

COMET VII Meeting 2018, Amsterdam

# The Cochrane Skin - Core Outcome Set Initiative (CS-COUSIN)



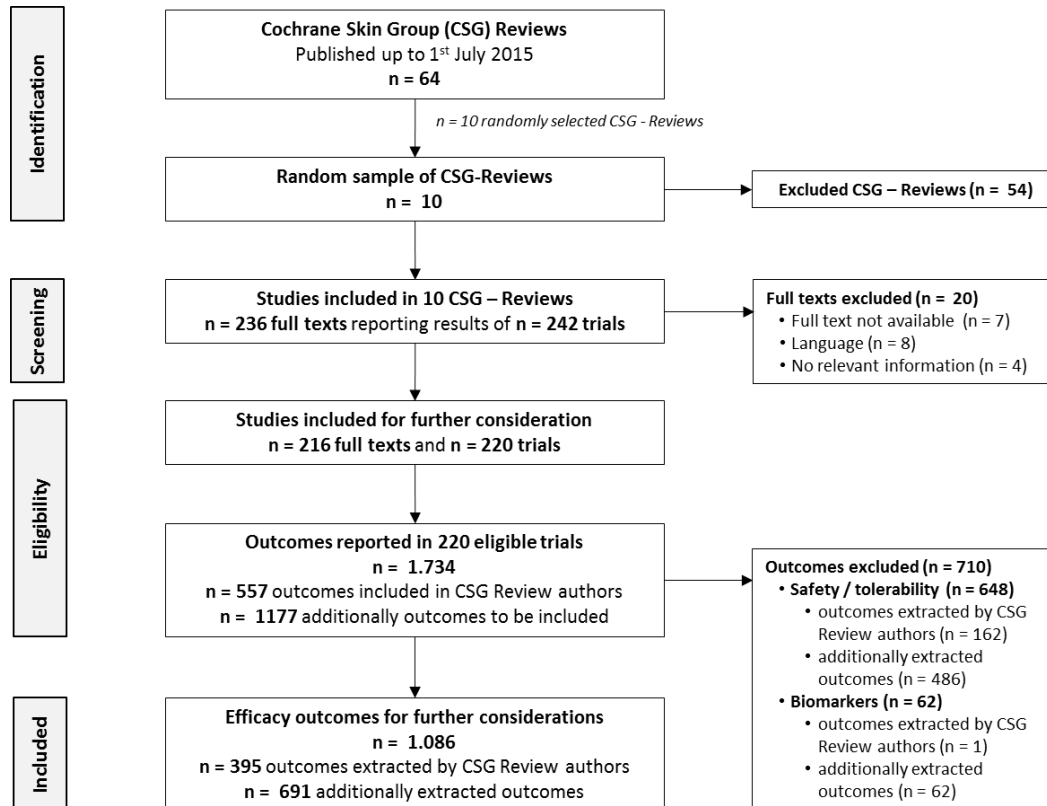
Jochen Schmitt

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# Background

- Extent of research waste due to outcome choice inconsistencies in dermatology?

→ Systematic review of 10 Cochrane Skin SRs and trials included in these SRs



# The need for COS in dermatology



21 primary efficacy outcomes in 10 Cochrane reviews

For 5 of these efficacy outcomes (24%) not assessed in a single trial.

Another 6 review outcomes were assessed in less than 50% of trials.

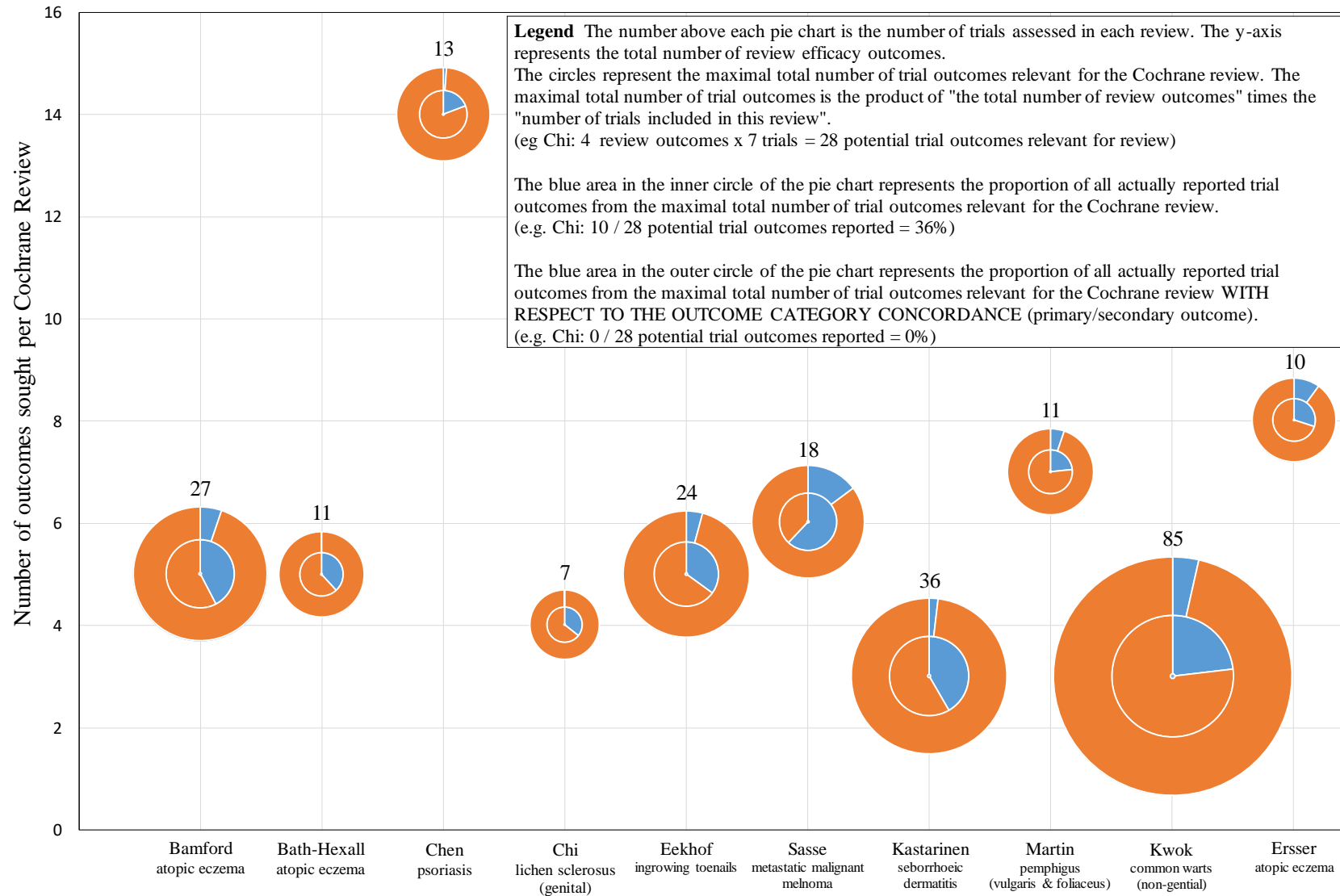
Only 1/21 primary review outcome was reported in all corresponding trials.

For 11/21 primary review outcomes (52%) meta-analysis could not be performed because outcomes were not reported at all, imprecisely defined, or measured inappropriately in review trials.

Very low overlap between primary review outcomes and trial outcomes.

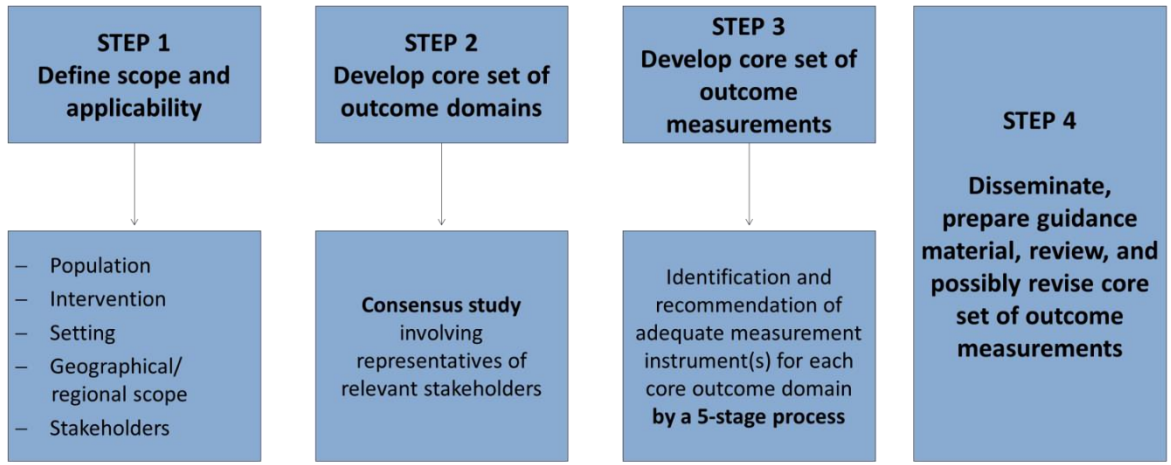
10 / 10 Cochrane review teams (100%) identified outcome assessment and reporting in trials as major barrier for evidence synthesis

# The need for COS in dermatology



Cochrane Reviews

# The HOME initiative



	Stage 1 →	Stage 2 →	Stage 3 →	Stage 4 →	Stage 5						
<b>Task</b>	Identify all instruments previously used to measure the domain.	Establish the extent and quality of testing of the identified instruments.	Determine which instruments are good enough quality and meet the requirements of the OMERACT filter and be shortlisted for further consideration.	Carry out validation studies on shortlisted scales.	Finalize of core outcome instrument for domain.						
<b>Methodology</b>	Systematic review of outcome instruments used.	Systematic review of validation studies of the long-list of identified instruments. Highlight any gaps in validation.	Apply OMERACT filter; truth, discrimination, and feasibility: <table border="1" data-bbox="529 878 904 1149"> <tr> <td><b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"</td> <td><b>Discrimination</b> "Does the measure discriminate between situation that are of interest?"</td> <td><b>Feasibility</b> "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"</td> </tr> <tr> <td>Consensus discussion and voting on truth: 1. Face validity 2. Content validity 3. Construct validity 4. Criterion validity</td> <td>Consensus discussion and voting on discrimination: 1. Reliability 2. Sensitivity to change</td> <td>Consensus discussion and voting on feasibility: 1. Time take 2. Cost 3. Interpretability</td> </tr> </table>	<b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"	<b>Discrimination</b> "Does the measure discriminate between situation that are of interest?"	<b>Feasibility</b> "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"	Consensus discussion and voting on truth: 1. Face validity 2. Content validity 3. Construct validity 4. Criterion validity	Consensus discussion and voting on discrimination: 1. Reliability 2. Sensitivity to change	Consensus discussion and voting on feasibility: 1. Time take 2. Cost 3. Interpretability	Consensus discussion and voting to determine what validation studies will be conducted on short-listed instruments. Gaps in testing were highlighted in stage 2 (systematic review). Appropriate methods used to fill the gaps in validation.	Reapply the OMERACT filter with the results of the completed validation studies. Consensus discussion and voting on core outcome to be recommended.
<b>Truth</b> "Is the measure truthful, does it measure what it intends to measure? Is the result unbiased and relevant?"	<b>Discrimination</b> "Does the measure discriminate between situation that are of interest?"	<b>Feasibility</b> "Can the measure be applied easily in its intended setting, given constraints of time, money, and interpretability?"									
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<b>Output</b>	Long list of all instruments previously used to measure the domain.	Summary of which instruments have been tested and the quality, extent, and results of any testing.	Short-list of potential instruments that meet the requirements of the OMERACT filter.	Short list of fully tested instruments.	Recommended core outcome instrument for the domain.						

# COS development and implementation ....



- ... requires the involvement of all relevant stakeholders in the field
- ... is not a straight forward process, but a lot of work
- ... is currently en vogue
- ... the quality of a COS may differ
- ... inappropriate COS will not resolve, but enforce the situation
- ... quality assurance in COS development is key

# The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)

Established in 2016, **structurally integrated** in Cochrane Skin

Basic idea: **To integrate clinical expertise, methodological expertise and stakeholder impact** in dermatology

in order **to develop and implement high quality COS** in dermatology

in order to improve and standardize outcome measurement in clinical trials to make trial evidence more useful for clinical decision making

Necessary to help Cochrane to meet its goals



Core Outcome Set Initiative

[www.cs-cousin.org/](http://www.cs-cousin.org/)

# The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)



Cochrane  
Skin



Core Outcome Set Initiative

## Methods Group

- Provides methodological advice
- Ensures uniformity of standards
- Undertakes methodological research
- *Linked with COMET and COSMIN*

Management  
Group

## Project Groups

- Develop topic-specific COS
- Researchers, clinicians, patients, other stakeholders

Methods  
Group

## Management Group

- Facilitates progress of Project Groups
- Assists administratively
- Delivers information & database management, holds library of key articles

Project  
Groups

# The Cochrane Skin Core Outcome Set Initiative (CS-COUSIN)

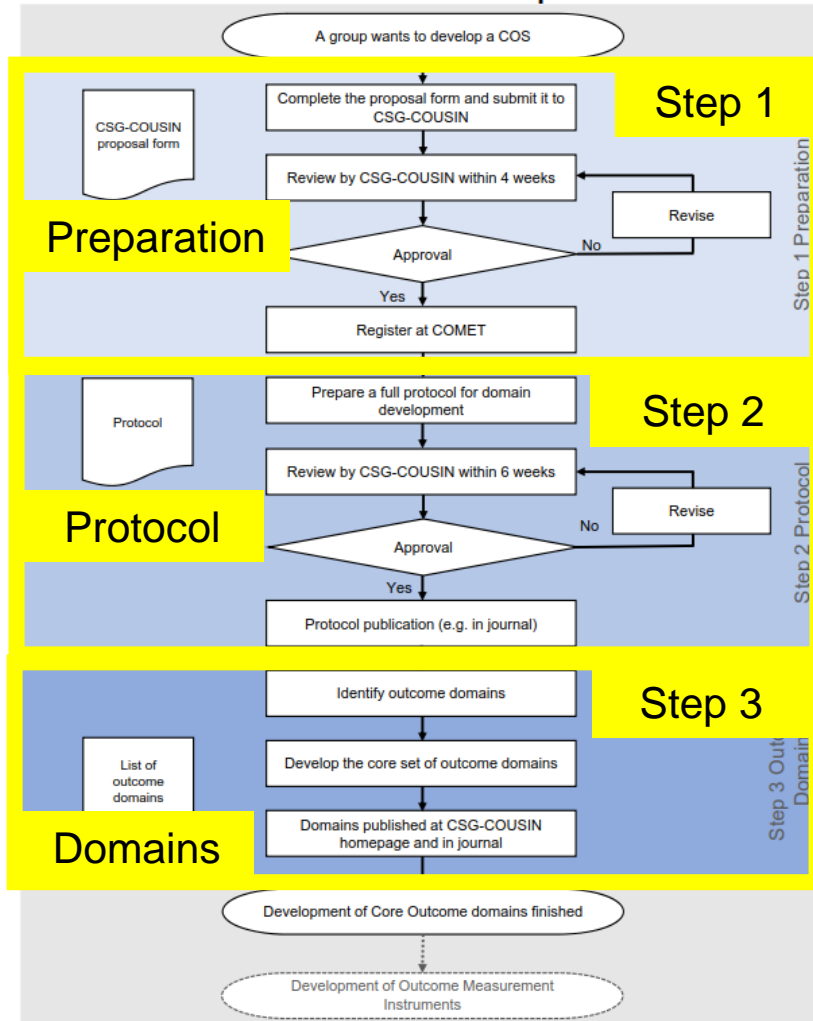


Cochrane Skin

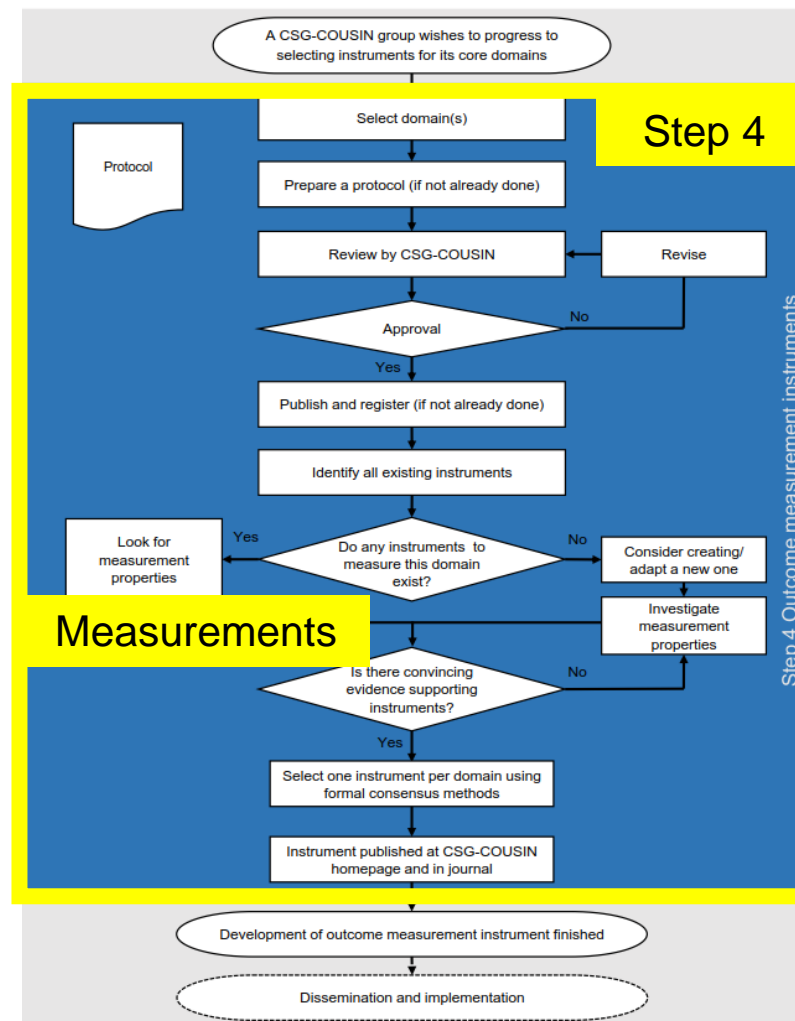


Core Outcome Set Initiative

## CSG-COUSIN COS Domain Development Process



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



→ Application of quality assurance and peer review principles

# Project groups

## Acne Core Outcomes Research Network (ACORN)

**ACORN**

The Acne Core Outcomes Research Network



Acne is one of the most prevalent diseases worldwide, being one of three dermatoses in the global top ten (Hay R et al. J Invest Dermatol 2014; 134: 1527–34). Despite this, the quality of the evidence base for the comparative efficacy of acne treatments is poor. Numerous ...

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## Core Outcome Measures in Chronic Spontaneous Urticaria



Chronic spontaneous urticaria (CSU) is a frequent, distressing, embarrassing and often disabling skin condition which can last for years. Its estimated point prevalence is 0.5-1% of the total population.[1]

> Mehr...

## Developing a Core Outcome Set for Chronic Wounds



Based on "The German national consensus on wound documentation and outcomes: Rationale, working program and current status"1 an international consensus and data base should be developed.

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## Harmonising Outcome Measures for Eczema (HOME)



The Harmonising Outcome Measures for Eczema (HOME) project is an international group working together to agree a core outcome set (COS) for atopic eczema clinical trials.

> Mehr...

## Core Outcome Set for the Appearance of Facial Aging



\*While aging is not a disease, it is treated as a condition in the context of efforts to treat aging by interventions like cosmetics, cosmeceuticals, minimally invasive cosmetic procedures, laser and energy procedures, and invasive cosmetic surgery, among others. There is hence ...

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## HECOS: Development of a Hand Eczema Core Outcome Set



Hand eczema (HE) is a common skin disease in the general population. Certain occupations are at increased risk to develop chronic, severe forms which may result in negative consequences in terms of long-term quality of life impairment, psychological co-morbidity and cost ...

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## Development of a Core Outcome Set in Hidradenitis Suppurativa (HS)



One of the key rate limiting steps in the design and funding of robust clinical trials to improve the care of people with hidradenitis suppurativa (HS) is heterogeneity of outcome measures used to determine treatment success or failure. This issue has been highlighted in the ...

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## CONSIDER – Core Outcome Set in IAD Research project: development of a core set of outcomes and measurement instruments for Incontinence-Associated Dermatitis (IAD) research



This project aims to develop a core set of outcomes and a core set of measurements to be assessed in clinical incontinence-associated dermatitis (IAD) research.

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## Developing a Core Outcome Set for Melanoma trials



In melanoma research there is no uniformity in outcome reporting. Further, it is unknown which outcomes, for example 'survival' and 'health-related quality of life', are most important to patients and healthcare providers. This causes inconsistencies in outcome reporting, ...

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# Project groups

## Development of a Core Outcome Set in Nail Psoriasis



Prof. Dr. Phyllis Spuls (a senior lecturer and consultant dermatologist with psoriasis and eczema expertise in Amsterdam, The Netherlands) and Dr. Marcel Pasch (a senior lecturer and consultant dermatologist with nail disease expertise, Nijmegen, The Netherlands), both authors ...

[> Mehr...](#)

## Core Outcome Set for Rosacea



"The purpose of this COS is to better detect difference in degree/type of presentation and track response to medical and procedural therapies."

[> Mehr...](#)

## The Outcomes for Pressure Ulcer Trials (OUTPUTs) project



The Outcomes for Pressure Ulcer Trials (OUTPUTs) project: Development of a core outcome set for trials evaluating the clinical efficacy or effectiveness of pressure ulcer prevention interventions

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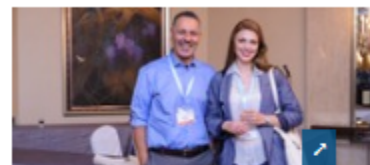
## Development of a Core Outcome Set for Vascular Malformations (OVAMA project)



The OVAMA project aims to develop a core outcome set (COS) for adult and pediatric patients with congenital vascular malformations.

[> Mehr...](#)

## Developing a Core Outcome Set for future clinical trials for the management of Vitiligo



Vitiligo is the most common depigmentation disorder, which affects around 1% of the population worldwide. Currently, no cure or firm clinical recommendations exist for the treatment of this disorder. One of the main issues identified by the Cochrane systematic review [1] was the ...

[> Mehr...](#)

## Core outcome set for clinical trials in Basal Cell Carcinoma



Basal cell carcinoma is the most common skin cancer worldwide. Treatment options include both surgical and topical modalities. Although risk of metastasis is low, basal cell carcinoma can be invasive and infiltrate important underlying structures such as bone or cartilage. While ...

[> Mehr...](#)

## European Laser TrEAtment Dermatology registry (LEAD)



During the past decades, advancements and modifications in laser technology has further widened its scope and greatly expanded the cutaneous laser surgeon's armamentarium to the point that is now considered the treatment of choice for numerous cutaneous disorders. Different ...

[> Mehr...](#)

# Priorities for the future



- To finish high quality COS in dermatology.
- To implement these COS in trials and reviews.
- To implement the standards and methods developed by COMET and COSMIN into our field and thus to validate these standards.
- To serve as a model for other clinical disciplines to bridge clinical and methodological expertise in COS development and implementation.
- To receive structural support / funding from Cochrane.

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