

**Prognosis Studies review proposal form**

**Review Proposal Form**

Please complete this form to outline your proposal for a Cochrane systematic review. Email the completed form to [email address], or send to [name], Managing Editor, Cochrane XXX Group, [postal address]. Ph: +XX XXXXXXXXX Fax: +XX XXXXXXXXX.

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| **Before completing this form:*** Read “Managing expectations: what does The Cochrane Collaboration expect of authors, and what can authors expect of The Cochrane Collaboration?” (see <http://community.cochrane.org/editorial-and-publishing-policy-resource/cochrane-review-development/managing-expectations> Note: this information is particularly for systematic reviews of intervention studies. A page for prognosis reviews is under construction.)
* Note that a Cochrane review of prognosis studies clearly differs from that of intervention studies and diagnostic test accuracy studies, in, e.g., searching, data extraction, critical appraisal and meta-analysis. Step-by-step guidance to help you understanding prognosis studies and the processes of conducting a review of prognosis studies is given in the papers in the reference list below.
* Cochrane reviews of prognosis require a multidisciplinary team. Below you find several question addressing the available expertise in the author team, and whether external expertise (e.g. from information specialists or methodologists) is needed to conduct this review. If additional expertise is needed, e.g. an information specialist, or methodological or statistical expertise, please provide this request to the Prognosis Methods Group (PMG) timely.
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| **Proposed title** |
|      *Choose preferably one of the formats below. See also the generic guidance on defining a review question for prognosis studies in the CHARMS checklist.* Incidence of [outcome] within [time] in [population][Prognostic factors] for predicting incidence of [outcome] in [population]Prediction of [outcome] in [population] using [prognostic factors]Prognostic models for predicting [outcome] in [population]Performance of [prognostic model] for predicting [outcome] in [population]Added/Incremental value of [prognostic factor] on top of [existing prognostic factors/prognostic model] for predicting [outcome] in [population][Predictive factors] predicting the [outcome of treatment] in [population][Factors / Models] predicting differential treatment response in [population][Factors / Models] for predicting treatment response in [population] |

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| **Contact person** |
| Name:Email: |            |
| **Short description of review proposal** *Provide brief but enough information to make sure that the clinical context and the actual question that is being asked is clear for non-content experts as well.**For explicit guidance to help filling in this title registration form and for the conduct of the review, from framing the review question, search strategy, study in/exclusion criteria, critical appraisal, risk of bias assessment, meta-analysis and reporting, please see the papers mentioned in the reference list below.* |
| **Type of prognosis review***Indicate what type of review you are going to perform (double click to check a box). See PROGRESS series in the reference list.* | [ ]  Overall prognosis[ ]  Prognostic factors[ ]  Prognostic models[ ]  Predictive/Treatment selection factors |
| **Motivation for the review** *For example, is this going to be part of a PhD thesis; is it part of a larger project; is it particularly topical at the present time?* |       |
| **Background***i) The clinical problem.**A short description of the existing clinical pathway of the targeted individuals/patients; their starting condition and moment of prognostication (time point in the clinical pathway); what prognostic outcomes are relevant to the targeted individuals. For predictive factor reviews also refer to the role of treatment.**ii) Why is this review relevant, including how might the results of the review be used: e.g., the prognostic or predictive factor(s) or model(s) under review may be used to determine treatment allocation or abstention, decide on closer follow-up or monitoring, etc.* *Reference to an existing systematic review on this topic outside Cochrane is helpful.* |       |
| **Review objective(s)***What is the review question, according to the PICOTS format? (see Box 1 in the paper of Debray et al, BMJ 2017, see reference list below.)* | Primary objective:      Secondary objective(s):       |
| **Participants / setting***Short outline of the targeted population and clinical setting, to be included and excluded for the review.* |       |
| **Prognostic model / factor***(Not applicable for overall prognosis)**Describe short the prognostic/predictive factor(s) or model(s) of interest. This might, for example, be a specific prognostic factor or model, a certain factor-treatment interaction, or a review of all predictive or prognostic factors/models for a certain outcome in certain patients.* *Where relevant, include one or two references to primary studies that will potentially be included.* |       |
| **Outcomes of interest***Describe short the prognosis outcomes of interest, including the time period (days, months, years) of their observation.*  |       |
| **Other information***Any other explanatory information that would help a reader to understand the aim and rationale for this review including relevant clinical information.* |       |
| **Related Cochrane reviews, protocols or registered titles** |       |

**Review author team and area of expertise**

Each person that makes a substantial contribution to the conception, design, analysis, interpretation or reporting of the review, including physicians, information specialists, methodologists, etc., must be author of the review, alike the way this is done regarding authorships of primary study reports by using the ICJME criteria.

Please list the names of all members of the review team, including short description of their experience with conducting systematic reviews of Cochrane reviews in general, and of prognosis studies in particular. As said, Cochrane systematic reviews of prognosis require a multidisciplinary team. The team must include the expertise listed below. Indicate below clearly whether the specific expertise is already present in the review team, or needs to be searched for, e.g. by contacting the PMG.

1. Is there a person on the review team who has sufficient expertise in the medical problem (e.g. targeted population or outcomes) under review?
2. Is there a person on the review team who has expertise in systematic reviews of prognosis studies? Please provide relevant publications.
3. Is there a person on the review team who has expertise or sufficient knowledge in methods of primary prognostic research?
4. Is there a person on the review team who has statistical expertise or sufficient knowledge or training in the meta-analysis of prognosis studies?

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|  | **Name** | **Area of expertise\*** |
| Contact author |  |  |
| Co-author |  |  |
| Co-author |  |  |
| Co-author |  |  |
| Co-author |  |  |
| Co-author |  |  |
| Co-author |  |  |

**\*** *please indicate the expertise each team member brings to the review team: content expertise, review expertise, searching skills, methodology, statistics. Also indicate clearly whether this person is already in the review team or needs to be recruited/asked for by the PMG.*

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| **Authors’ responsibilities** |
| By completing this form, you accept responsibility for preparing, maintaining and, if needed, updating the review in accordance with Cochrane policy. The Cochrane Review Group (CRG) will provide as much support as possible to assist with the review.A draft protocol must be submitted to the CRG within **XXX** months. If drafts are not submitted before the agreed deadlines, or if we are unable to contact you for an extended period, the CRG has the right to de‑register the title or transfer the title to alternative authors. The CRG also has the right to de‑register or transfer the title if it does not meet the standards of the CRG and/or Cochrane. |
| **Publication in the *Cochrane Database of Systematic Reviews*** |
| The support of the CRG in preparing your review is conditional upon your agreement to publish the protocol, finished review and subsequent updates in the *Cochrane Database of Systematic Reviews*. By completing this form you undertake to publish this review in the *Cochrane Database of Systematic Reviews* before publishing elsewhere (concurrent publication in other journals may be allowed in certain circumstances with prior permission from the CRG). |
| I understand the commitment required to **undertake** a Cochrane review, and agree to publish first in the *Cochrane Database of Systematic Reviews*.**Signed on behalf of the authors**:      |
| **Form completed by:**       | **Date:**       |

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| **Declaration of interest** |
| The Cochrane Collaboration’s general policy states, “The performance of the review must be free of any real or perceived bias introduced by receipt of any benefit in cash or kind, any hospitality, or any subsidy derived from any source that may have or be perceived to have an interest in the outcome of the review.” (see <http://community.cochrane.org/editorial-and-publishing-policy-resource/ethical-considerations/conflicts-interest-and-cochrane-reviews>).  |
| Do the authors have any potential conflict of interest? Yes [ ]  No [ ]  |
| If ‘yes’, what are they?      |

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| **Review context** |
| Is the review subject to any specific funding? If yes, please give details. |       |
| Is there a deadline for completing the review? If yes, please give details. |       |
| Has the review already been carried out or published? If yes, where has it been published? |       |

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| **Proposed deadlines** |
| Date you plan to submit a draft protocol: (within **XXX** months) |       |
| Date you plan to submit a draft review: (within **XXX** months) |       |
| **Review authors** (see Handbook section 4.2.2.)Each person that makes a substantial contribution to the conception, design, analysis, interpretation or reporting of the review, including physicians, information specialists, methodologists, etc., must be authors of the review, alike the way this is done regarding authorships of primary study reports by using the ICJME criteria.  |

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| Contact person / Author 1 (see Handbook section 4.2.3) |
| Is the contact person an author of the review? | Yes [ ]  No [ ]   |
| Prefix (e.g. Ms, Dr): |       | Given name: |       |
| Middle initial(s): |       | Family name: |       |
| Suffix (e.g. MD, PhD): |       | Web address: |       |
| Preferred full name for review byline: | e.g. John Smith = Smith JB; Chen Ming Yu = Chen MY      |
| Do you already have a user account and password for the Archie database? | Yes [ ]  No [ ]  |
| Email address(es): | 1)     2)      |
| Job Title/Position: |       |
| Department: |       |
| Organisation: |       |
| Street/Address: |       |
| City: |       | Post/Zip code: |       |
| State/Province: |       | Country: |       |
| Telephone number: |       | Fax number: |       |
| Mobile/cell number: |       |
| Privacy: | As the contact person, your address and email will be published with the completed protocol or review. Your details will be stored on our central database, known as ‘Archie’, and may be accessed by members of The Cochrane Collaboration. Details of our privacy policy are available at <http://ims.cochrane.org/archie/terms-of-use/archie-privacy-policy>. Within Archie, would you like to:Hide your address and phone numbers: [ ]  Hide your email address: [ ]  |
| Country of origin: |       | Gender: | Female [ ]  Male [ ]  |
| What expertise do you bring to the review? | (e.g. clinical, review methods, statistics)      |
| Have you prepared a systematic review before? | Yes [ ]  No [ ]   |
| If yes, have you prepared a Cochrane review? (please state most recent title)      | Yes [ ]  No [ ]  |
| Are you already a member of another Cochrane Review Group? Which one(s)?      | Yes [ ]  No [ ]  |
| Have you followed training on systematic reviews of prognosis studies? If yes, which one(s)?      If no, contact the prognosis methods group or participate in one of the courses we offer via <http://methods.cochrane.org/prognosis/welcome>. | Yes [ ]  No [ ]  |
| At what level are you able to speak and write English? |       |
| Translating trials published in languages other than English is a vital role in Cochrane. If you speak any other languages and would be willing to do partial translations on behalf of other author teams, please let us know. | I would be willing to assist with translation of clinical trials published in the following language(s):  |

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| Author 2You must have at least two authors to register a title. Copy this table for additional authors. |
| Prefix (e.g. Ms, Dr): |       | Given name: |       |
| Middle initial(s): |       | Family name: |       |
| Suffix (e.g. MD, PhD): |       | Web address: |       |
| Preferred full name for review byline: | e.g. John Smith = Smith JB; Chen Ming Yu = Chen MY      |
| Do you already have a user account and password for the Archie database? | Yes [ ]  No [ ]  |
| Email address(es): | 1)     2)      |
| Job Title/Position: |       |
| Department: |       |
| Organisation: |       |
| Street/Address: |       |
| City: |       | Post/Zip code: |       |
| State/Province: |       | Country: |       |
| Telephone number: |       | Fax number: |       |
| Mobile/cell number: |       |
| Privacy: | As the contact person, your address and email will be published with the completed protocol or review. Your details will be stored on our central database, known as ‘Archie’, and may be accessed by members of The Cochrane Collaboration. Details of our privacy policy are available at <http://ims.cochrane.org/archie/terms-of-use/archie-privacy-policy>. Within Archie, would you like to:Hide your address and phone numbers: [ ]  Hide your email address: [ ]  |
| Country of origin: |       | Gender: | Female [ ]  Male [ ]  |
| What expertise do you bring to the review? | (e.g. clinical, review methods, statistics)      |
| Have you prepared a systematic review before? | Yes [ ]  No [ ]   |
| If yes, have you prepared a Cochrane review? (please state most recent title)      | Yes [ ]  No [ ]  |
| Are you already a member of another Cochrane Review Group? Which one(s)?      | Yes [ ]  No [ ]  |
| Have you followed training on systematic reviews of prognosis studies? If yes, which one(s)?      If no, contact the prognosis methods group or participate in one of the courses we offer via <http://methods.cochrane.org/prognosis/welcome>. | Yes [ ]  No [ ]  |
| At what level are you able to speak and write English? |       |
| Translating trials published in languages other than English is a vital role in Cochrane. If you speak any other languages and would be willing to do partial translations on behalf of other author teams, please let us know. | I would be willing to assist with translation of clinical trials published in the following language(s):  |

**Roles and responsibilities**

It is the contact author’s responsibility to discuss and assign roles for individual members of the review team and to develop the review team including all necessary expertise (see above). Whilst keeping in mind that roles may change during the review, it is important to discuss at an early stage how each co-author will contribute. Please give an indication that the responsibility for the preparation of the review is in hand by specifying who has agreed to complete the listed tasks.

| **Task** | **Who has agreed to undertake the task?** |
| --- | --- |
| Draft the protocol |       |
| Develop and run the search strategy |       |
| Obtain copies of studies |       |
| Select which studies to include |       |
| Extract data from studies |       |
| Enter data into RevMan |       |
| Carry out the analysis |       |
| Interpret the analysis |       |
| Draft the final review |       |
| Update the review |       |

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| **Team resources (summary)** |
| Have you read the introductory papers listed below (first two references listed)? | Yes [ ]  No [ ]  |
| Have you or a co-author written a systematic review before?If yes, was it a Cochrane review? | Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| Have you attended a Cochrane Prognosis review training workshop?If no, do you plan to? Which workshop did you/will you attend?       | Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| Which computer operating system do you use: MAC or Windows? |       |
| Have you downloaded and installed RevMan, the Cochrane review software?(see <http://community.cochrane.org/tools/review-production-tools/revman-5>) | Yes [ ]  No [ ]  |
| Do you have access to these electronic databases: *The Cochrane Library*MEDLINEEMBASE | Yes [ ]  No [ ] Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| Do you have access to a medical library?If yes, can you order journal articles not held in the library?Do you have access to advice from a medical librarian? | Yes [ ]  No [ ] Yes [ ]  No [ ] Yes [ ]  No [ ]  |
| Do you have access to reference management software (e.g. Endnote)?If yes, which software, and what version?       | Yes [ ]  No [ ]  |
| Are you familiar with RevMan? If not, to whom will you turn for help?       | Yes [ ]  No [ ]  |
| Do you have access to a statistician (required)?If yes, who?      | Yes [ ]  No [ ]  |
| Do you or does your statistician have access to and knowledge of advanced statistical software?If yes, which software?      (e.g. R, STATA, SAS, Stan, WinBugs, JAGS, OpenBUGS) *(NB. SPSS, EpiData or EpiInfo are not enough)* | Yes [ ]  No [ ]  |
| Do you have contact with consumer groups relevant to this review?If yes, which one(s)?      | Yes [ ]  No [ ]  |
| Have you identified appropriate time and resources to complete the review? | Yes [ ]  No [ ]  |
| Would you like to be assigned a mentor (an experienced author who hasvolunteered to help new authors)? | Yes [ ]  No [ ]  |

**Cochrane Review Timeline**

**Title Registration:** approval of final title by Editorial Board and registration **within six weeks**.

**Protocol Submission:** protocols should be submitted to the Editorial Office **within XXX months** of title registration. If a protocol has not been received **within XXX months**, the Editorial Office reserves the right to make the title available to other interested review teams.

**Review Submission:** completed reviews should be submitted to the Editorial Office **within XXX months** of publication of the protocol. If a review has not been received **within XXX years**, the Editorial Office reserves the right to make the title available to other interested review teams.

**Review Update:** reviews should be updated and submitted to the Editorial Office **within XXX years** of publication of the review. If an updated review has not been received within four years, the Editorial Office reserves the right to make the title available to other interested review teams.

*Thank you for completing this form.*

**List of useful references for conduct of systematic reviews of prognosis studies**

*Introduction to systematic reviews of prognosis studies*

* *Prognosis research: toward evidence-based results and a Cochrane methods group (Riley et al, J Clin Epidemiol 2007).*
* *Implementing systematic reviews of prognosis studies in Cochrane (Moons et al, Cochrane Database Syst Rev 2018).*

*Full description of the review process (including meta-analysis), from A to Z:*

* *A guide to systematic review and meta-analysis of prediction model performance (Debray et al, BMJ 2017).*
* *A guide to systematic review and meta-analysis of prognostic factor studies (Riley et al, BMJ 2019).*

*Searching for studies:*

* *Search Filters for Finding Prognostic and Diagnostic Prediction Studies in Medline to Enhance Systematic Reviews (Geersing et al, PLOS One 2012).*
* *Optimal search strategies for retrieving scientifically strong studies of treatment from Medline: analytical survey (Haynes et al, BMJ 2005).*
* *Searching for clinical prediction rules in MEDLINE (Ingui et al, J Am Med Inform Assoc 2001).*

*Formulating the review question, data extraction and critical appraisal:*

* *Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies: The CHARMS Checklist (Moons et al, PLOS Med 2014).*

*Risk of bias assessment:*

* *Assessing Bias in Studies of Prognostic Factors (Hayden et al, Ann Intern Med 2013).*
* *Evaluation of the Quality of Prognosis Studies in Systematic Reviews (Hayden et al, Ann Intern Med 2006)*
* *PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies (Wolff et al, Ann Intern Med 2019).*
* *PROBAST: A Tool to Assess Risk of Bias and Applicability of Prediction Model Studies: Explanation and Elaboration (Moons et al, Ann Intern Med 2019).*
* *See* [*www.probast.org*](http://www.probast.org) *for the latest version of the PROBAST tool and examples*

*Meta-analysis:*

* *Meta-analysis and aggregation of multiple published prediction models (Debray et al, Stat Med 2014).*
* *External validation of clinical prediction models using big datasets from e-health records or IPD meta-analysis: opportunities and challenges (Riley et al, BMJ 2016).*
* *Meta-analysis of prediction model performance across multiple studies: Which scale helps ensure between-study normality for the C-statistic and calibration measures? (Snell et al, Stat Methods Med Res 2017).*
* *Meta-analysis of a binary outcome using individual participant data and aggregate data (Riley et al, Res Synth Methods 2010)*

*GRADE:*

* *Judging the quality of evidence in reviews of prognostic factor research: adapting the GRADE framework (Huguet et al, Syst Rev 2013)*
* *Use of GRADE for assessment of evidence about prognosis: rating confidence in estimates of event rates in broad categories of patients (Iorio et al, BMJ 2015)*

*Reporting of systematic reviews:*

* *Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement (Moher et al, PLOS Med 2009)*
* *Meta-analysis of observational studies in epidemiology: a proposal for reporting (Stroup et al, JAMA 2000)*

*Different types of primary prognosis studies:*

* *Prognosis Research Strategy (PROGRESS) 1: A framework for researching clinical outcomes (Hemingway et al, BMJ 2013).*
* *Prognosis Research Strategy (PROGRESS) 2: Prognostic Factor Research (Riley et al, PLOS Med 2013).*
* *Prognosis Research Strategy (PROGRESS) 3: Prognostic Model Research (Steyerberg et al, PLOS Med 2013).*
* *Prognosis Research Strategy (PROGRESS) 4: Stratified medicine research (Hingorani et al, BMJ 2013).*