

COMET VII Meeting 2018, Amsterdam

# **Cochrane Skin - Core Outcome Set Initiative (CS-COUSIN): Integration of clinical and methodological expertise to develop standards for high quality COS in dermatology**

Jan Kottner, Jochen Schmitt, Hywel Williams on behalf of the CS-COUSIN methods group

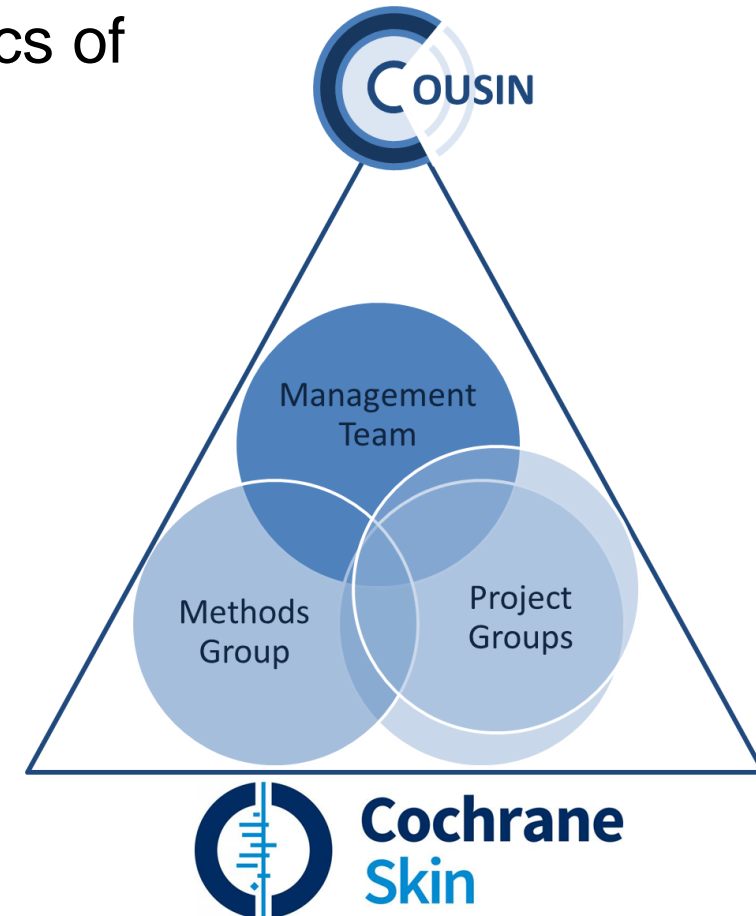


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Carl Gustav Carus  
DIE DRESDNER.



# CS-COUSIN methodological support

- Current challenges: keeping up-to-date, heterogeneous quality of COS development, general vs. specific guidance, specifics of disciplines and areas...
- COS development guidance document
- Flow charts for domain and instrument development
- Proposal form
- Protocol template
- Status update document
- Peer review



# Guidance document



## Guidance on how to develop a core outcome set for skin disease by the CS-COUSIN methods group

### Summary

The Cochrane Skin Group - Core Outcome Set Initiative (CS-COUSIN) is a working group within the international Cochrane Skin Group. It recommends using the Harmonising Outcome Measures for Eczema (HOME) roadmap (Schmitt et al. 2015) to structure the core outcome set (COS) development process (or parts of it). The HOME roadmap provides guidance how to define, select and recommend the most important **core outcome domains** and how to identify the **best outcome measurement instruments** for these identified domains. Despite the existence of guidance on how to develop COS (e.g. Boers et al. 2015), optimal methods for COS development are not known and uncertainty exists (Kirkham et al. 2016, Gargon et al. 2017). For instance, there is no 'gold' standard on how to do consensus studies (e.g. which decision rules to use) and how to select/develop core outcome domains and outcome measurement instruments (e.g. Kirwan et al. 2015). This document is intended to provide guidance and essential references in order to ensure that a new COS is developed with an appropriate high quality methodological level. Among others, developing a protocol a priori for the COS development is mandatory. Inappropriately developed and published COS are potentially worse than no COS if they end up measuring the wrong things in the wrong way. Formal guidelines for COS development, outcome measurement instrument selection and for reporting for COS development studies are published and must be used (Kirkham et al. 2016, Kirkham et al. 2017, Prinsen et al. 2016) and a handbook by the Core Outcome Measures in Effectiveness Trials (COMET) initiative was published in 2017 (Williamson et al. 2017). The following outlines some key principles that need to be considered when developing a COS in a stepped fashion based on the current state of knowledge.

### References

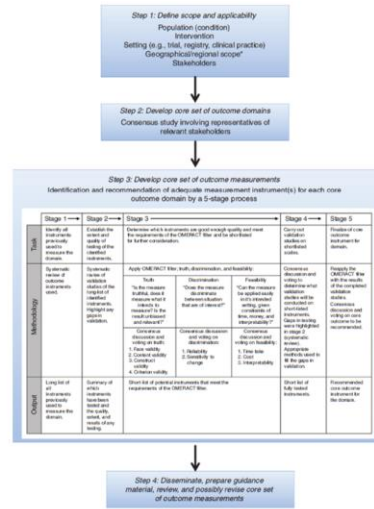
- Boers M et al. The OMERACT Handbook 2015. [http://www.omeract.org/pdf/OMERACT\\_Handbook.pdf](http://www.omeract.org/pdf/OMERACT_Handbook.pdf)
- Gargon E et al. Improving Core Outcome Set Development: Qualitative Interviews with Developers Provided Pointers to Inform Guidance. *J Clin Epidemiol.* 2017 May 8. [Epub ahead of print]
- Kirkham JJ et al. Core Outcome Set-Standards for Reporting: The COS-STAR Statement. *PLoS Med.* 2016;13(10):e1002148.
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- Kirwan JR, Boers M, Hewlett S et al. Updating the OMERACT filter: core areas as a basis for defining core outcome sets. *J Rheumatol.* 2014;41(5):994-9.
- Prinsen CA et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. *Trials.* 2016;17(1):449.
- Williamson et al. The COMET Handbook: version 1.0. *Trials.* 2017;18(Suppl3):280.

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Schmitt J, Apfelbacher C, Spuls PI, et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. *J Invest Dermatol.* 2015;135(1):24-30.

Resources
<ul style="list-style-type: none"> <li>Electronic databases (e.g. Medline)</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials.</i> 2017;18(Suppl3):280.</li> </ul>
<ul style="list-style-type: none"> <li><a href="http://www.comet-initiative.org/">http://www.comet-initiative.org/</a></li> <li><a href="https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zevg/cousin">https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zevg/cousin</a></li> <li>Electronic databases (e.g. Medline)</li> </ul>
<ul style="list-style-type: none"> <li><a href="https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zevg/cousin">https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zevg/cousin</a></li> </ul>
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Intervention	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. The OMERACT Handbook 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Kirkham JJ et al. Core Outcome Set-Standards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Kirkham JJ et al. Core Outcome Set-Standards for Development: The COS-STAD recommendations. <i>PLoS Med.</i> 2017;14(11):e1002447.</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials.</i> 2017;18(Suppl3):280.</li> </ul>
Priority	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. <i>J Clin Epidemiol.</i> 2014;67(7):745-53.</li> <li>Boers M et al. The OMERACT Handbook 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Kirkham JJ et al. Core Outcome Set-Standards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials.</i> 2017;18(Suppl3):280.</li> <li>COMET PoPPIe Working Group. <a href="http://www.comet-initiative.org/pppi/poppei#">http://www.comet-initiative.org/pppi/poppei#</a></li> </ul>
Quality of life	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. The OMERACT Handbook 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Sinha IP et al. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. <i>PLoS Med.</i> 2011;8(11):e1000393.</li> <li>Kirkham JJ et al. Core Outcome Set-Standards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Kirkham JJ et al. Core Outcome Set-Standards for Development: The COS-STAD recommendations. <i>PLoS Med.</i> 2017;14(11):e1002447.</li> <li><a href="http://www.comet-initiative.org/assets/downloads/Tips%20for%20Designing%20an%20Accessible%20Core%20Outcome%20Set%20Consensus%20Meeting%20final%2026-10-17.pdf">http://www.comet-initiative.org/assets/downloads/Tips%20for%20Designing%20an%20Accessible%20Core%20Outcome%20Set%20Consensus%20Meeting%20final%2026-10-17.pdf</a></li> </ul>
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- First version developed 2015

# Guidance document

## Specific guidance on the HOME and CS-COUSIN COS development process

	Step	Key questions/ tasks	To dos and explanations	Resources
1	Preparation	<ul style="list-style-type: none"> <li>Do we really need a COS?</li> </ul>	<ul style="list-style-type: none"> <li>Look into the literature and into epidemiological data</li> <li>The answer should be “yes” if                             <ol style="list-style-type: none"> <li>there is a high incidence, prevalence, and/or high impact in terms of quality of life, costs and/or mortality of the disease or condition (burden of disease)</li> <li>various non-comparable outcomes are used in clinical research especially in clinical trials and/or systematic reviews/meta-analyses</li> <li>outcomes in clinical research are unlikely to be relevant and meaningful (e.g. for patients or service users)</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>Electronic databases (e.g. Medline)</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials</i>. 2017;18(Suppl3):280.</li> </ul>
		<ul style="list-style-type: none"> <li>Is there already a COS of interest available and/or under development?</li> </ul>	<ul style="list-style-type: none"> <li>Check the COMET database</li> <li>Check with the COMET Project Coordinator</li> <li>Visit the CSG-COUSIN homepage</li> <li>Consult the CSG-COUSIN coordinator</li> <li>Search the internet via common search engines</li> <li>Search electronic databases</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.comet-initiative.org/">http://www.comet-initiative.org/</a></li> <li><a href="https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin">https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin</a></li> <li>Electronic databases (e.g. Medline)</li> </ul>
		<ul style="list-style-type: none"> <li>Proposal</li> </ul>	<ul style="list-style-type: none"> <li>Download, complete and submit the proposal form to the CSG-COUSIN</li> <li>Submitting the proposal form implies that the COS will be developed according to CSG-COUSIN standards</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin">https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin</a></li> </ul>
2	Protocol	<ul style="list-style-type: none"> <li>Write a protocol for the COS domain development (after approval from CSG-COUSIN)</li> </ul>	<ul style="list-style-type: none"> <li>Specify all relevant steps, tasks, expected results, planned people to involve and why</li> <li>Consider the protocol requirements for the domain development process according to CSG-COUSIN</li> <li>Register your initiative at COMET</li> <li>Set up the COS development group consisting of at least clinicians and methodologists and patients</li> <li>The protocol must include the domain development process. It may also contain steps for instrument selection but this can also be done later.</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.comet-initiative.org/">http://www.comet-initiative.org/</a></li> <li><a href="https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin">https://www.uniklinikum-dresden.de/de/das-klinikum/universitaetscentren/zegv/cousin</a></li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials</i>. 2017;18(Suppl3):280.</li> </ul>

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Core Outcome Set Initiative

		<ul style="list-style-type: none"> <li>Does the protocol follow current best practice for COS development?</li> </ul>	<ul style="list-style-type: none"> <li>Clearly define the health problem, the population, setting and intervention types (e.g. 'all interventions', 'pharmacological interventions', etc.)</li> <li>Study the latest methodological recommendations</li> <li>Make sure that you meet the 11 Core Outcome Set-Standards for Development (COS-STAP)</li> <li>Include experts in your group</li> <li>Look for (external) feedback for your protocol</li> <li>Include relevant stakeholders in a meaningful way</li> </ul>	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Kirkham JJ et al. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Kirkham JJ et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. <i>PLoS Med.</i> 2017;14(11):e1002447.</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials.</i> 2017;18(Suppl3):280.</li> </ul>
3	Core Outcome domains	<ul style="list-style-type: none"> <li>Identify possible outcome domains</li> </ul>	<ul style="list-style-type: none"> <li>Outcome domains define "what" to be measured</li> <li>Essential features of the disease/conditions e.g. in terms of mortality, life impact, resource use, pathophysiological manifestations</li> <li>Use and/or do a (systematic) review and make a preliminary selection of outcomes (domains) covering at least the two databases Medline and Embase</li> <li>When doing systematic reviews, register at PROSPERO</li> <li>Develop inductively and iteratively possible outcome domains</li> <li>Look for further input, e.g. from experts</li> <li>Involve patients/service users (What is important for them? )</li> <li>Consider to involve regulating authorities (FDA, EMA)</li> <li>Define the domains</li> </ul>	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. <i>J Clin Epidemiol.</i> 2014;67(7):745-53.</li> <li>Boers M et al. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Kirkham JJ et al. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Keeley T et al. The use of qualitative methods to inform Delphi surveys in core outcome set development. <i>Trials.</i> 2016;17(1):230.</li> <li>Williamson et al. The COMET Handbook: version 1.0. <i>Trials.</i> 2017;18(Suppl3):280.</li> <li>COMET PoPPIE Working Group, <a href="http://www.comet-initiative.org/ppi/poppie#">http://www.comet-initiative.org/ppi/poppie#</a></li> </ul>
		<ul style="list-style-type: none"> <li>Select the core outcome domains</li> </ul>	<ul style="list-style-type: none"> <li>Do a consensus study (Delphi or Nominal groups) involving relevant stakeholders (patients, clinicians, clinical researchers) to be followed by a face-to-face group meeting (if possible) plus voting (anonymous voting pads are essential) to define and/or select outcome domains for outcome measurement development</li> <li>Present definitions of the domains</li> <li>Define decision rules a priori</li> <li>Select outcome domains</li> <li>Publish the results according to the COS-STAR Statement</li> </ul>	<ul style="list-style-type: none"> <li>Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>Boers M et al. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>Sinha IP et al. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. <i>PLoS Med.</i> 2011;8(1):e1000393.</li> <li>Kirkham JJ et al. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. <i>PLoS Med.</i> 2016;13(10):e1002148.</li> <li>Kirkham JJ et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. <i>PLoS Med.</i> 2017;14(11):e1002447.</li> <li><a href="http://www.comet-initiative.org/assets/downloads/Tips%20for%20Designing%20an%20Accessible%20Core%20Outcome%20Set%20Consensus%20Meeting%20final%202026-10-17.pdf">http://www.comet-initiative.org/assets/downloads/Tips%20for%20Designing%20an%20Accessible%20Core%20Outcome%20Set%20Consensus%20Meeting%20final%202026-10-17.pdf</a></li> </ul>

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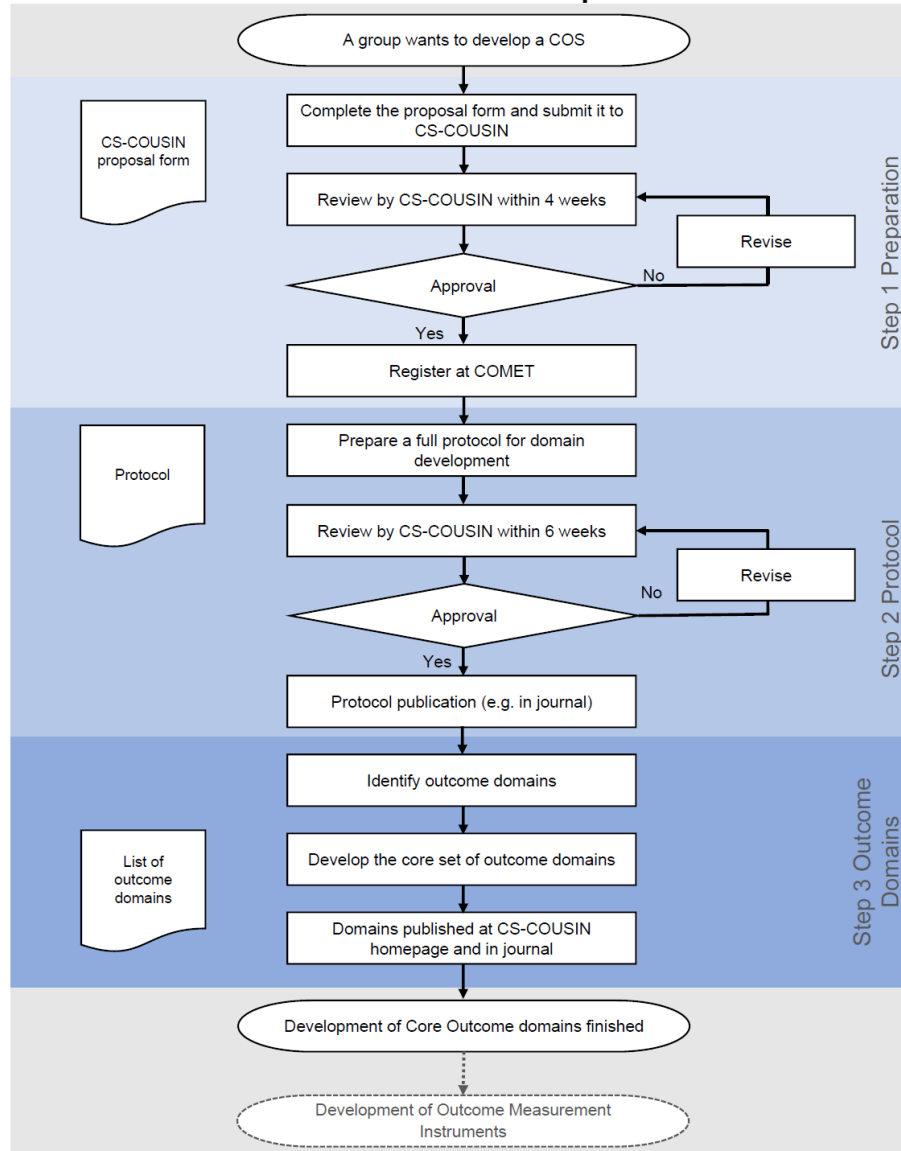


Core Outcome Set Initiative

4	Outcome measurement instruments to measure core outcome domains	<ul style="list-style-type: none"> <li>• What instruments exist per domain?</li> </ul>	<ul style="list-style-type: none"> <li>• Identify all measurement instruments of the domain of interest using a systematic review covering at least the two databases Medline and Embase to create a list of existing instruments</li> </ul>	<ul style="list-style-type: none"> <li>• Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>• Boers M et al. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>• <a href="http://www.cosmin.nl/">http://www.cosmin.nl/</a></li> <li>• Prinsen CA et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. <i>Trials.</i> 2016 Sep 13;17(1):449.</li> <li>• Terwee CB, Jansma EP, Riphagen II, et al. Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. <i>Qual Life Res.</i> 2009 Oct;18(8):1115-23.</li> </ul>	
		<ul style="list-style-type: none"> <li>• What are the measurement properties of these instruments?</li> </ul>	<ul style="list-style-type: none"> <li>• Identify the empirical evidence supporting the validity of the scores or parameters</li> <li>• Consider to use the search algorithms and filters provided by COSMIN</li> <li>• Do a methodological and quality appraisal of the validation studies, by applying quality criteria. COSMIN is one of the best developed framework for doing this.</li> <li>• Identify missing validation evidence</li> </ul>		
		<ul style="list-style-type: none"> <li>• Generate missing validation evidence (if needed)</li> </ul>	<ul style="list-style-type: none"> <li>• Plan, conduct, and report the validation studies based on highest methodological standards (e.g. following STARD 2015; GRRAS; COSMIN)</li> </ul>		<ul style="list-style-type: none"> <li>• Bossuyt PM et al. STARD 2015: an updated list of essential items for reporting diagnostic accuracy studies. <i>BMJ.</i> 2015;351:h5527.</li> <li>• Schmitt J et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>• Kottner J et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. <i>J Clin Epidemiol.</i> 2011;64(1):96-106.</li> </ul>
		<ul style="list-style-type: none"> <li>• Evaluate the quality of the instruments</li> </ul>	<ul style="list-style-type: none"> <li>• Appraise the validation evidence taking the methodological appraisal of the study quality into account (e.g. using COSMIN methodology and/or OMERACT filter)</li> <li>• Perform a best evidence synthesis / apply levels of evidence in order to come to a short list of instruments that have the potential to be included in the COS</li> </ul>		<ul style="list-style-type: none"> <li>• Schmitt J, Apfelbacher C, Spuls PI, et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>• Prinsen CA et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. <i>Trials.</i> 2016 Sep 13;17(1):449.</li> <li>• Boers M, Kirwan, JR, Tugwell P. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>• <a href="http://www.cosmin.nl/">http://www.cosmin.nl/</a></li> </ul>
		<ul style="list-style-type: none"> <li>• Define the core outcome measurement instruments</li> </ul>	<ul style="list-style-type: none"> <li>• Do a consensus study (Delphi or Nominal groups) involving the relevant stakeholders (patients, clinicians, clinical researchers) to be followed by a face-to-face group meeting plus voting (anonymous voting pads are essential) to select one core outcome instrument per core outcome domain</li> <li>• Define decision rules a priori</li> <li>• Select one core outcome measurement instrument per core outcome domain</li> </ul>		<ul style="list-style-type: none"> <li>• Schmitt J, Apfelbacher C, Spuls PI, et al. The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. <i>J Invest Dermatol.</i> 2015;135(1):24-30.</li> <li>• Boers M, Kirwan, JR, Tugwell P. The OMERACT Handbook. 2015. <a href="http://www.omeract.org/pdf/OMERACT_Handbook.pdf">http://www.omeract.org/pdf/OMERACT_Handbook.pdf</a></li> <li>• Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. <i>PLoS Med.</i> 2011;8(1):e1000393.</li> <li>• Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. <i>Trials.</i> 2012;13:132.</li> </ul>

# Flow charts

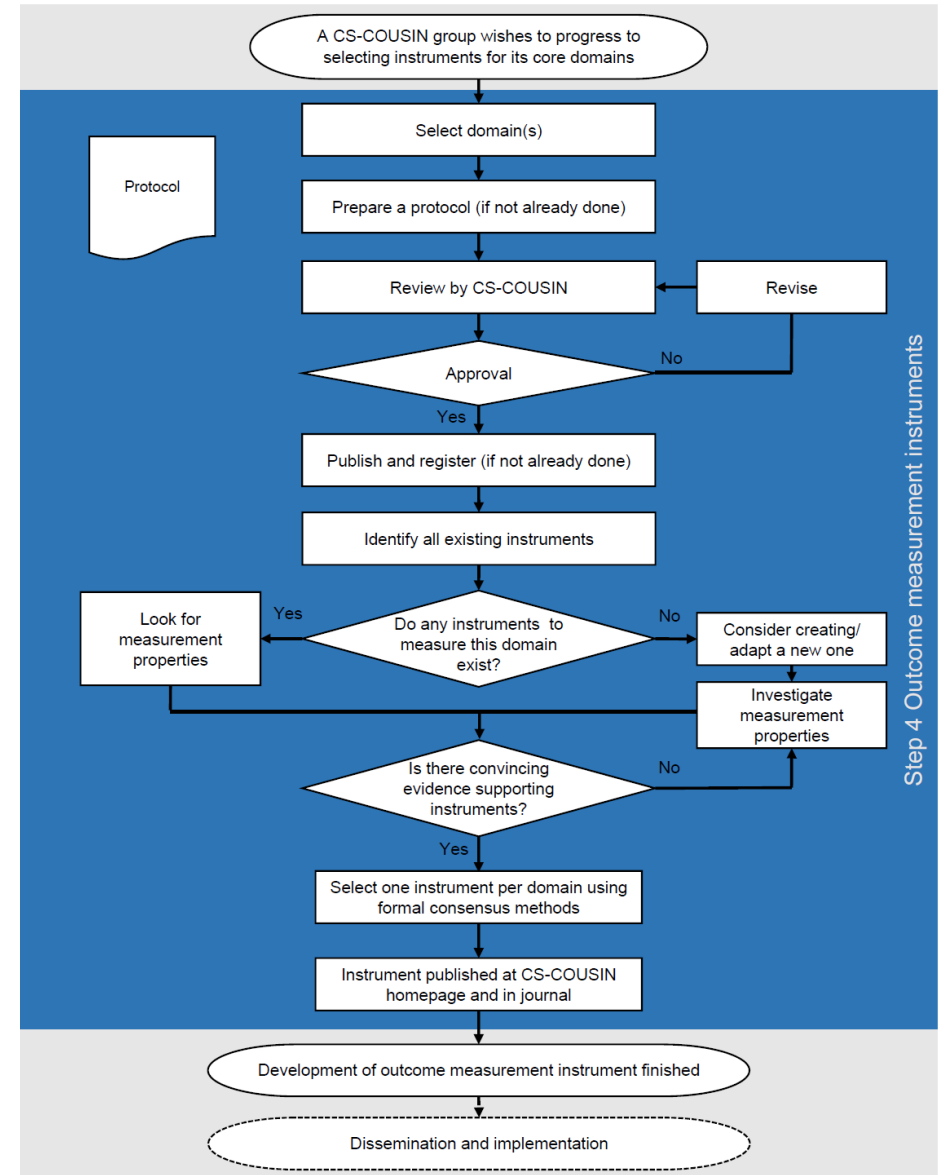
## CS-COUSIN COS Domain Development Process



Authors: CS-COUSIN Methods Group

Date: 5 September 2018

## CS-COUSIN COS Outcome Measurement Instrument Selection/Development Process



Authors: CS-COUSIN group

Date: 5 September 2018

# Proposal form

## CSG-COUSIN Proposal Form

Dear COS Developers,

Please provide a short description of your intended Core Outcome Set according to the following table not exceeding four pages. After completion please email this to [Toni.Lange@uniklinikum-dresden.de](mailto:Toni.Lange@uniklinikum-dresden.de) and [jan.kottner@charite.de](mailto:jan.kottner@charite.de)

Date	
Proposed Title	
Contact Author Name (This is the person taking primary responsibility for the project)	
Affiliation	
Address	
Phone number	
E-mail	
Additional Names and Roles (Please describe responsibilities per person/group involved)	
<b>Composition of the COS project team</b>	
<b>The group has ...</b>	<b>Please tick</b>
...experience in clinical trial methodology.	Yes <input type="checkbox"/> No <input type="checkbox"/>
...experience in leading a systematic review.	Yes <input type="checkbox"/> No <input type="checkbox"/>
...experience in COS development.	Yes <input type="checkbox"/> No <input type="checkbox"/>
...patient representative(s).	Yes <input type="checkbox"/> No <input type="checkbox"/>
...healthcare professionals with experience of patients with the condition.	Yes <input type="checkbox"/> No <input type="checkbox"/>
...experience in consensus methodology.	Yes <input type="checkbox"/> No <input type="checkbox"/>

...a good command of written English.	Yes <input type="checkbox"/> No <input type="checkbox"/>
...representatives from different countries.	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Brief description of project</b>	
Provide a rationale: Why is a COS important in <u>this specific field</u> ?	
Is anyone else working on a COS in this field already? What is different to yours?	
Define scope and applicability of the COS	
Setting(s)	
Conditions(s)	
Population(s) (including geographical spread)	
Intervention(s)	
Objectives (Please clearly state whether you would like to develop domains and/or instruments)	
Basic methodological approach	
Which stakeholders do you plan to involve?	
Expected outcomes	
Do you have any funding	

or non-financial support for this COS work?	
Intended Timeline	
Conflicts of interest	
Have you been in contact with any other COS initiative to date? (COMET, IDEOM)	

**Terms and conditions:** The support of CS-COUSIN in preparing and conducting your COS project is conditional upon your agreement to develop the COS according to CS-COUSIN standards and to refer to CS-COUSIN in all publications arising from this project. The following statement must be included in the acknowledgements section of all publications to ensure that support from CS-COUSIN is recognised: "The work was developed with support from the Cochrane Skin-Core Outcome Set Initiative (CS-COUSIN)."

\_\_\_\_\_  
Date, Place, Full name, Signature

# Protocol form

## CS-COUSIN Core Domain Development Process

### Guidance on how to develop a protocol for COS domains

Dear COS Developers,

Please structure your COS domain development protocol according to the following table. If you focus on certain stages of this process only, please make this clear. The length of the document should not no more than approximately 20 pages.

	Item No.	Explanations
<b>Title/Abstract</b>		
Title	1	Identify in the title that the protocol is about the development of COS domains and specify disease / population of interest.
Abstract	2	Provide a structured summary.
<b>Introduction</b>		
Scientific background and relevance	3	Provide an overview of the need of the COS (more detailed than in the proposal form).
Objectives	4	State your objectives.
Define scope and applicability of the COS	5	Describe the setting(s) including geographical region, health condition(s), population(s), and intervention(s).
<b>Methods</b>		
Workplan and milestones	6	Describe work packages (e.g. protocol development, registration, literature search, databases). Specify the expected results of each work package. Provide the milestones (planned timelines for the work packages).
COS development group	7	Describe the COS project team consisting of at least patients, clinicians, and methodologists (and if applicable, Steering Committee and/or Advisory group members).
Method for involving Stakeholders	8	Describe who your stakeholders will be and how stakeholders will be contacted and involved. Describe the eligibility criteria for stakeholders for each group. Describe in detail how you will involve the patient perspective, healthcare professionals and provide (if possible at this stage) a list of potential representatives and stakeholders: names, affiliation, roles.

Method for the <u>identification</u> of core outcome domains	9	Provide a detailed plan for the identification of the core outcome domains (e.g. literature searches, focus groups, interviews).
Consensus Process and Definition, Method for the <u>definition</u> of core outcome domains	10	Provide a detailed plan for conducting the consensus process (e.g. Delphi study, face to face group meetings). Describe the proposed consensus definition. Describe the analysis plan (i.e. how outcome domains will be scored and how scores will be summarized. Describe the consensus definition and criteria for including/dropping/adding domains.
Ethics and consent	11	Describe the ethics and consent issues. If this is not applicable please state this.
Results	12	Describe broadly how you will present your expected results.
<b>Other Information</b>		
Dissemination and Publication	13	Develop a dissemination and implementation plan.
Future research plan for developing a core set of outcome measurement instruments	14	Indicate if you intend to develop a core set of outcome measurement instruments for your identified core outcome domains and how you would do this.
Funding, Conflict of interest	15	State any sources of funding that you have received or plan to apply for and conflicts of interest (e.g. development or copyright for any instruments in this area, involvement in any other COS, involvement in any related groups).
Timeline	16	Please indicate the intended timeline from the study start until the Core Set of outcome domains will be completed

18, Amsterdam

# Peer review system

- Assignment of one 'methods peer' from the methods group to COS development group
- Review of documents
- Methodological advice
- Link and reporting to methods group
- Structured updates

Name	Affiliation
Christian Apfelbacher	Universität Regensburg, Germany
Joanne Chalmers	Centre of Evidence Based Dermatology, University of Nottingham, United Kingdom
Stefanie Deckert	Center for Evidence-based Healthcare, Medizinische Fakultät Carl Gustav Carus, TU Dresden, Germany
Jamie Kirkham	Department of Biostatistics, University of Liverpool, United Kingdom
Jan Kottner	Department of Dermatology and Allergy, Charité-Universitätsmedizin Berlin, Germany
Sanna Prinsen	Department of Epidemiology and Biostatistics, VU University Medical Center, Amsterdam, The Netherlands
Jochen Schmitt	Center for Evidence-based Healthcare, Medizinische Fakultät Carl Gustav Carus, TU Dresden, Germany Centre of Evidence-Based Dermatology, Nottingham University, United Kingdom
Eric Simpson	OHSU Department of Dermatology, United States
Phyllis Spuls	Department of Dermatology, Academic Medical Center, Amsterdam, The Netherlands
Kim Thomas	Centre of Evidence Based Dermatology, UK

# Project groups

- |    |   |  |
|----|---|--|
| 1  | <b>Acne vulgaris</b>                      | Acne Core Outcomes Research Network (ACORN)  |
| 2  | <b>Appearance of facial aging</b>         | Appearance of Facial Aging (IMPROVED)  |
| 3  | <b>Atopic eczema</b>                      | Harmonizing Outcome Measures for Eczema (HOME)   |
| 4  | <b>Basal cell carcinoma</b>               | Basal cell carcinoma (IMPROVED)  |
| 5  | <b>Chronic wounds</b>                     | Chronic wounds   |
| 6  | <b>Congenital Melanocytic Naevus</b>      | Outcome measures for COngenital MELanocytic Naevi (OCOMEN)                                       |
| 7  | <b>Hand eczema</b>                        | Hand Eczema Core Outcome Set (HECOS)   |
| 8  | <b>Hidradenitis suppurativa</b>           | Hidradenitis suppurativa (HISTORIC)  |
| 9  | <b>Incontinence-associated dermatitis</b> | Core Outcome Set in the Incontinence Associated Dermatitis (CONSIDER)                            |
| 10 | <b>Laser treatment in dermatology</b>     | Developing a generic Core Outcome Set for Medical Indications for laser treatment in Dermatology |
| 11 | <b>Melanoma</b>                           | MELANOMA   |
| 12 | <b>Nail Psoriasis</b>                     |  |
| 13 | <b>Pressure ulcer</b>                     | Outcomes for Pressure Ulcer Trials (OUTPUTs)   |
| 14 | <b>Rosacea</b>                            |  |
| 15 | <b>Vascular malformations</b>             | Outcome measures for Vascular Malformations (OVAMA)  |
| 16 | <b>Vitiligo</b>                           |  |
| 17 | <b>Vulvovaginal skin disorders</b>        |  |

# Project groups

## CS-COUSIN Progress Report Form

General information		
Date of completion	...../...../20.....(dd/mm/yyyy)	
COS group name	.....	
Main contact (name, email)	.....	
CS-COUSIN methods group member (name, email)	.....	
Progress information on domain development process		
		Comments
Have you completed a CS-COUSIN proposal form?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Is your COS project registered in the COMET database?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If so, please add the link: .....
Have you prepared (a) protocol(s) for your COS development?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Have you made progress in identifying Core Outcome Domains?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Do you have a final set of Core Outcome Domains?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Have you published your Core Outcome Domains?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If so, please add the PubMed link(s): .....

Progress information on outcome measurement instrument selection/development process		
		Comments
Have you prepared (a) protocol(s) for instrument selection/development?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Have you made progress in identifying instruments?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Do you have selected instruments for each domain?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If so, for which domains: .....
Have you published your instrument(s) per outcome domain(s)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If so, please add the PubMed link(s): .....
Progress information on dissemination		
Have you conducted any activities to disseminate your COS?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....
Please list other publications resulting from your COS projects.	.....	
Have the COS or any partial results been up taken?	<input type="checkbox"/> Yes <input type="checkbox"/> No	.....

\_\_\_\_\_  
Date, Full name, Signature

# General remarks

- Continuous review and revision of processes and documents
- Continuous screening of literature
- COS groups must comply with the proposed standards
- CS-COUSIN is not going to...
  - Be a competitor to major initiatives like COMET
  - Develop something 'different' which does not comply with the latest research and recommendations
  - Give an answer to every unanswered question in the COS field
  - Prescribe how the COS groups must develop their COS
- Standardization of processes key to ensure high quality COS



## Contact

You can help Core Outcome Sets improve evidence-based dermatology as a patient, researcher, clinician or any other stakeholder.

All teams are open and welcome to interested new members

- who wants to develop a new Core Outcome Set
- who wants to be a part of a COS-project team
- who wants to use a specific COS
- who are searching for methodical advice
- who wants to work methodical in the field of COS

If you have any queries please do get in touch either with the form below or direct to [info@cs-cousin.org](mailto:info@cs-cousin.org)