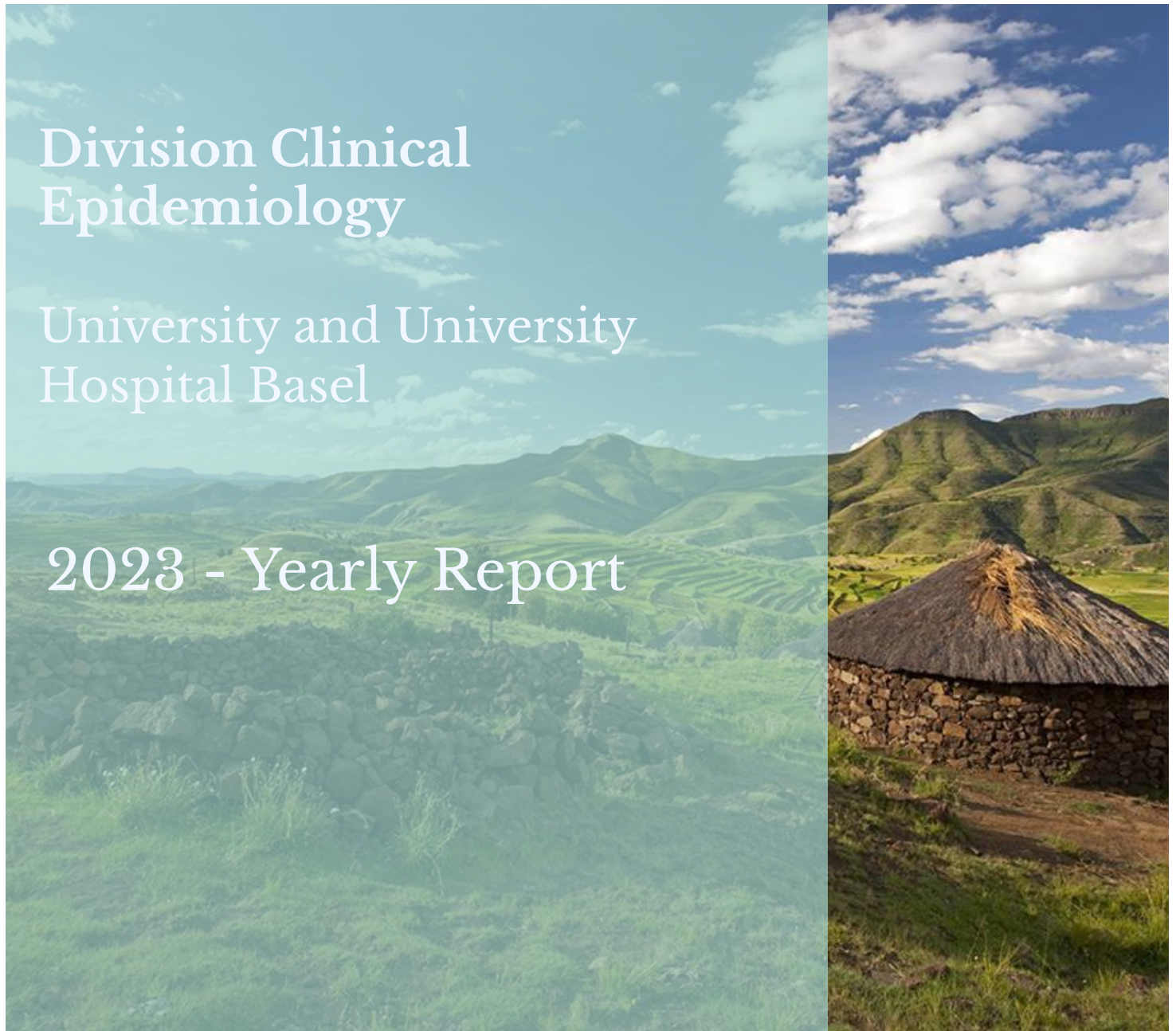


Division Clinical Epidemiology

University and University
Hospital Basel

2023 - Yearly Report



Foreword

Following the appointment of Niklaus Labhardt as the chair of Clinical Epidemiology, the Division of Clinical Epidemiology was established as part of the University Hospital Basel in August 2022. This division, integrated within the Department of Clinical Research at the University of Basel, encompasses three units: *Clinical Research Empirical Assessment & Recommendations* (CLEAR) led by **Matthias Briel**, *Evidence-based Insurance Medicine* (EbIM) under **Regina Kunz**, and *International Clinical and Health Services Research* (ICHSR) led by **Niklaus Labhardt**.

In 2023, the division hosted 6 postdocs and senior scientific collaborators, 16 PhD candidates, 4 Dr.med. candidates, 2 MSc epidemiology students, and 14 medical master students. Our division produced 63 peer-reviewed publications as first or last author and secured several competitive grants.

In addition to student supervision, Clinical Epidemiology was in charge of the medical undergraduate lecture block entitled *Patient Oriented Evidence Based Medicine* (POEM) and contributed lectures to numerous further undergraduate and graduate courses at University of Basel, Swiss Tropical and Public Health Institute, ETH Zürich, and McMaster University (Canada).

Our division is characterized by its diverse research interests and a shared goal of generating evidence to improve research and health globally, thereby supporting evidence-based decision-making at clinical, public health, and policy levels.

We extend our gratitude to the Medical Faculty, University Hospital Basel, our national and international partners, collaborators, and various funders for their trust and support.

Regina Kunz, Head of EbIM

Matthias Briel, Head of CLEAR

Niklaus Labhardt, Division Head and Head of ICHSR



Our division is characterized by its diverse research interests and a shared goal of generating evidence to improve research and health globally, thereby supporting evidence-based decision-making at clinical, public health, and policy levels.



International Clinical and Health Services Research Unit (ICHSR)

ICHSR continues with a strong focus on pragmatic clinical trials addressing urgent health needs in Southern and Eastern Africa. In 2023 eight randomized trials in Lesotho, Malawi, Tanzania, and South Africa were initiated or ongoing where Clinical Epidemiology is the principal investigator or sponsor-investigator. Further, research within the Viral Load Cohort North East Lesotho (VICONEL) and the Community-based chronic care Lesotho (ComBaCaL) project continued. Health topics covered by our work encompass HIV, tuberculosis, arterial hypertension, type 2 diabetes, and mental health, including alcohol use disorder.

Additionally, two new health topics emerged as research focal area during 2023.

Infection prevention and control at hospitals in Lesotho and infection prevention and control outside hospital settings in Switzerland, i.e., during homecare and at asylum reception centres.

During 2023, the ICHSR had 5 senior staff members and supervised eleven PhD candidates four MD and several MSc students.

Highlights of 2023



Emmanuel Firima successfully defended his thesis entitled *Improving community-based care for diabetes mellitus and hypertension in Lesotho*. Supported by a personal career grant from GlobalP3HS, Emmanuel Firima framed his PhD around the question if and how diagnosis and care for chronic non-communicable diseases in remote areas in Southern Africa could be improved through community-based interventions. His PhD encompassed a scoping review on community-based care for diabetes, and original research on optimization of household-based diagnosis of hypertension, implementation of community-based echocardiography, the prevalence of chronic pain and the prevalence of hepatitis B in Lesotho. After his PhD he continues as a Clinical Research Fellow at the University of Sheffield, UK.

Lucia Gonzalez successfully defended her thesis entitled *Towards improved knowledge and optimization of health care for non-communicable diseases in Lesotho*. Her thesis focused on public health and policy aspects around non-communicable chronic diseases in Southern Africa. Her PhD encompassed household-based surveys on the prevalence of cardio-vascular risk factors and mental health conditions in Lesotho and a scoping review on community-based care for hypertension in Africa. She further worked on models for efficient screening and diagnosis for COVID-19 at hospitals in Lesotho. After her PhD she got a position at The Global Fund to Fight AIDS, Tuberculosis and Malaria, where she works as a Public Health and M&E specialist.



Career Grants to unit members



Anne-Valérie Burgener-Gasser obtained a three-year post-doctoral career grant from the Béatrice Ederer-Weber Foundation for her project entitled *Incidence and burden of hospital-acquired infections in Lesotho, Southern Africa*.



Jennifer Brown received a **Swiss National Science Foundation PostDoc Mobility Grant**. With this grant, she will employ causal inference methodologies on large observational datasets to assess various aspects of HIV care in the UK and South Africa. She will be hosted by the University of Oxford, UK and CAPRISA, South Africa.



Andréa Williams received a three-year **Swiss Government Excellence Scholarship (ESKAS)** to conduct her PhD studies at the Division of Clinical Epidemiology. Her focus will be on community-based HIV and Sexual and Reproductive Health Services in rural Lesotho.



Natalie Johnson secured a 7 month grant from the Fulbright Visiting Scholar Program to advance her studies in Lesotho.

Other large Grants



Jennifer Belus obtained a competitive Swiss National Science Foundation Solution-Oriented Research For Development (SOR4D) grant for a project focusing on adolescent and young adult well-being in Zambia, Zimbabwe and South Africa.

Publications Highlights

1

Improving blood pressure diagnosis during prevalence surveys

Introduction of unattended blood pressure measurement into prevalence surveys may improve accuracy in hypertension prevalence estimates. This publication shows that the World Health Organization STEPS algorithm used for prevalence surveys globally may be improved by replacing the standard blood pressure measurement with the unattended blood pressure measurement.

Firima E, Retselisitsoe L, Leisa I, Manthabiseng M, Sematle MP, Bane M, Khomolishoele M, Gonzalez L, Gupta R, McCrosky S, Lee T, Chammartin F, Leigh B, Weisser M, Amstutz A, Burkard T, Labhardt ND. *Head-to-head comparison of the WHO STEPwise approach with immediate unattended and delayed unattended automated blood pressure measurements during household-based screening: a diagnostic accuracy study in Lesotho.*

EClinicalMedicine. 2023 Aug 30;63:102197. doi: 10.1016/j.eclinm.2023.102197.

<https://pubmed.ncbi.nlm.nih.gov/37680951/>

2

Real world effectiveness of dolutegravir for people with HIV

First routine two-year outcome data after changing from non-nucleoside reverse transcriptase inhibitor to dolutegravir-based antiretroviral therapy show that the roll-out of dolutegravir across Africa was a game-changer for millions of people living with HIV.

Tschumi N, Lerotholi M, Motaboli L, Mokete M, Labhardt ND, Brown JA.

Two-Year Outcomes of Treatment-Experienced Adults After Programmatic Transitioning to Dolutegravir: Longitudinal Data From the VICONEL Human Immunodeficiency Virus Cohort in Lesotho. **Clin Infect Dis.** 2023 Nov 11;77(9):1318-1321. doi: 10.1093/cid/ciad390.

<https://pubmed.ncbi.nlm.nih.gov/37358226/>

3

Viewpoint on the debate around same-day ART initiation

In collaboration with colleagues from the World Health Organization and the Boston University, authors from Clinical Epidemiology argue in a viewpoint that differences in the denominator account for most of the discrepancies seen between randomized trials and cohort studies that compare same-day vs non same-day initiation of antiretroviral therapy. Whereas the trials usually included all individuals at the moment they test HIV positive, most cohort studies started inclusion at first clinic contact, thus excluding persons lost from care between HIV testing and accessing the HIV clinic.

Labhardt ND, Brown JA, Sass N, Ford N, Rosen S.

Treatment Outcomes After Offering Same-Day Initiation of Human Immunodeficiency Virus Treatment-How to Interpret Discrepancies Between Different Studies.

Clin Infect Dis. 2023 Oct 13;77(8):1176-1184. doi: 10.1093/cid/ciad317.

<https://pubmed.ncbi.nlm.nih.gov/37229594/>

Clinical Research Empirical Assessment & Recommendations (CLEAR)

In 2023 the CLEAR Methods Center managed to consolidate a group of three senior staff members and supervised three PhD candidates in addition to several medical master students. In the future we will continue our main research lines of applied clinical studies and empirical meta-research projects in close collaboration with local, national, and international research consortia. We plan to intensify our methodological support for local research groups and young clinical investigators through the Department of Clinical Research in Basel following our motto: CLEAR methods for better clinical research!

Highlights of 2023

Stefan Schandelmaier and **Benjamin Speich** both successfully completed their habilitation promoting them to Privatdozenten (PD) at the Medical Faculty of Basel.

PD Dr. Stefan Schandelmaier

Stefan Schandelmaier is a physician researcher with a PhD in research methodology. His research aims to improve methodological decision-making and develop practical tools for researchers. His areas of expertise include clinical trials, meta-analysis, subgroup analysis, qualitative methods, and teaching of research methods.



PD Dr. Benjamin Speich

Benjamin Speich is a senior researcher, specialized in the conduct of randomized clinical trials. He is also strongly engaged in research projects aimed at identifying challenges in conducting clinical trials and finding interventions to address these hurdles.



Career Grants to unit members



Alain Amstutz secured several competitive personal grants (Uni Forschungsfonds, Novartis Foundation, SNSF PostDoc Mobility) boosting his career towards an independent research group leader.



Christof Schönenberger received an SNSF MD-PhD grant for his innovative Trial-within-a-Cohort (TwiC) testing a smoking cessation intervention in the Swiss HIV Cohort Study.

After securing further funding from the Swiss Tobacco Prevention Fund, he led the process to implement the TwiCs design for the first time in a large national cohort.

Other grants and awards to members of the unit



Christof Schönenberger, Alain Amstutz, and Matthias Briel received a project grant from the Swiss Tobacco Prevention Fund for the TwiC about reducing tobacco use in people with HIV in Switzerland (RETUNE-HIV trial).



Alain Amstutz received a seed grant from the Participatory Science Academy at the Competence Centre Citizen Science for a project on hair salons as an innovative community space to address sexual and reproductive health issues among young Black women in Lesotho and Switzerland.

Furhermore, **Alain Amstutz** won the first price at the Clinical Research Day 2023. His short presentation was titled: Remdesivir in hospitalized patients with COVID-19: Individual patient data meta-analysis



Stefan Schandelmaier and colleagues received the Lighthouse Project Award from the German Society of Medical Information Specialists for the initiation of the *Library of Guidance for Health Scientists* (LIGHTS).

Publications Highlights

Individual patient data meta-analysis on remdesivir in COVID-19

1

Remdesivir was the first antiviral approved for COVID-19 treatment, but results from several randomized clinical trials (RCTs) have been mixed. We reanalyzed data from over 10,000 hospitalized patients in more than 40 countries. The pooled analysis showed a significant survival benefit for patients receiving no or conventional oxygen therapy, reducing mortality by about 2%, or 20 fewer deaths per 1,000 patients treated. Remdesivir did not lead to more adverse events compared to standard treatment. This study, part of a pan-European platform trial network spanning 21 university hospitals in 16 countries, involved our methodology group.

Amstutz A, Speich B, Mentré F, Rueegg CS, Belhadi D, Assoumou L, Burdet C, Murthy S, Dodd LE, Wang Y, Tikkinen KAO, Ader F, Hites M, Bouscambert M, Trabaud MA, Fralick M, Lee TC, Pinto R, Barratt-Due A, Lund-Johansen F, Müller F, Nevalainen OPO, Cao B, Bonnett T, Griessbach A, Taji Heravi A, Schönenberger C, Janiaud P, Werlen L, Aghlmandi S, Schandelmaier S, Yazdanpanah Y, Costagliola D, Olsen IC, Briel M. *Effects of remdesivir in patients hospitalised with COVID-19: a systematic review and individual patient data meta-analysis of randomised controlled trials.* *Lancet Respir Med.* 2023 May;11(5):453-464. doi: 10.1016/S2213-2600(22)00528-8. Epub 2023 Feb 21. Erratum in: *Lancet Respir Med.* 2023 Aug;11(8):e77. PMID: 36828006; <https://pubmed.ncbi.nlm.nih.gov/36828006/>

Link to the University of Basel News: <https://www.unibas.ch/de/Aktuell/News/Uni-Research/Wann-Remdesivir-zur-Behandlung-von-Covid-19-nuetzlich-ist.html>

Two randomized trials testing peer-review interventions

2

Lack of transparent reporting in published trials is a major issue. We conducted two randomized trials with journals like The BMJ, BMJ Open, and PLOS Medicine to see if asking peer reviewers to check specific reporting guidelines improves reporting quality. Results from 421 manuscripts (intervention vs. control) showed no improvement. More randomized trials are needed to find effective interventions for better trial reporting.

Speich B, Mann E, Schönenberger CM, Mellor K, Griessbach AN, Dhiman P, Gandhi P, Lohner S, Agarwal A, Odotayo A, Puebla I, Clark A, Chan AW, Schlüssel MM, Ravaud P, Moher D, Briel M, Boutron I, Schroter S, Hopewell S. *Reminding Peer Reviewers of Reporting Guideline Items to Improve Completeness in Published Articles: Primary Results of 2 Randomized Trials.* *JAMA Netw Open.* 2023 Jun 1;6(6):e2317651. doi: 10.1001/jamanetworkopen.2023.17651. PMID: 37294569; <https://pubmed.ncbi.nlm.nih.gov/37294569/>

LIGHTS database to promote methods guidance in health research

3

In 2023 we published an article that introduces the *Library of Guidance for Health Scientists* (LIGHTS). LIGHTS is a new searchable database designed specifically to support clinical researchers in finding appropriate methods guidance for their studies. End of 2023 LIGHTS included about 1,600 methods guidance articles and had 6,000 users per month. In a related article, we elaborate on the challenges that researchers and methodologists typically face when they search for a methodological topic and suggest practical solutions.

Hirt J, Schönenberger CM, Ewald H, Lawson DO, Papola D, Rohner R, Suter K, Lin S, Germini F, Zeng L, Shahabinezhad A, Chowdhury SR, Gao Y, Bhattacharjee A, Lima JP, Marusic A, Buljan I, Agarwal A, Guyatt GH, Briel M, Schandelmaier S. *Introducing the Library of Guidance for Health Scientists (LIGHTS): A Living Database for Methods Guidance.* *JAMA Netw Open.* 2023 Feb 1;6(2):e2253198. <https://pubmed.ncbi.nlm.nih.gov/36787138/>

Hirt J, Ewald H, Briel M, Schandelmaier S. *Searching a methods topic: practical challenges and implications for search design.* *J Clin Epidemiol.* 2023 Oct 30;166:111201. <https://pubmed.ncbi.nlm.nih.gov/37914105/>

Evidence-based Insurance Medicine (EbIM)

In summer 2022, we integrated our Unit EbIM into the newly founded Division of Clinical Epidemiology. This merger will enable synergies in topics we address, in the methodologies we use, and in the people who carry out the work. Our key tasks continue to be the production of high-quality evidence-based research on current topics, with a focus on the quality of medical evaluations, the transfer of knowledge of the results to a (inter-) national audience and involvement at undergraduate, postgraduate and continuing education.

“



One highlight was the publication of the theme issue *Versicherungsmedizin* (insurance medicine) in the *Therapeutische Umschau*, where we - together with our (inter-) national network - published 12 flagship examples on how insurance medicine can be (and become increasingly) evidence-based, using research evidence to guide practice and inform about the current landscape of educational activities in Switzerland in which we participate.

Prof. Dr. Regina Kunz

Theme issue: selected articles

- Verbeek J, Raatz H, **Kunz R**, Hoving J. *Hausärztliche Betreuung bei der Rückkehr zur Arbeit [How can general practitioners best help their depressed patients to resume work?]*. *Ther Umsch.* 2023;80(2):49-54. German. doi: 10.1024/0040-5930/a001408. PMID: 37067082. <https://pubmed.ncbi.nlm.nih.gov/37067082/>
- Marelli R, Baer N. *Psychische Gesundheit und Arbeitsplatz [Mental health and workplace - What tools are available to primary care physicians to facilitate the return to work for patients with workplace problems?]*. *Ther Umsch.* 2023;80(2):55-60. German. doi: 10.1024/0040-5930/a001409. PMID: 37067081. <https://pubmed.ncbi.nlm.nih.gov/37067081/>
- Donker-Cools BHPM, van Bennekom CAM, **Kunz R**. *Erworbene Hirnschädigung und Teilhabe am Arbeitsleben [Acquired Brain Injury and Work Participation - A Dutch Interdisciplinary Guideline for Occupational and Insurance Physicians]*. *Ther Umsch.* 2023;80(2):61-66. German. doi: 10.1024/0040-5930/a001410. PMID: 37067093. <https://pubmed.ncbi.nlm.nih.gov/37067093/>
- Klipstein A, **Trippolini M**. *Instrumente und Arbeitshilfen bei der Einschätzung der Arbeitsfähigkeit [Instruments and Tools in the Medical Evaluation of Work Capacity]*. *Ther Umsch.* 2023;80(2):69-73. German. doi: 10.1024/0040-5930/a001412. PMID: 37067089. <https://pubmed.ncbi.nlm.nih.gov/37067093/>
- **Rosburg T**, Lohss R, Bachmann MS, Meyer BW, Boer W, Fischer K, **Kunz R**. *Integration der Versichertenperspektive in die Qualitätsbewertung der Begutachtung [Integration of the Insured Person's Perspective in the Quality Assessment of Medical Evaluations]*. *Ther Umsch.* 2023;80(2):78-84. German. doi: 10.1024/0040-5930/a001414. PMID: 37067091. <https://pubmed.ncbi.nlm.nih.gov/37067091/>

Core Outcome Set (COS) on Work Participation

EbIM is collaborator in the international research team of COS on Work (www.cosforwork.org). founded in 2020. A COS is an agreed standardized set of outcomes that should be measured and reported as a minimum in all clinical trials in specific areas of health or health care to ensure better comparability of research findings when pooling study results. In 2023, we published the 4th and 5th study of this development process. In 2024/25, we anticipate to finalize this research project.

Ravinskaya M, Verbeek JH, Langendam M, Madan I, Verstappen SMM, Kunz R, Hulshof CTJ, Hoving JL and Delphi participants.

Which outcomes should always be measured in intervention studies for improving work participation for people with a health problem? BMJ Open 2023;13: e069174.

<https://pubmed.ncbi.nlm.nih.gov/36792339/>



New Cochrane Thematic Group Work & Health & Social Security

In the context of the ongoing restructuring of the Cochrane Collaboration, our Cochrane group Insurance Medicine (located at EbIM) together with the longstanding collaborating Cochrane Work group had successfully applied to pilot (as one of 6 groups) the thematic group Work & Health & Social Security.

This new Cochrane Group takes on a broader range of diverse tasks, identifies priority review topics in their respective areas, contributes to methodological developments, engages in dissemination, contributes to methods development such as the Core Outcome Set for Work Participation, teams up with global partners, such as 'Evidence for Work', and engages with (inter-) national researchers and stakeholders active in organizations such as European Union of Medicine in Assurance and Social Security (EUMASS) and International Commission on Occupational Health.

The Cochrane Thematic Group Work & Health & Social Security presenting itself in September 2023 at the European Parliament in Strasbourg during the 50th anniversary of the European Union in Medicine of Assurance and Social Security (EUMASS).



The Board of Cochrane Insurance Medicine (CIM) Board (left to right): Jan Hoving (NL), Regina Kunz (CH), Emilie Friberg (SE), Karen Walseth Hara (NO), Maurizio Trippolini (CH)



Unit Heads
Briel, Matthias
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Kunz, Regina

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Ehrenzeller, Selina
Sendi, Pedram

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Kindler, Kevin
Sanchez, Giuliana
Tahirsylaj, Thesar

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Belus, Jennifer
Brockhaus, Lisa
Brown, Jennifer
Burgener-Gasser, Anne Valérie
Chammartin Frédérique
Falgas, Irene
Giezendanner, Stephanie
Klicpera, Anna
Rosburg, Timm
Schandelmaier, Stefan
Speich, Benjamin
Trippolini, Maurizio
Tschumi, Nadine

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Gonzalez, Lucia
Griessbach, Alexandra
Johnson, Natalie
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Lerotholi, Malebanye
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Taji Heravi, Ala
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Kohler, Maurus

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Covino, Manuela
Elalfy, Mona
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Gürke, Simon
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Harder, Michelle
Hausherr, Lena
Hüllstrung, Julia
King, Rayco
Meierkord, Lars
Wnfried Ramirez, Hillary
Wüthrich, Linda



FUNDERS
OF ONGOING PROJECTS

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Swiss Development Cooperation
Swiss National Science Foundation
Tobacco Prevention Fonds

Division Clinical Epidemiology



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Publication List

First- and / or Last Authorship

Aghlmandi S, Halbeisen FS, Godet P, Signorell A, Sigrist S, Saccilotto R, Widmer AF, Zeller A, Bielicki J, **Bucher HC**. *Impact of the COVID-19 pandemic on antibiotic prescribing in high-prescribing primary care physicians in Switzerland. Clin Microbiol Infect.* 2024 Mar;30(3):353-359. doi: 10.1016/j.cmi.2023.11.010. Epub 2023 Nov 22. PMID: 38000535.

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