

Supplemental Appendix 1. Search strategies.**Embase (Ovid, inception-12 September 2023)**

- 1 ("external control arm*" or "external control group*" or "external control*" or "external comparator*").mp.
- 2 ("synthetic control arm*" or "synthetic control group*" or "synthetic control*" or "synthetic comparator*").mp.
- 3 ("externally controlled" or "externally-controlled" or "synthetically controlled" or "synthetically-controlled").mp.
- 4 "external data".mp.
- 5 ("baseline control*" or "baseline-control*" or "registry control*" or "registry-control*" or "sequential control*" or "sequential-control*" or "historical control*" or "historical-control*").mp.
- 6 ("real world" and "control").mp.
- 7 "external placebo".mp.
- 8 "historical placebo".mp.
- 9 "historic cohort".mp.
- 10 exp Crohn disease/
- 11 Crohn*.mp.
- 12 exp ulcerative colitis/
- 13 colitis.mp.
- 14 exp arthritis, rheumatoid/
- 15 "rheumatoid arthritis".mp.
- 16 exp Ankylosing spondylitis/
- 17 Ankylosing spondylitis.mp.
- 18 "inflammatory bowel disease".mp.
- 19 "IBD".mp.
- 20 exp psoriatic arthritis/
- 21 "psoriatic arthritis".mp.
- 22 exp psoriasis/
- 23 "psoriasis".mp.
- 24 exp dermatitis, atopic/
- 25 "atopic dermatitis".mp.
- 26 or/1-9
- 27 or/10-25
- 28 26 and 27

MEDLINE (Ovid, inception-12 September 2023)

- 1 ("external control arm*" or "external control group*" or "external control*" or "external comparator*").mp.
- 2 ("synthetic control arm*" or "synthetic control group*" or "synthetic control*" or "synthetic comparator*").mp.
- 3 ("externally controlled" or "externally-controlled" or "synthetically controlled" or "synthetically-controlled").mp.
- 4 "external data".mp.

- 5 ("baseline control*" or "baseline-control*" or "registry control*" or "registry-control*" or "sequential control*" or "sequential-control*" or "historical control*" or "historical-control*").mp.
- 6 ("real world" and "control").mp.
- 7 "external placebo".mp.
- 8 "historical placebo".mp.
- 9 "historic cohort".mp.
- 10 exp Crohn disease/
11 Crohn*.mp.
- 12 exp ulcerative colitis/
13 colitis.mp.
- 14 exp arthritis, rheumatoid/
15 "rheumatoid arthritis".mp.
- 16 exp Ankylosing spondylitis/
17 Ankylosing spondylitis.mp.
- 18 "inflammatory bowel disease".mp.
- 19 "IBD".mp.
- 20 exp psoriatic arthritis/
21 "psoriatic arthritis".mp.
- 22 exp psoriasis/
23 "psoriasis".mp.
- 24 exp dermatitis, atopic/
25 "atopic dermatitis".mp.
- 26 or/1-9
27 or/10-25
28 26 and 27

Cochrane Central Register of Controlled Trials (CENTRAL) (inception-12 September 2023)

- #1 "external control arm*" or "external control group*" or "external control*" or "external comparator*"
- #2 "synthetic control arm*" or "synthetic control group*" or "synthetic control*" or "synthetic comparator*"
- #3 "externally controlled" or "externally-controlled" or "synthetically controlled" or "synthetically-controlled"
- #4 "external data"
- #5 "baseline control*" or "baseline-control*" or "registry control*" or "registry-control*" or "sequential control*" or "sequential-control*" or "historical control*" or "historical-control*"
- #6 "real world" and "control"
- #7 "external placebo"
- #8 "historical placebo"
- #9 "historic cohort"
- #10 MeSH descriptor: [Crohn Disease] explode all trees
#11 Crohn*
- #12 MeSH descriptor: [Colitis, Ulcerative] explode all trees
#13 colitis
- #14 MeSH descriptor: [Arthritis, Rheumatoid] explode all trees
#15 "rheumatoid arthritis"

- #16 MeSH descriptor: [Spondylitis] explode all trees
- #17 Ankylosing spondylitis
- #18 "inflammatory bowel disease"
- #19 "IBD"
- #20 MeSH descriptor: [Arthritis, Psoriatic] explode all trees
- #21 "psoriatic arthritis"
- #22 MeSH descriptor: [Psoriasis] explode all trees
- #23 "psoriasis"
- #24 MeSH descriptor: [Dermatitis, Atopic] explode all trees
- #25 "atopic dermatitis"
- #26 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9
- #27 #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25
- #28 #26 and #27

Supplemental Table 1. External control data source quality checklist.^a

Key domain	Criteria for judgement
Quality of data source	<ul style="list-style-type: none">• Patient data sourced from RCTs or prospective cohort studies• Baseline characteristics data relevant to the target population were collected
Similarity of study populations	<ul style="list-style-type: none">• Sufficiently similar disease definitions and inclusion/exclusion criteria• Sufficiently similar patient demographics• Appropriate use of statistical adjustments, subgroup analyses, or sensitivity analyses if patient characteristics differ
Similarity of outcome definitions	<ul style="list-style-type: none">• Sufficiently similar outcome definitions and timepoints of assessment• Appropriate use of sensitivity analyses if timepoints differ
Reliability and comprehensiveness	<ul style="list-style-type: none">• Use of multiple sources of data• Sufficient sample size and covariates• Low proportion of missing data or appropriate use of sensitivity analyses to assess the effect of missing data
Other limitations	<ul style="list-style-type: none">• No other dataset limitations that may limit the reliability and validity of comparisons apparent

Abbreviations: RCT, randomised controlled trial.

^aAdapted from Thorlund et al.¹

Supplemental Table 2. Excluded studies.

#	Study ID	Reason for exclusion
1.	Backhouse 2012 ²	Non-interventional
2.	Banerjee 2016 ³	Active arm not from a clinical study
3.	Baraliakos 2011 ⁴	Secondary publication of included study (Baraliakos 2014)
4.	Braun 2018 ⁵	Secondary publication of included study (Braun 2019)
5.	Braun 2018 ⁶	Secondary publication of included study (Braun 2019)
6.	Carter 2009 ⁷	Secondary publication of included study (Carter 2012)
7.	Carter 2011 ⁸	Secondary publication of included study (Carter 2012)
8.	Cavallaro 2019 ⁹	Active arm not from a clinical study
9.	Cozzi 2022 ¹⁰	No external control
10.	Cruz 2010 ¹¹	Insufficient information for inclusion; study population not specified
11.	Curtis 2015 ¹²	Secondary publication of included study (Curtis 2015)
12.	Deery 2020 ¹³	Ineligible study population
13.	Descalzo 2012 ¹⁴	Non-interventional
14.	Eslamy 2014 ¹⁵	Intervention for the treatment of immune-mediated disease not assessed
15.	Favalli 2018 ¹⁶	No external control
16.	Flor-de-Lima 2013 ¹⁷	Active arm not from a clinical study
17.	Garg 2010 ¹⁸	Secondary publication of included study (Garg 2011)
18.	Girleanu 2019 ¹⁹	Insufficient information for inclusion; control group source not specified
19.	Glintborg 2019 ²⁰	Active arm not from a clinical study
20.	Gorgun 2004 ²¹	Active arm not from a clinical study
21.	Grass 2019 ²²	Active arm not from a clinical study
22.	Haifer 2019 ²³	No external control
23.	Hallgren 1990 ²⁴	Insufficient information for inclusion; control group source not specified
24.	Harold 2018 ²⁵	Intervention for the treatment of immune-mediated disease not assessed
25.	Harris 2019 ²⁶	Insufficient information for inclusion; control group source not specified
26.	Haugeberg 2019 ²⁷	Insufficient information for inclusion; control group source not specified
27.	Hjuler 2018 ²⁸	Intervention for the treatment of immune-mediated disease not assessed
28.	Holroyd 2018 ²⁹	No external control
29.	Hunter 2014 ³⁰	Insufficient information for inclusion; control group source not specified
30.	Hunter 2014 ³¹	Insufficient information for inclusion; control group source not specified
31.	Iannone 2016 ³²	No external control
32.	Ito 2002 ³³	Ineligible study population
33.	Jamal 2019 ³⁴	No external control
34.	Jani 2020 ³⁵	Active arm not from a clinical study
35.	Jani 2022 ³⁶	Active arm not from a clinical study
36.	Karakan 2013 ³⁷	Insufficient information for inclusion; control group source not specified
37.	Kaur 2018 ³⁸	Non-interventional; historical control not used to assess the efficacy or safety of a medical intervention
38.	Kaur 2020 ³⁹	Non-interventional; historical control not used to assess the efficacy or safety of a medical intervention
39.	Klein 2019 ⁴⁰	Active arm not from a clinical study
40.	Lamplot 2015 ⁴¹	Intervention for the treatment of immune-mediated disease not assessed
41.	Lebwohl 2015 ⁴²	No external control
42.	Lebwohl 2016 ⁴³	No external control
43.	Lee 2019 ⁴⁴	No external control
44.	Lippuner 1996 ⁴⁵	Ineligible study population
45.	Loftus 2009 ⁴⁶	No external control
46.	Loftus 2009 ⁴⁷	No external control
47.	Luglio 2016 ⁴⁸	No external control
48.	Maas 2016 ⁴⁹	Insufficient information for inclusion; control group source not specified
49.	Mahil 2021 ⁵⁰	Intervention for the treatment of immune-mediated disease not assessed
50.	McDaniel 2020 ⁵¹	Intervention for the treatment of immune-mediated disease not assessed
51.	Medel 2011 ⁵²	Intervention for the treatment of immune-mediated disease not assessed
52.	Murphy 2013 ⁵³	Intervention for the treatment of immune-mediated disease not assessed
53.	Neva 2003 ⁵⁴	Intervention for the treatment of immune-mediated disease not assessed
54.	Okazaki 2016 ⁵⁵	Ineligible study population
55.	Pal 2018 ⁵⁶	Insufficient information for inclusion; control group source not specified
56.	Pal 2019 ⁵⁷	Insufficient information for inclusion; control group source not specified
57.	Papa 2012 ⁵⁸	Insufficient information for inclusion; control group source not specified

#	Study ID	Reason for exclusion
58.	Papa 2012 ⁵⁹	Insufficient information for inclusion; control group source not specified
59.	Papa 2012 ⁶⁰	Insufficient information for inclusion; control group source not specified
60.	Papadopoulou 1995 ⁶¹	Insufficient information for inclusion; control group source not specified
61.	Pena-Sagredo 2009 ⁶²	Active arm not from a clinical study
62.	Petit 2020 ⁶³	Intervention for the treatment of immune-mediated disease not assessed
63.	Petit 2021 ⁶⁴	Intervention for the treatment of immune-mediated disease not assessed
64.	Prats-Urbe 2020 ⁶⁵	No external control
65.	Reddy 2006 ⁶⁶	Intervention for the treatment of immune-mediated disease not assessed
66.	Reich 2001 ⁶⁷	No external control
67.	Rodewald 2001 ⁶⁸	Active arm not from a clinical study
68.	Schulert 2018 ⁶⁹	Active arm not from a clinical study
69.	Sebastian 2021 ⁷⁰	Intervention for the treatment of immune-mediated disease not assessed
70.	Shashi 2020 ⁷¹	Active arm not from a clinical study
71.	Sigurdardottir 2018 ⁷²	Active arm not from a clinical study
72.	Sigurdardottir 2019 ⁷³	Active arm not from a clinical study
73.	Simpson 2010 ⁷⁴	Insufficient information for inclusion; control group source not specified
74.	Spinelli 2013 ⁷⁵	No external control
75.	Spinelli 2015 ⁷⁶	No external control
76.	Spinelli 2019 ⁷⁷	Intervention for the treatment of immune-mediated disease not assessed
77.	Stein 2016 ⁷⁸	Intervention for the treatment of immune-mediated disease not assessed
78.	Strand 2021 ⁷⁹	No external control
79.	To 2012 ⁸⁰	Insufficient information for inclusion; control group source not specified
80.	Tweehuysen 2017 ⁸¹	Secondary publication of included study (Tweehuysen 2018)
81.	Tweehuysen 2018 ⁸²	Secondary publication of included study (Tweehuysen 2018)
82.	Vadlamudi 2010 ⁸³	Active arm not from a clinical study
83.	Varkas 2016 ⁸⁴	Active arm not from a clinical study
84.	Weidner 2000 ⁸⁵	Intervention for the treatment of immune-mediated disease not assessed
85.	Weinstein 2021 ⁸⁶	Intervention for the treatment of immune-mediated disease not assessed
86.	Wolf 2015 ⁸⁷	Active arm not from a clinical study
87.	Wolf 2015 ⁸⁸	Active arm not from a clinical study
88.	Wolf 2015 ⁸⁹	Active arm not from a clinical study
89.	Wolf 2016 ⁹⁰	Active arm not from a clinical study
90.	Yoshii 2016 ⁹¹	Ineligible study population
91.	Zhou 2004 ⁹²	Intervention for the treatment of immune-mediated disease not assessed
92.	Feagan 2023 ⁹³	Insufficient information for inclusion; control group source not specified
93.	Chou 2022 ⁹⁴	Active arm not from a clinical study
94.	So 2023 ⁹⁵	Insufficient information for inclusion; control group source not specified
95.	Hagino 2023 ⁹⁶	No external control
96.	Loughlin 2022 ⁹⁷	Insufficient information for inclusion; control group source not specified
97.	Hagino 2022 ⁹⁸	No external control

Supplemental Table 3. External control data quality assessment.^a

Study ID	Quality of data source	Similarity of study populations	Similarity of outcome definitions	Reliability and comprehensiveness of the datasets	Other limitations
Baker 1989 ⁹⁹	Unclear	Unclear	High	Unclear	Unclear
Rosenberg 1990 ¹⁰⁰	Unclear	Unclear	High	Unclear	Unclear
Stenger 1998 ¹⁰¹	Unclear	Low	Low	Unclear	Low
Marotte 2007 ¹⁰²	Unclear	Low	Low	Low	Low
Shen 2007 ¹⁰³	Unclear	Low	Low	Unclear	Low
Moul 2007 ¹⁰⁴	Low	Unclear	Low	Unclear	Low
van der Heijde 2008 ¹⁰⁵	Low	Low	Low	Unclear	Unclear
Boyle 2008 ¹⁰⁶	Unclear	Unclear	Low	Unclear	Unclear
van der Heijde 2009 ¹⁰⁷	Low	Unclear	Low	Unclear	Low
Garg 2011 ¹⁰⁸	Unclear	Unclear	Unclear	Unclear	Unclear
Yong 2011 ^{109 b}	Unclear	Unclear	Unclear	Unclear	Low
Carter 2012 ¹¹⁰	Low	Unclear	Low	Unclear	Unclear
Hueber 2012 ¹¹¹	Low	Low	Low	Low	Low
Hyams 2012 ¹¹²	Low	Unclear	Unclear	Low	Low
Hodkinson 2013 ¹¹³	Unclear	Unclear	Low	Unclear	Unclear
Kwok 2012 ¹¹⁴	Unclear	Unclear	Low	Unclear	Unclear
Baraliakos 2014 ¹¹⁵	Unclear	Unclear	Low	Unclear	Unclear
Horneff 2014 ¹¹⁶	Low	Unclear	High	Unclear	Unclear
Lichtenstein 2014 ¹¹⁷	Low	Low	Unclear	Unclear	Unclear
Gardenbroek 2015 ¹¹⁸	Unclear	Low	Low	Unclear	Unclear
Mahajan 2018 ¹¹⁹	Unclear	Unclear	Low	Unclear	Low
Rozette 2018 ¹²⁰	Unclear	Unclear	Low	Unclear	Unclear
Tweehuysen 2018 ¹²¹	Unclear	Unclear	Low	Unclear	Unclear
Horneff 2018 ¹²²	Unclear	Unclear	Low	Unclear	Unclear
Inui 2018 ¹²³	Unclear	Unclear	Low	Unclear	Low
Braun 2019 ¹²⁴	Low	Low	Low	Unclear	Unclear
Kawashiri 2020 ^{125 c}	Low	Unclear	Unclear	Unclear	Unclear
Muskens 2020 ¹²⁶	Unclear	Low	Low	Unclear	Low
Sanchez-Hernandez 2020 ¹²⁷	Unclear	Low	Low	Low	Low
Croft 2021 ¹²⁸	Low	Unclear	Low	Low	Low
Hupf 2021 ^{129 b}	Low	Unclear	Unclear	Low	Low

Study ID	Quality of data source	Similarity of study populations	Similarity of outcome definitions	Reliability and comprehensiveness of the datasets	Other limitations
Reed 2021 ¹³⁰ ^b	Low	Unclear	Unclear	Unclear	Unclear
Rudrapatna 2021 ¹³¹ ^b	Unclear	Unclear	Low	Unclear	Low
Wang 2021 ¹³² ^b	Low	Low	Low	Low	Low
Sagami 2021 ¹³³	Unclear	Low	Low	Unclear	Low
Gasparetto 2021 ¹³⁴	Unclear	Unclear	Unclear	Unclear	Low
Danese 2021 ¹³⁵	Low	Low	Unclear	Low	Low
Magnolo 2022 ¹³⁶	Low	Low	Low	Low	Low
Norvang 2022 ¹³⁷ ^b	Low	Low	Low	Unclear	Low
Holland 2022 ¹³⁸	Unclear	Low	Low	Unclear	Unclear
Huang 2022 ¹³⁹	Unclear	Low	Low	Unclear	Low
Truong 2022 ¹⁴⁰	Unclear	Low	Low	Unclear	Low
Takei 2022 ¹⁴¹	Unclear	Low	Low	Unclear	Unclear

Abbreviations: ECA, external control arm.

^a The quality assessment is based on the control quality checklist developed by Thorlund et al.¹

^b Primary study objective was to examine methodological approaches for complementing prior or concurrent RCT data with external control data.

^c Protocol for an upcoming single-arm study with an ECA.

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