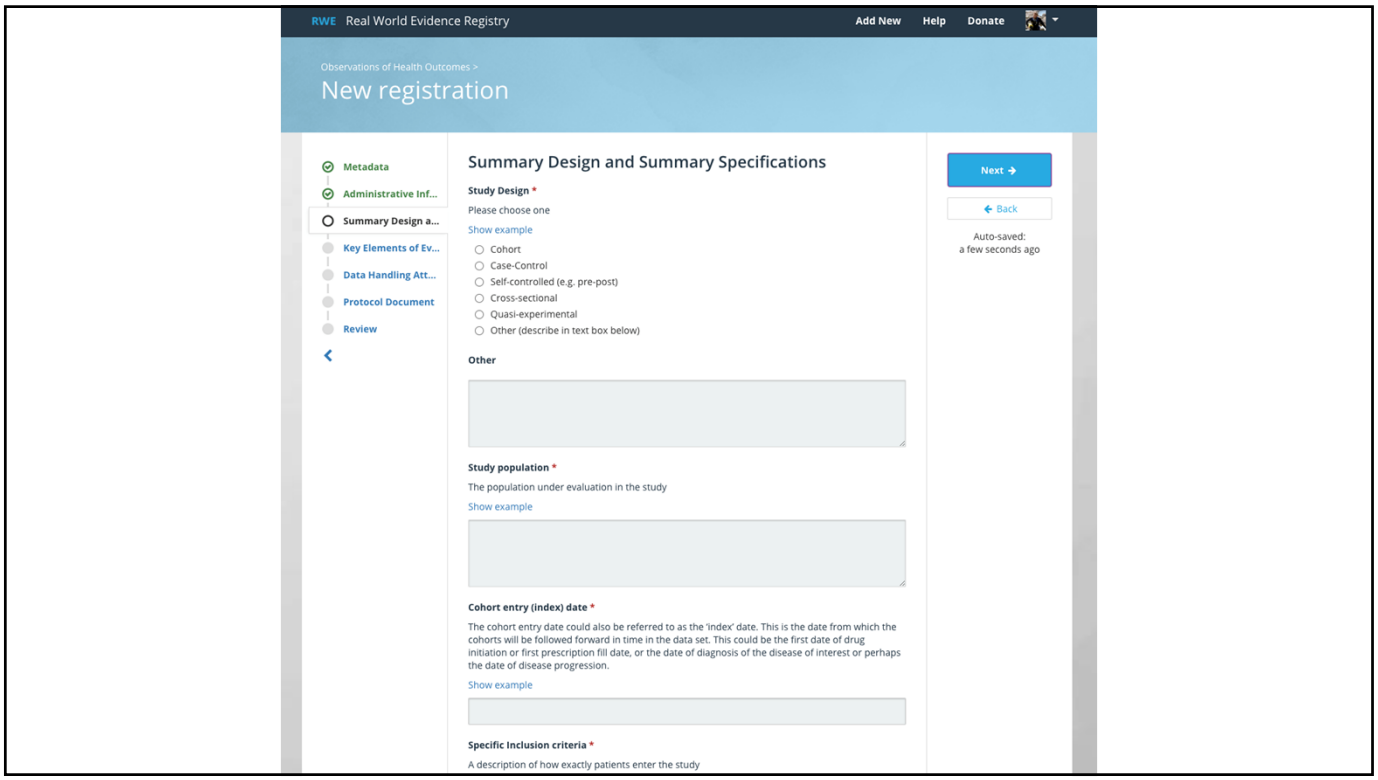
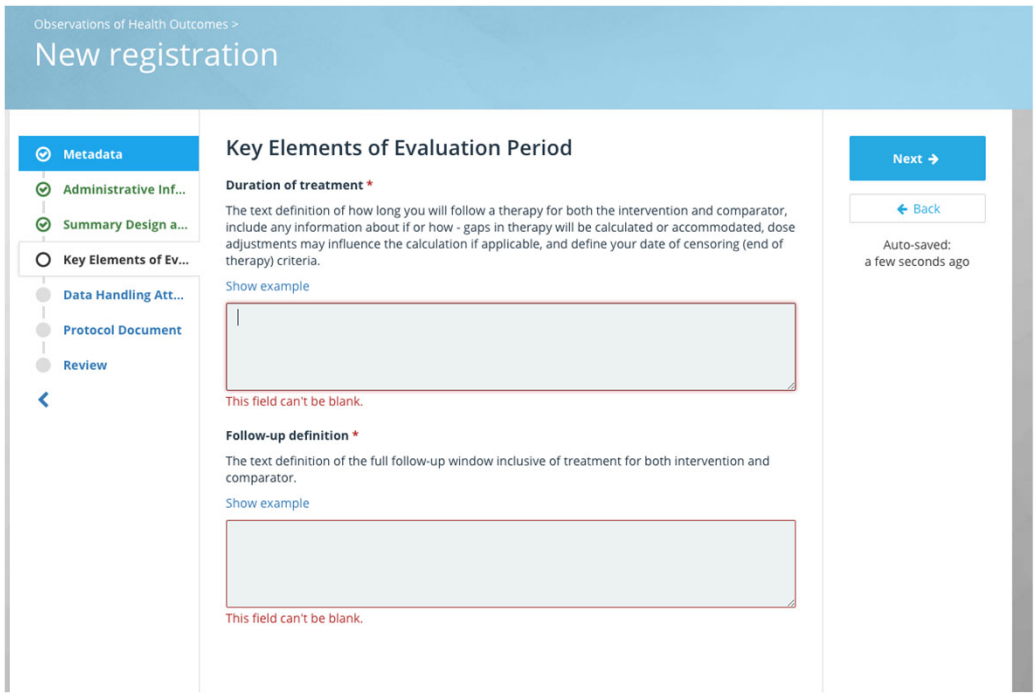
58


Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Administrative Information
Research question *
The research question is essential to guide the research project and should pinpoint exactly what you are attempting to test. For hypothesis evaluating treatment effect or comparative effectiveness research the question should include the population of interest, exposure, comparator and outcome(s) to be evaluated.
Show example
Funding source(s) *
Please include grant numbers and funding source, or company name
Show example
Data source(s) *
Please list the databases or other source of data for this secondary data use study
Show example
Extraction date *
This refers to either the extraction version number or the date of the final analytic dataset of extraction for the RWD database that will be used to implement the study protocol.
Show example
Study period(s) *
The calendar time boundaries for data used to create the analyzed study data set, including exposures, inclusion and exclusion criteria, covariates, outcome, and follow-up. This is the full window of data observation – from the date of the earliest data point to the date of the last data point, across all subjects.
Show example
Next
Metadata
Auto-saved: 4 minutes ago

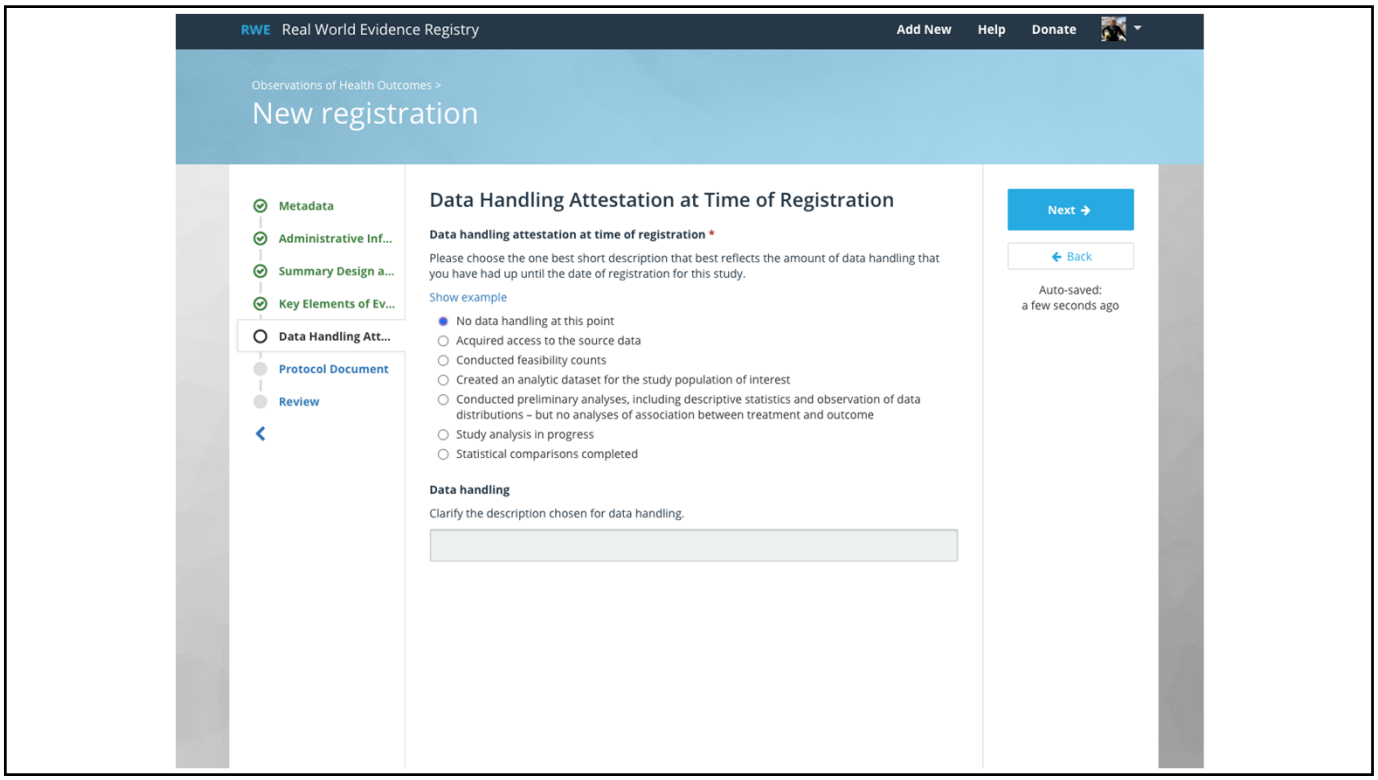
59


RWE Real World Evidence Registry
Add New
Help
Donate
Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Summary Design and Summary Specifications
Study Design *
Please choose one
Show example
Cohort
Case-Control
Self-controlled (e.g. pre-post)
Cross-sectional
Quasi-experimental
Other (describe in text box below)
Other
Study population *
The population under evaluation in the study
Show example
Cohort entry (index) date *
The cohort entry date could also be referred to as the 'index' date. This is the date from which the cohorts will be followed forward in time in the data set. This could be the first date of drug initiation or first prescription fill date, or the date of diagnosis of the disease of interest or perhaps the date of disease progression.
Show example
Specific Inclusion criteria *
A description of how exactly patients enter the study
Next
Back
Auto-saved:
a few seconds ago

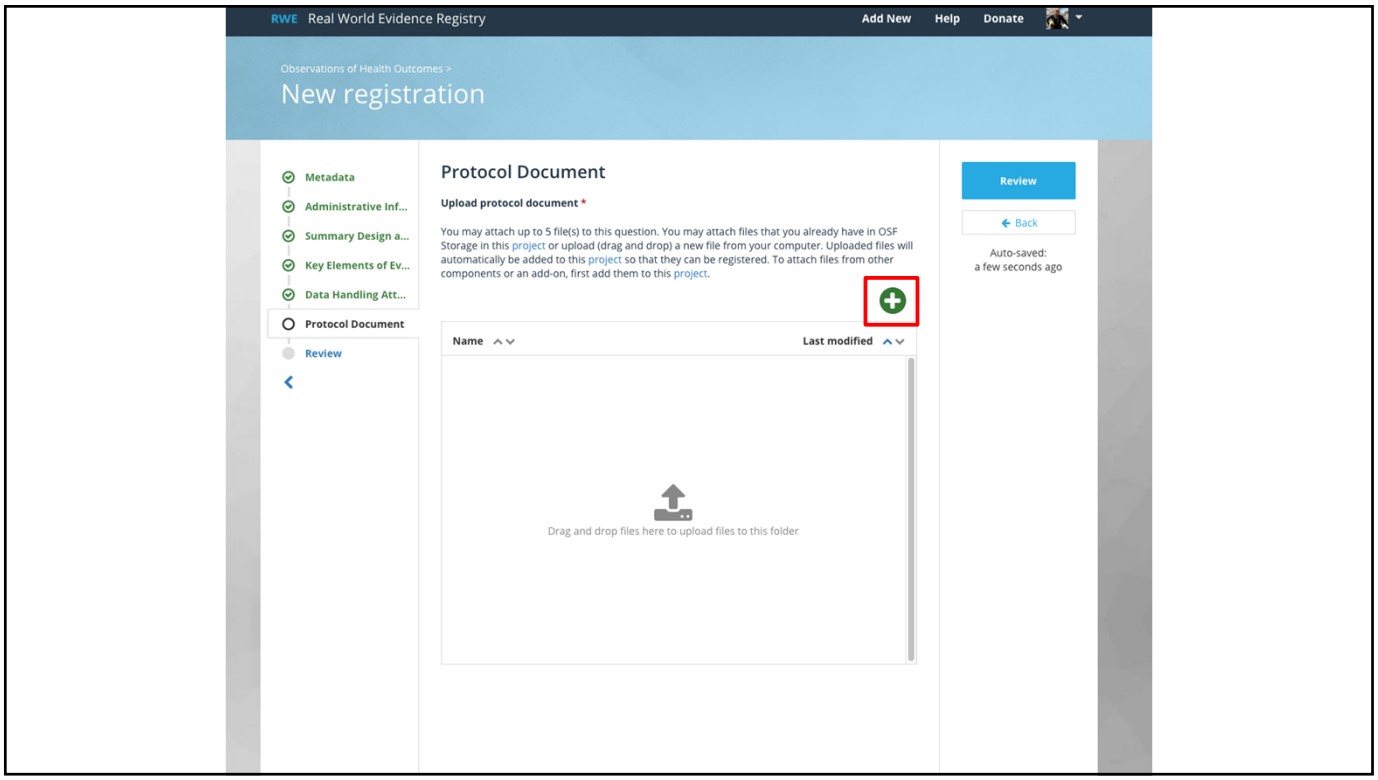
60


Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Key Elements of Evaluation Period
Duration of treatment *
The text definition of how long you will follow a therapy for both the intervention and comparator, include any information about if or how - gaps in therapy will be calculated or accommodated, dose adjustments may influence the calculation if applicable, and define your date of censoring (end of therapy) criteria.
Show example
This field can't be blank.
Follow-up definition *
The text definition of the full follow-up window inclusive of treatment for both intervention and comparator.
Show example
This field can't be blank.
Next
Back
Auto-saved:
a few seconds ago

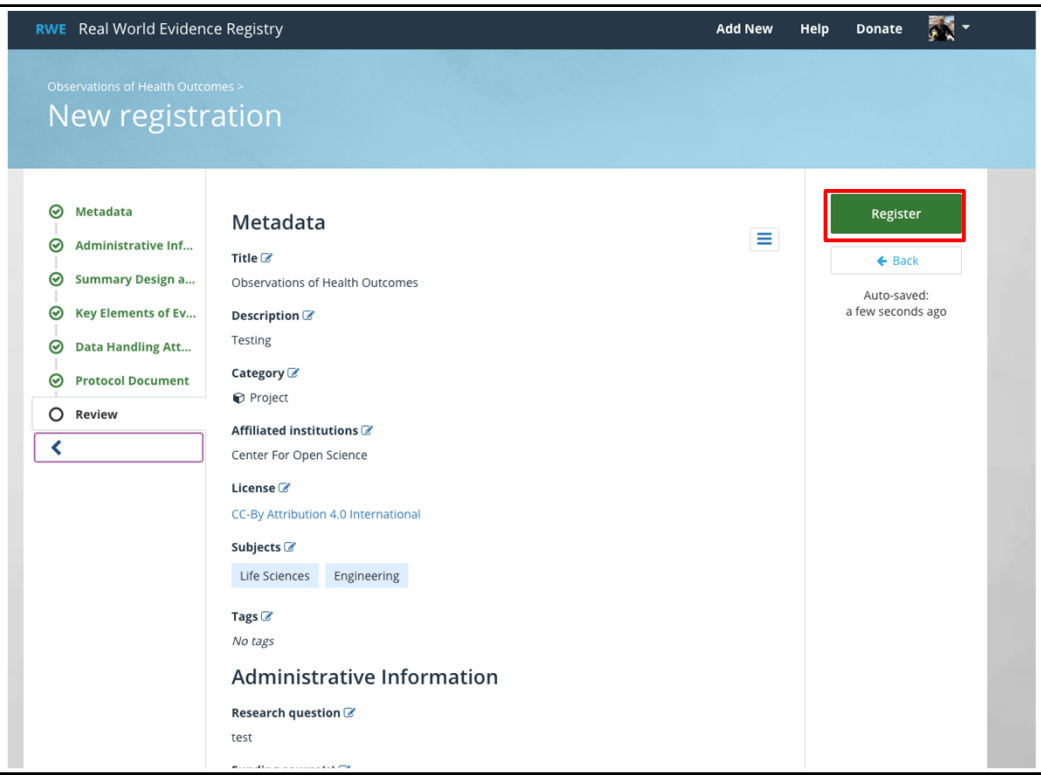
61


RWE Real World Evidence Registry
Add New
Help
Donate
Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Data Handling Attestation at Time of Registration
Data handling attestation at time of registration *
Please choose the one best short description that best reflects the amount of data handling that you have had up until the date of registration for this study.
Show example
No data handling at this point
Acquired access to the source data
Conducted feasibility counts
Created an analytic dataset for the study population of interest
Conducted preliminary analyses, including descriptive statistics and observation of data distributions – but no analyses of association between treatment and outcome
Study analysis in progress
Statistical comparisons completed
Data handling
Clarify the description chosen for data handling.
Next
Back
Auto-saved:
a few seconds ago

62


RWE Real World Evidence Registry
Add New
Help
Donate
Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Protocol Document
Upload protocol document *
You may attach up to 5 file(s) to this question. You may attach files that you already have in OSF Storage in this project or upload (drag and drop) a new file from your computer. Uploaded files will automatically be added to this project so that they can be registered. To attach files from other components or an add-on, first add them to this project.
Name
Last modified
Drag and drop files here to upload files to this folder
Review
Back
Auto-saved:
a few seconds ago

63


RWE Real World Evidence Registry
Add New
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Donate
Observations of Health Outcomes >
New registration
Metadata
Administrative Inf...
Summary Design a...
Key Elements of Ev...
Data Handling Att...
Protocol Document
Review
Metadata
Title
Observations of Health Outcomes
Description
Testing
Category
Project
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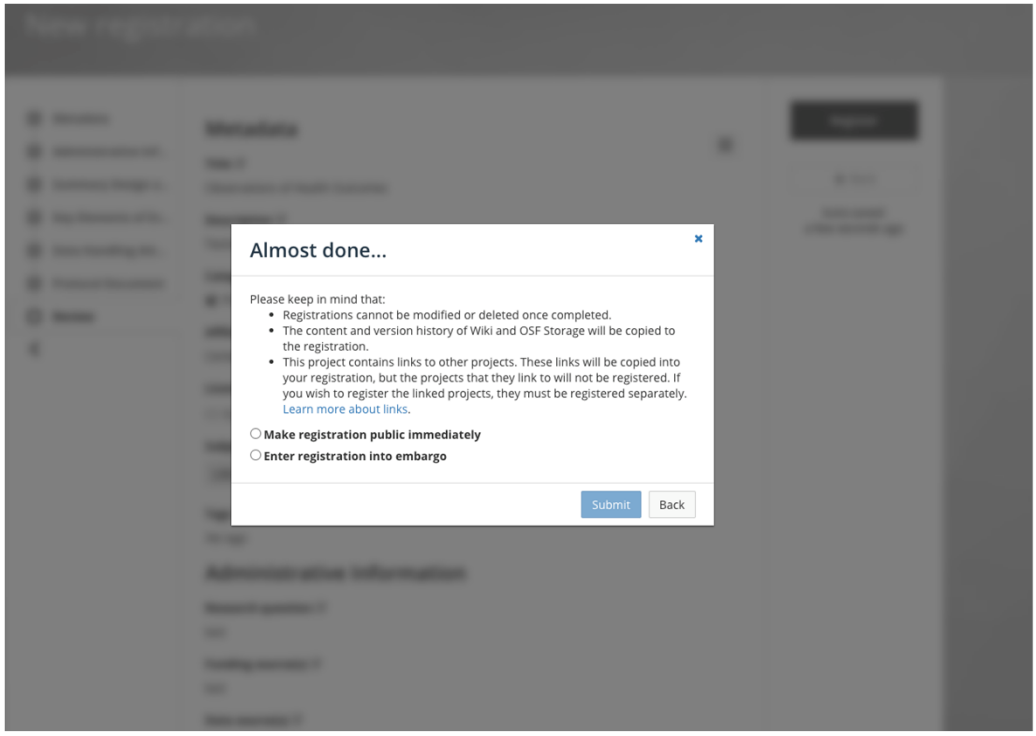
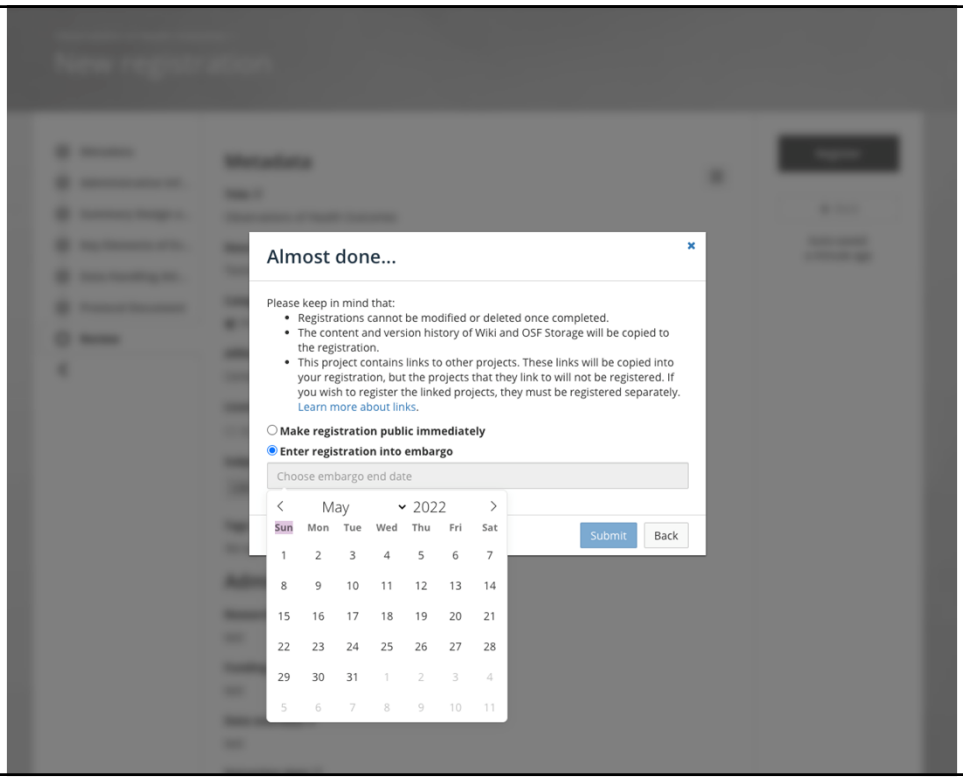
Subjects
Life Sciences
Engineering
Tags
No tags
Administrative Information
Research question
test
Register
Back
Auto-saved:
a few seconds ago

64

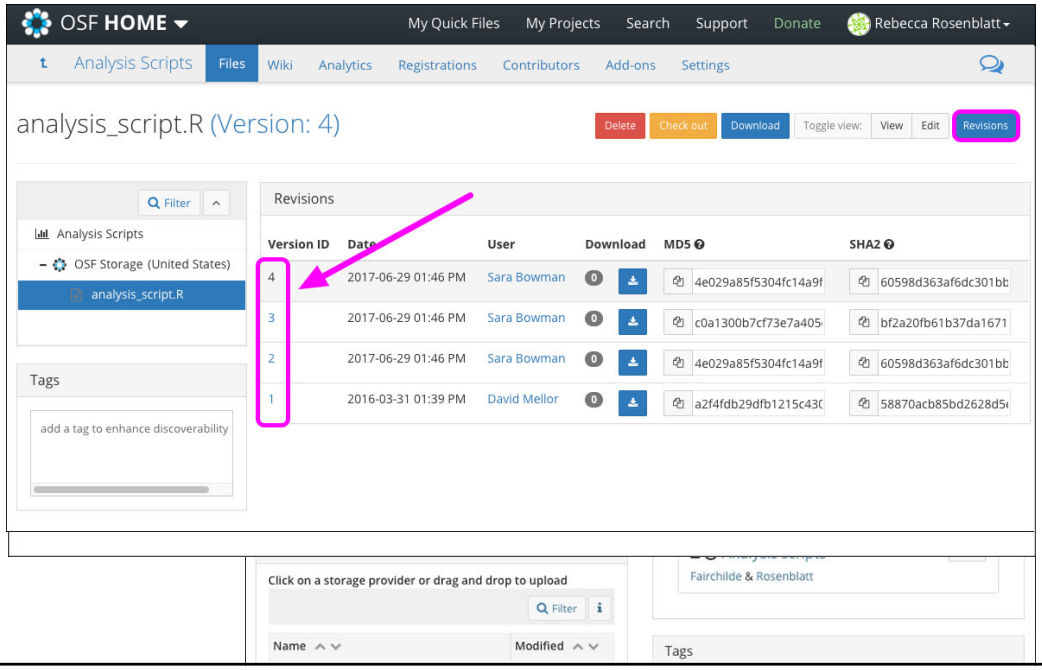

Almost done...
Please keep in mind that:
Registrations cannot be modified or deleted once completed.
The content and version history of Wiki and OSF Storage will be copied to the registration.
This project contains links to other projects. These links will be copied into your registration, but the projects that they link to will not be registered. If you wish to register the linked projects, they must be registered separately.
Learn more about links.
Make registration public immediately
Enter registration into embargo
Submit
Back

65

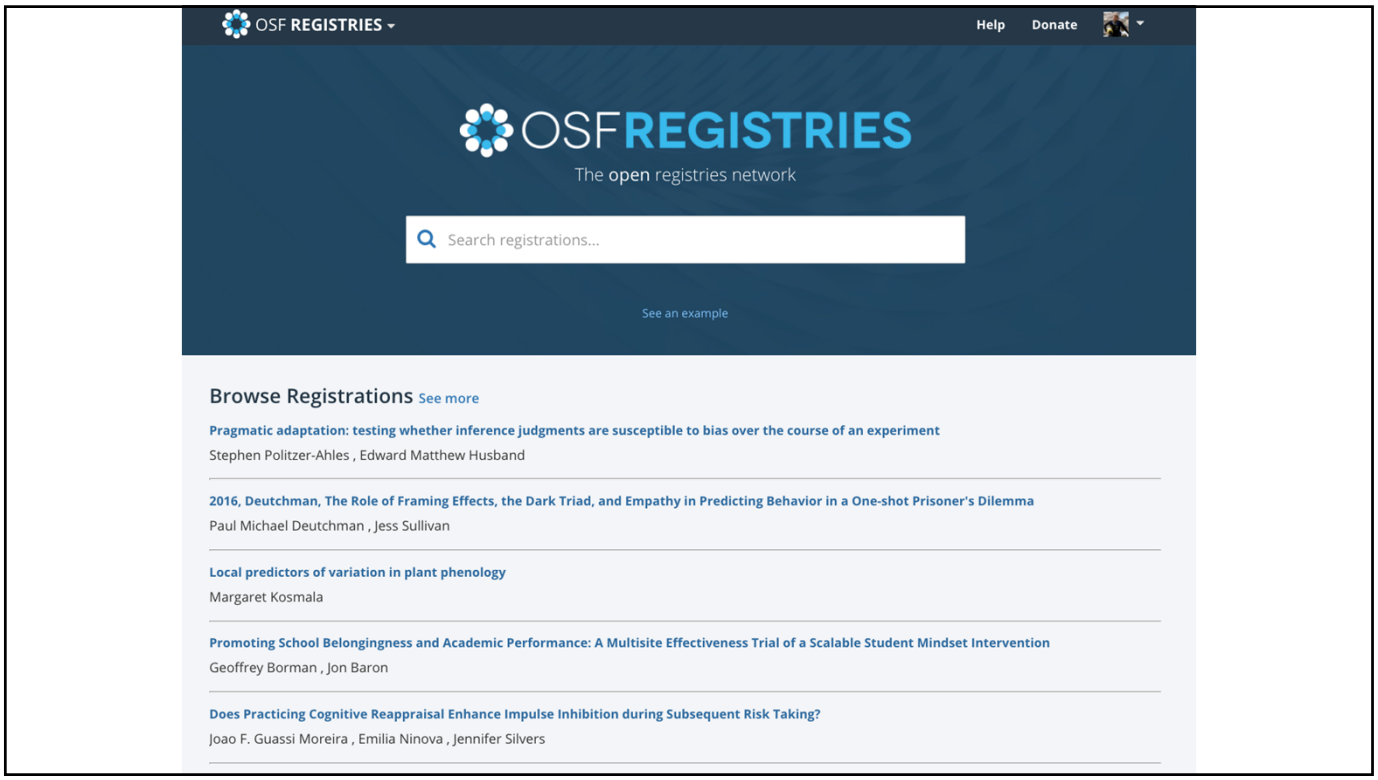


66

Version Control for Protocols



67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Paul Michael Deutchman , Jess Sullivan
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Margaret Kosmala
Promoting School Belongingness and Academic Performance: A Multisite Effectiveness Trial of a Scalable Student Mindset Intervention
Geoffrey Borman , Jon Baron
Does Practicing Cognitive Reappraisal Enhance Impulse Inhibition during Subsequent Risk Taking?
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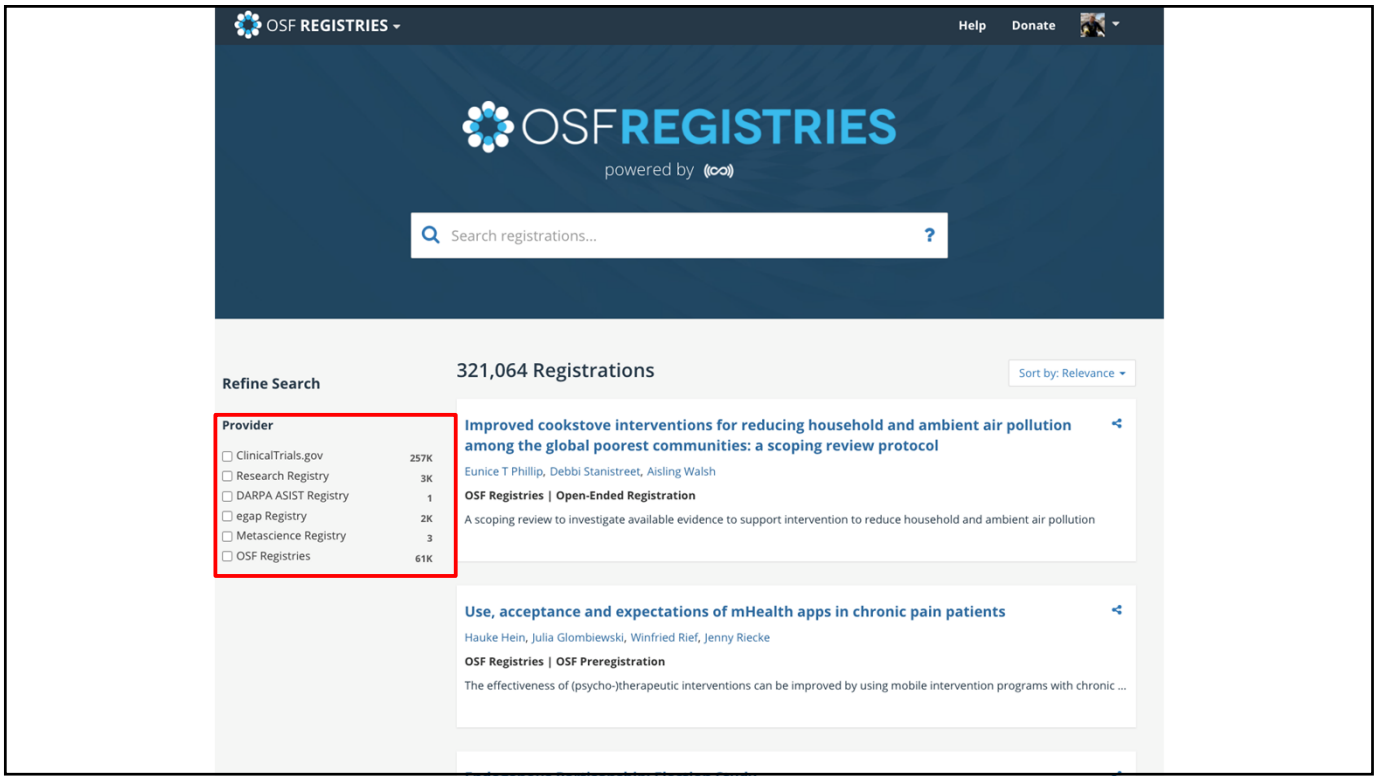
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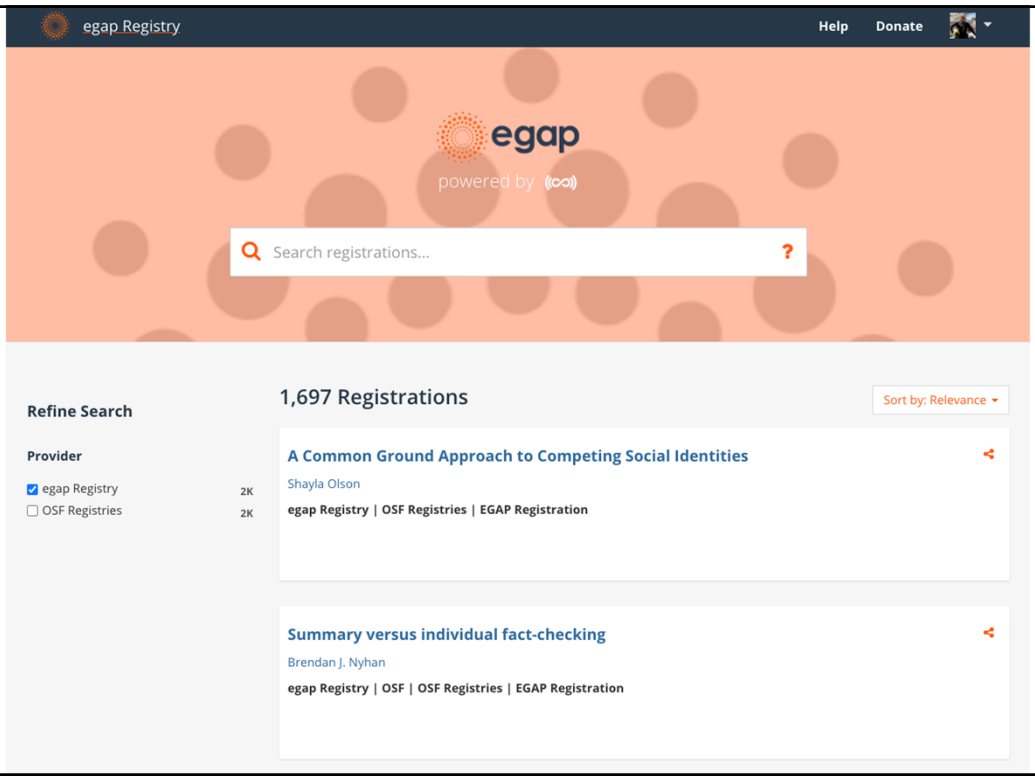

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Thank you!

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