

# CER Demo Walkthrough: Aspiration Catheter

Welcome to the walkthrough of the *Medical Device: Aspiration Catheter “Penumbra Indigo”* demo Nest for Clinical Evaluation Reports (open in your original tab). In this walkthrough, we'll explain the core functionalities of Nested Knowledge through this Nest. We encourage you to work through the Nest as you follow the walkthrough. The Nest available to you is a copy of the original and may be freely modified, so roll up your sleeves and get your hands dirty!

This Nest is a demonstration of a previously-completed review as part of a CER project, presenting the tools at each stage to appraise the Aspiration Catheter: Penumbra Indigo. It is partially completed to allow you to explore the site.

## Nest Home

Home: (Demo) CER of Aspiration Catheter

Nest Home

Dashboard

Settings

Literature Search

1 / 1

Other Sources

Duplicate Review

Search Exploration

Abstract Screening

20 / 49

Configure Screening

Full Text Screening

5 / 9

Tagging

2 / 4

Configure Tagging

Study Inspector

Synthesis

Manuscript Editor

Abstract Editor

Export

Show Table of Contents

Protocol

This Protocol is a recommended template to document your approach, but may be modified to better fit your review. Hit Edit to get started!

Clinical Data Appraisal Protocol

This document provides the results of the literature search that is performed as part of the Clinical Evaluation of the Aspiration Catheter: Penumbra Indigo. The search is performed according to the applicable Clinical Evaluation Plan. In this nest, the search terms used, the period of the search and the exclusion criteria are presented. The found articles are given with their full reference.

Introduction

Papers identified in the literature searches and retained following the selection process will be subject to detailed appraisal using the criteria defined in Sections B-1.1 and B-1.2 together with other clinical data sets generated and held by the manufacturer such as pre- or post-market clinical studies.

Appraisal in Relation to Search Objective 1: Safety and Performance of the Device

Table B-1.1 Criteria for Suitability

Suitability Criteria	Score		
	1	2	3
(D) Appropriate device – Were the data generated from the device in question?	Actual device	Equivalent device	Other device
(A) Appropriate device application – Was the device used for the same intended use?	Same use	Minor deviation	Major deviation
(P) Appropriate patient group- Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	Applicable	Limited	Different population
(R) Acceptable report/data Collation- Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	High Quality	Minor deficiencies	Insufficient information
	High quality reports or collations of data, containing sufficient information to be able to undertake a rational and objective assessments	Reports with limited data	Reports with little data

Notes

Your Mentions

All Mentions

Jade Thurnham

2/17/23, 11:13 AM

This space can be used for general comments to all collaborators or to contact specific collaborators e.g. @Ranita Tarchand who will receive an email and nest link

B

I

U

≡

≡

Comment

You've landed on your demo Nest in AutoLit, and you're looking at the Nest Home page. This page includes a menu on the left of the page, the protocol in the center, and discussion about the Nest on the right. The menu includes links to all modules & configurations available to you in AutoLit. We'll now walk through these modules one by one. (click the title in the menu to navigate to the the corresponding module).

## Literature Search

The Literature Search page allows import of studies to a nest and shows where studies were sourced. This review includes one API-based (automatic integration) search of PubMed. Hover and click the “More” button to see greater detail about the searches, including when they were run and any query

structuring available. Click “Run” to update the search at any time.

You have a choice of an automatic search (present in this demo nest) or a file import from any database by clicking “Add Search.”

The screenshot shows the 'Literature Search' interface. On the left is a sidebar with navigation options: Nest Home, Dashboard, Settings, Literature Search (1/1), Other Sources, Duplicate Review, Search Exploration, Abstract Screening (20/49), Full Text Screening (5/9), Tagging (2/4), Study Inspector, and Synthesis. The main area displays a search query: 'Penumbra Indigo OR Penumbra Indigo® OR Penumbra's Indigo® Aspiration System OR Penumbra Indi...'. The search engine is PubMed, and the schedule is set to Monthly. The search was run on 2023-06-22, resulting in 49 records. A red box highlights the 'Run' button and the 'Results: 49' text.

## Other Sources

Records may be imported through other means. Click the “Other Sources” menu item under “Literature Search” to view records that were individually added as expert recommendations. 1 study was imported into this Nest. Try importing the DOI or PMID of your desired study using the “Add by Identifier” form on the right of the page. You can also add manual records or upload records in bulk if you have their pdfs downloaded to your device, the software will parse out all relevant information to fill the metadata.

The screenshot shows the 'Add by Identifier' and 'Add Manually' forms. The 'Add by Identifier' form has fields for PubMed ID and DOI. The 'Add Manually' form has fields for Title, Abstract, DOI, PubMed ID, PubMed Central ID, Embase ID, NCT Number, External Link, Ref ID, External ID, and Journal. A red box highlights the 'Match' column in the table below the forms.

Match	Title	Author	Source	Date Added
Match	Comparison of Aspiration Catheters with Modi...	Franziska Schubert	Cardiovasc Intervent ...	1/20/2023

Note: all records uploaded to the nest by any means, will be de-duplicated. i.e. any duplicates will be automatically removed.

# Screening

## Abstract Screening

Once studies are imported into a nest, they are “Screened” for relevance to the review in the Screening Module. Since this nest was setup to comply with CER requirements, its Screening mode is set to **Two Pass Screening**. This means the single reviewer can screen all abstracts first, then all full texts. First up, Abstract Screening:

Abstract Screening: (Demo) CER of Aspiration Catheter

Navigation: 20 / 49

Abstract Screening: 20 / 49

Full Text Screening: 5 / 9

Tagging: 2 / 4

Study Inspector

Synthesis

Manuscript Editor

Abstract Editor

Export

Abstract: Full Text | Supplements | Related Reports

93 1 46 0 PubMed

Sista, 2021

**Indigo Aspiration System for Treatment of Pulmonary Embolism: Results of the EXTRACT-PE Trial.**

**OBJECTIVES** This study sought to prospectively evaluate the safety and efficacy of the Indigo aspiration system in submassive acute pulmonary embolism (PE). **BACKGROUND** PE treatment with thrombolytics has bleeding risks. Aspiration thrombectomy can remove thrombus without thrombolytics, but data are lacking. **METHODS** This study was a prospective, single-arm, multicenter study that enrolled patients with symptomatic acute PE ≤14 days, systolic blood pressure ≥90 mm Hg, and right ventricular-to-left ventricular (RV/LV) ratio >0.9. The primary efficacy endpoint was change in RV/LV ratio from baseline to 48 h post-procedure on core lab-adjudicated computed tomography angiography. The primary safety endpoint was a composite of 48-h major adverse events: device-related death, major bleeding, and device-related serious adverse events (clinical deterioration, pulmonary vascular, or cardiac injury). All sites received Institutional Review Board approval. **RESULTS** A total of 119 patients (mean age 59.8 ± 15.0 years) were enrolled at 22 U.S. sites between November 2017 and March 2019. Median device insertion to removal time was 37.0 (interquartile range: 23.5 to 60.0) min. Two (1.7%) patients received intraprocedural thrombolytics. Mean RV/LV ratio reduction from baseline to 48 h post-procedure was 0.43 (95% confidence interval: 0.38 to 0.47; p < 0.0001). Two (1.7%) patients experienced 3 major adverse events. Rates of cardiac injury, pulmonary vascular injury, clinical deterioration, major bleeding, and device-related death at 48 h were 0%, 1.7%, 1.7%, 1.7%, and 0.8%, respectively. **CONCLUSIONS** In this prospective, multicenter study the Indigo aspiration system was associated with a significant reduction in the RV/LV ratio and a low major adverse event rate in submassive PE patients. Intraprocedural thrombolytic drugs were avoided in 98.3% of patients. (Evaluating the Safety and Efficacy of the Indigo aspiration system in Acute Pulmonary Embolism [EXTRACT-PE]; NCT03218566).

Population/Problem Intervention Outcome Your Keywords

Keywords Bibliographic fields Edit

Navigation: Skip

Screening: Full Text Review, Upload Full Text, Train Screening Model

Exclude: Search Reasons

Select Reason

No original results reported; secondary only

Pre-clinical setting

Not Relevant

Publication has not been peer-reviewed

No available full text (e.g. conference abstracts)

Technical study

Advance: Advance

Tagging

Comments (0)

History

This screening module displays abstracts that have yet to be screened, allowing you to decide to advance or exclude from the next stage of full text screening. You can either click “Advance” or a specific exclusion reason from the drop-down menu. Try including a reference by clicking the include button. Exclude a reference by selecting an exclusion reason from the drop-down menu and then clicking the exclude button. You may also skip studies you aren't yet sure about, or jump to a prior study, using the buttons under the Navigation menu. These exclusion reasons were configured under **Configure Screening** in the left hand menu under Abstract Screening.

## Abstract Highlighting

Why are study abstracts so colorful? We perform machine learning-based PICO annotation of abstracts using a model derived from **RobotReviewer**. To turn off PICO highlighting, toggle off the slide button in the legend just beneath the abstract text.

Abstract text may also be highlighted in different colors with User Keywords, which are configured in Configure Screening or when you click on Your Keywords.

## Full Text Screening

Full Text Screening works and looks the same as Abstract Screening but you will primarily be in the Full Text tab (in red below) and you will make decisions to “Include” a study instead of “Advance” a study. Exclusion reasons stay the same.

Full Text Screening: (Demo) CER of Aspiration Catheter

Navigation: Back, Skip

Screening: Full Text Review (checked), Full Text Uploaded! (X), Exclude: Search Reasons (Q), Select Reason: No original results reported; secondary only, Pre-clinical setting, Not Relevant, Publication has not been peer-reviewed, No available full text (e.g. conference abstracts), Technical study, Include: Include

Tagging: Tagging, Comments (0), History

Abstract Full Text Supplements Related Reports

Peripheral Arteries Eur J Vasc Endovasc Surg (2021) 61, 820–828

**Safety and Efficacy of Vacuum Assisted Thrombo-Aspiration in Patients with Acute Lower Limb Ischaemia: The INDIAN Trial**

Gianmarco de Donato <sup>a,\*</sup>, Edoardo Pasqui <sup>a</sup>, Massimo Sponza <sup>a</sup>, Francesco Intriero <sup>a</sup>, Angelo Spinazzola <sup>a</sup>, Roberto Silingardi <sup>a</sup>, Giuseppe Guzzardi <sup>a</sup>, Maria Antonella Ruffino <sup>a</sup>, Giancarlo Palasciano <sup>a</sup>, Carlo Setacci <sup>a</sup>, the INDIAN trial collaborators

<sup>a</sup>University of Siena, Siena, Italy  
<sup>b</sup>Ospedale S. Maria della Misericordia, Udine, Italy  
<sup>c</sup>Ospedale Santa Annunziata, Cosenza, Italy  
<sup>d</sup>ASST Crema, Crema, Italy  
<sup>e</sup>University of Modena, Modena, Italy  
<sup>f</sup>Ospedale Maggiore della Carità, Novara, Italy  
<sup>g</sup>AOU Città della Salute e della Scienza, Torino, Italy

**WHAT THIS PAPER ADDS**  
 This is the first prospective trial investigating the safety and efficacy of vacuum assisted thrombo-aspiration systems in patients with acute lower limb ischaemia in a controlled setting. Results of this investigation give more evidence for a shift of treatment recommendation towards endovascular options in patients with acute lower limb ischaemia, as already suggested by the recent European Society for Vascular Surgery/European Society for Cardiology guidelines.

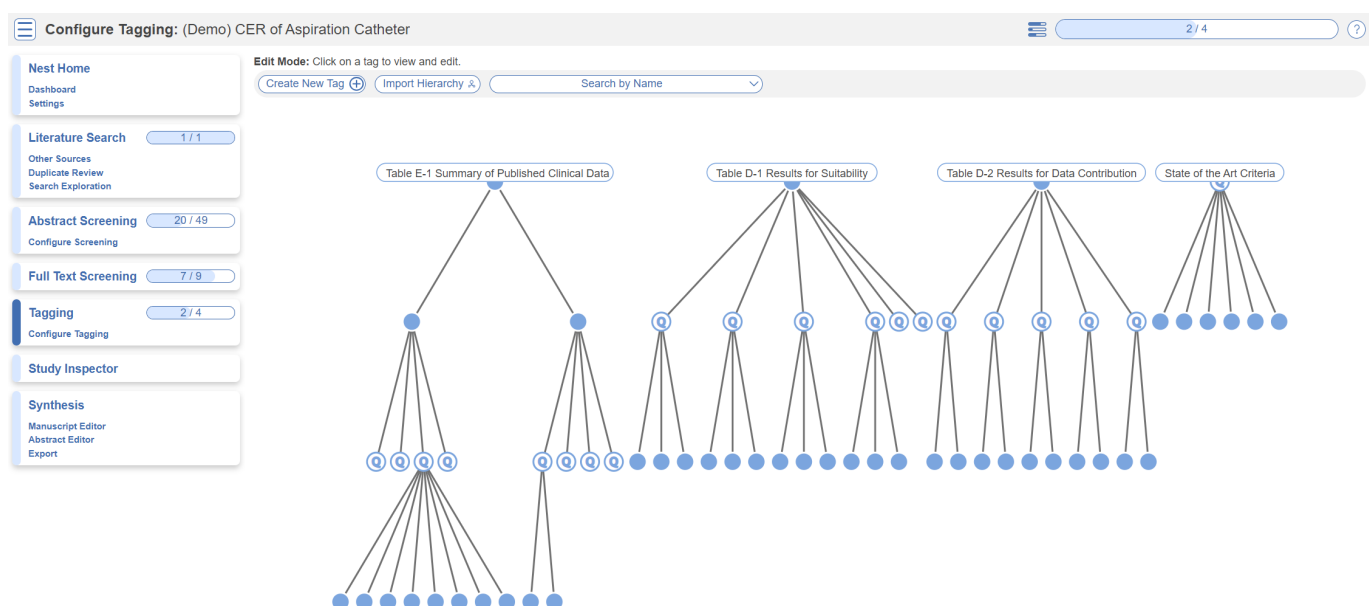
**Objective:** The aim was to evaluate the short term safety and effectiveness of the Penumbra/Indigo aspiration

## Tagging

The Tagging module allows you to report data from included studies in the form of “tags”. There are two modes for Tagging, Standard or Form-based. Since this nest is configured to best meet CER requirements, it is in Form-based mode. This just means Tagging is in Q&A format for ease of collecting data. Learn more about [Form-based Tagging](#).

## Tag Hierarchy

Click the “Configure Tagging” menu item to get started. Tag hierarchies consist of tags (visualized as points) and relationships between them (visualized as connecting lines). The tag hierarchy in this review consists of a set of questions (root tags labelled Q) and answers (child tags) required for this section of the CER.



## Tagging Module

Inside the Tagging module, tags may be applied to studies, by answering questions indicating that a concept is relevant to a study.

Tagging: (Demo) CER of Aspiration Catheter

Nest Home

Dashboard

Settings

Literature Search

1 / 1

Other Sources

Duplicate Review

Search Exploration

Abstract Screening

20 / 49

Configure Screening

Full Text Screening

7 / 9

Tagging

2 / 4

Configure Tagging

Study Inspector

Synthesis

Manuscript Editor

Abstract Editor

Export

Abstract

Full Text

Supplements

Related Reports

1

0

0

1

0

PMC

Catheter-Directed Thrombectomy for Pulmonary Embolism in the Setting of Acute Stroke

Clay H. Hoster<sup>1</sup>, Michael J. Herring<sup>1</sup>, Maria Isabel C. Planek<sup>1</sup>, Steve Attanasio<sup>2</sup>

1. Internal Medicine, Rush University Medical Center, Chicago, USA 2. Cardiovascular Medicine, Rush University Medical Center, Chicago, USA

Corresponding author: Clay H. Hoster, clay\_h\_hoster@rush.edu

Abstract

A 79-year-old male presented with an acute stroke and was treated with tissue plasminogen activator (tPA). His neurological symptoms improved, but he subsequently developed hemodynamic instability requiring intubation and vasopressors. Imaging studies revealed a massive pulmonary embolism as the cause of his worsening clinical picture. Mechanical thrombectomy using traditional devices was deemed too risky as the patient could not safely tolerate the usual anticoagulation dosage these devices require. The Penumbra Indigo® system (Alameda, CA, USA) was thus chosen for its ability to achieve thrombus aspiration within a lower therapeutic heparin range. Pulmonary artery aspiration thrombectomy was done using the device, and three days after the procedure, he was extubated and weaned completely off vasopressors. The therapy's efficacy despite the patient's unique life-threatening conditions demonstrates a novel application of the state-of-the-art pulmonary embolism treatment currently in research.

Categories: Cardiology, Internal Medicine, Healthcare Technology

Keywords: pulmonary embolism, thrombectomy, echocardiography, pulmonary angiography, cerebrovascular accident, catheter-directed thrombolysis, deep vein thrombosis (dvt)

Introduction

Pulmonary embolism (PE) is the third-leading cause of cardiovascular-related death in the United States, accounting for around 100,000 deaths per year [1]. Specifically, massive (or high-risk) PE, defined as acute PE with sustained hypotension and hemodynamic instability, accounts for an estimated 4.5%-10% of all PE cases and has over 50% mortality [2,3]. Historically, the primary treatment options for PE have been

Navigation

2 / 4

Back

Skip

Complete

Questions (0/20)

Search

Objectives: What is the study objective?

Annotate or Enter Text

Not Relevant

Apply

Method: What are the study methods?

Annotate or Enter Text

Not Relevant

Apply

Level of Evidence: State the level(s) of evidence.

Select Tag

Tagging

Comments (0)

History

In the Tagging form, go through question by question and select tags from the dropdown menu or fill out a text excerpt. You can highlight, select an area or simply copy and paste using the circled icons above. When you apply a tag this indicates the data is present in the report and is illustrated in [Qualitative Synthesis](#).

## Study Inspector

Study Inspector is the tool in AutoLit for reviewing and searching your past extracted data. Each row in Study Inspector is a study, and columns may be user-selected in the upper left dropdown menu. Studies may be searched into the table by creating Filters. Filters may be created using the Add Filter dropdown menu, but often times the type ahead search bar is fastest. In the below example, we are filtering to studies that were included in the Screening process.

Study Inspector: (Demo) CER of Aspiration Catheter

Nest Home

Dashboard

Settings

Literature Search

1 / 1

Other Sources

Duplicate Review

Search Exploration

Abstract Screening

20 / 49

Configure Screening

Full Text Screening

7 / 9

Tagging

2 / 4

Configure Tagging

Study Inspector

Synthesis

Manuscript Editor

Abstract Editor

Export

Add Filter

Final Screening

Included

Start Typing

Bulk Actions

Download

Clear Filters

Title	Author	Publication Year	Final Screening Status	...
Comparison of Aspiration Catheters with Modified ...	Schubert, Franziska	2022	Included	
Case Report: Catheter-based mechanical thrombe...	Soszyn, Natalie	2023	Included	
Catheter-Directed Thrombectomy for Pulmonary E...	Hoster, Clay H	2020	Included	
Continuous Aspiration Thrombectomy in High- and ...	Araszkievicz, Aleksander	2020	Included	

Nested Knowledge - <https://wiki.nested-knowledge.com/>

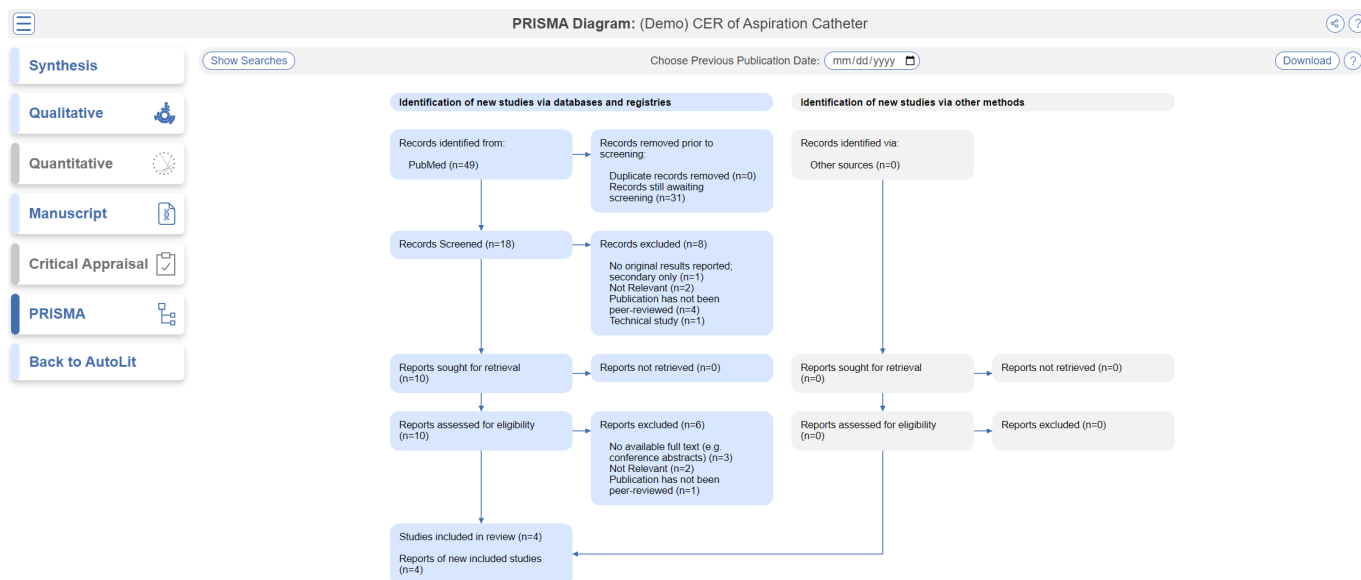
# Synthesis

At this point, we've reviewed all the evidence gathered in AutoLit for this Nest. Now let's navigate to Synthesis Home to draw some conclusions from our evidence, by clicking the Synthesis menu heading.

The screenshot shows the 'Synthesis' tab selected in the left sidebar. The main content area displays an 'Abstract' section with a message: 'This nest does not yet have an abstract. You can create an abstract by heading back to AutoLit's Abstract Editor under the Synthesis tab.' Below this is a 'Key Insights' section with a sub-header 'Insights appear here' and a 'View in Context' button. A descriptive text below states: 'Insights consist of a title, description, and a Synthesis configuration. You can create insights and directly associate the supporting data in the Qualitative Synthesis tab.'

## PRISMA

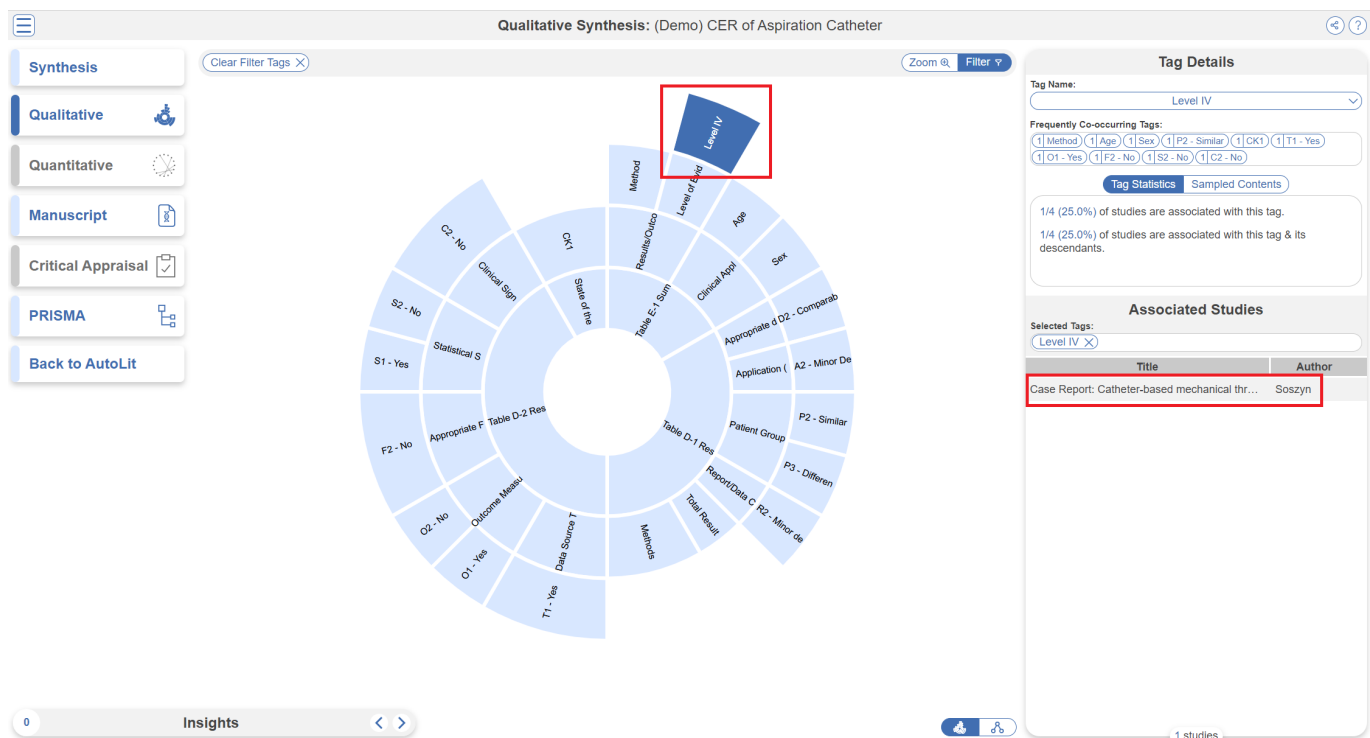
Click the PRISMA button in the bottom left of the page to view a PRISMA 2020 flow diagram. The diagram is auto-populated based on searches imported and studies screened in AutoLit.



## Qualitative Synthesis

Navigate back to Synthesis Home and click the Qualitative Synthesis box. Qualitative Synthesis (QLS) displays data gathered in the Tagging Module. Each slice in the sunburst diagram is a tag. Its width corresponds to how frequently it was applied. Its distance from the center corresponds to its depth in the hierarchy (distance between child and root tag). Click a slice to filter studies displayed to those where the tag was applied. Clicking multiple slices filters to studies with all the selected tags applied.

The rightmost bar shows relevant studies (bottom) and some data about the tag (top), like its frequency, excerpts, and tags that were commonly applied with the selected tag.



In this tag selection, we see that Level IV evidence was reported in one study. Click the rows of the study table to take a deep dive into the extracted data.

## Optional: Meta-analytical Extraction

You may notice in Synthesis, the option for Quantitative Synthesis is disabled. Quantitative Synthesis is the output for our Meta-Analytical Extraction module, which is an optional step only for users who wish to conduct a meta-analysis. This particular review did not include a meta-analysis so the module is disabled.

## Closing Remarks

You've now seen how a review in compliance with CER guidelines may be completed & shared with the Nested Knowledge platform. We encourage you to head back to AutoLit and explore the variety of configuration options, and ever-growing feature set we didn't get to cover here. If you're feeling ambitious, start your own Nest from scratch!

Use this documentation to guide you through more complex topics, and as always, please reach out to our support team via email and make requests on [Nolt](#).

From:

<https://wiki.nested-knowledge.com/> - **Nested Knowledge**

Permanent link:

[https://wiki.nested-knowledge.com/doku.php?id=wiki:start:demo:cer\\_aspiration](https://wiki.nested-knowledge.com/doku.php?id=wiki:start:demo:cer_aspiration)

Last update: **2023/07/07 23:34**