

## Perspective

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# Encouraging student-driven clinical research in Germany: the CHIR-Net SIGMA network

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**Abstract:** Evidence should define and guide modern clinical care, yet many relevant questions in surgical practice remain unconfirmed by substantial data. Evidence-based medicine requires both the implementation of its principles in day-to-day work and the acquisition of new evidence preferably by randomized controlled trials and systematic reviews. Meaningful clinical research, however, is challenging to conduct, and its overall infrastructure in Germany was, until recently, considered poor compared to other leading countries. Although this has been significantly improved after the establishment of the Study Center of the German Surgical Society (SDGC) and the surgical clinical trial network CHIR-Net, limited focus has been put on the training, teaching, and recruitment of medical students to become competent clinical researchers and clinician scientists. To ensure continuing comprehensive clinical research in surgery, CHIR-Net aims to establish a student-driven multicenter research network in Germany, which is embedded in both the national CHIR-Net and the pan-European and international frameworks. Student-Initiated German Medical Audits (SIGMA) is a product of the strong collaboration between clinical scientists and medical trainees, enabling students to contribute to high-quality clinical trials.

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Additionally, participants are offered extensive training to support the next generation of research-active clinicians. Starting on 2018, SIGMA will perform its first multicenter observational study in Germany.

**Keywords:** CHIR-Net; clinical trial; evidence-based medicine; medical education; PATRONUS; research personnel; SIGMA.

## Introduction

Modern clinical care should be performed evidence-based. Findings from controlled clinical trials and meta-analyses are considered to offer the best available evidence. However, clinical research is challenging to conduct, particularly in surgery, where relevant questions in day-to-day care are yet to be built on evidence [1, 2]. Evidence-based medicine (EbM) requires both the implementation of EbM principles in everyday clinical work and the acquisition of new evidence preferably by randomized controlled trials (RCTs) and systematic reviews.

Although the latter has improved in Germany after the establishment of the Study Center of the German Surgical Society (SDGC) and the surgical clinical trial network CHIR-Net [3], limited focus has been put on the training, teaching, and recruitment of medical students to become competent clinical researchers and clinician scientists. Although funding bodies including the Deutsche Forschungsgesellschaft (DFG) have lamented the lack of support and structured clinician scientist programs, the proposed changes/curricula focus solely on postgraduate education (residency training) while neglecting graduate medical education [4, 5].

At the same time, graduate medical education in Germany has come under scrutiny in recent years for a lack of teaching scientific competencies, including EbM [6, 7]. Consequently, the recently published “Masterplan Medizinstudium 2020” outlining the future of medical education in Germany demands to strengthen the scientific knowledge and competencies of medical

students [8, 9]. However, although a framework for graduate EbM teaching has been developed [10, 11] and some medical schools have started to implement EbM features in their curricula, these efforts focus mostly on the application of EbM principles in everyday clinical practice but not on teaching scientific methodology or performing scientific work (i.e. generating new scientific evidence). Similarly, the overall scientific quality of medical doctorate (MD) thesis in Germany has faced severe criticism in recent years. Finally, as a consequence of more comprehensive, patient-oriented medical curricula, free periods for medical students that have previously been available for potential scientific activity have been reduced.

In summary, a reinforcement of graduate and postgraduate scientific education in medicine is necessary with regard not only to the training of critically thinking physician-scientists but also to the safeguarding of quality clinical care, as the “scientific and statistical illiteracy” of patients and medical professionals is a growing concern [12].

The participation of medical students in clinical research may allow for the practical interaction with the concept and methods of EbM. Projects to provide such research experiences are emerging and show that medical students can improve their clinical capabilities by contributing to student-initiated clinical trials [13–15]. Professional orientation toward academic careers may be inspired by such initiatives, as a future shortfall in physicians concomitant with a deficit in academic faculty seems likely in European countries [16–18].

To address these challenges, CHIR-Net has established a student-initiated and -led clinical trial network (SIGMA; Student-Initiated German Medical Audits) in 2017. Inspired by similar initiatives from the United Kingdom (UK), this network enables students to participate in academic research projects and serves as an exchange platform between students and research-experienced physicians [19]. As part of the SIGMA network, students contribute to national multicenter trials while improving clinical and research skills and gaining an insight into clinical academia.

## Objectives of the CHIR-Net SIGMA network

Given the above-mentioned challenges, the CHIR-Net SIGMA network has the following objectives:

1. Creation of a national multicenter *network* of medical students and associated clinician scientists, clinical

researchers, and associated professions (biostatisticians, study nurses, etc.).

2. Establishment of a *clinical trial infrastructure* to enable the conduct of student-led multicenter clinical trials.
3. *Education* and training of medical students in clinical trial methodology, regulatory affairs, and ethical clinical trial conduct.
4. Design, initiation, conduction, analysis, and publication of prospective multicenter *clinical trials* initiated and led by medical students.

## SIGMA structure and collaborations

The Student Audit and Research in Surgery (STARSurg; [www.starsurg.org](http://www.starsurg.org)) is a UK-based research collaborative founded by medical students and surgical trainees. The network has been able to recruit 250 students in numerous national hospitals to participate in prospective trials. In their first trial, outcomes of 1503 patients were reported across 109 centers on the effect of postoperative non-steroidal anti-inflammatory drugs (NSAIDs) on adverse events after gastrointestinal surgery, resulting in a publication where all collaborating students are citable coauthors [20]. Based on the idea and principles of STARSurg, SIGMA was founded as a student-driven German research network and aims at recruiting students from CHIR-Net regional centers and non-CHIR-Net hospitals (Figure 1).

As part of SIGMA’s organizational structure (Figure 2), students of each participating center form “mini-teams” consisting of two to three students supervised by a local research-active surgeon. Each mini-team is independently obtaining clinical data and recruiting patients to SIGMA-led trials. Multiple mini-teams are coordinated by center-specific local leads. Local leads are medical students that take on the responsibility of coordinating and running the local mini-teams. Local leads are supported by CHIR-Net coordinators of the appropriate regional centers ([www.chir-net.de/regionalzentren-karte/](http://www.chir-net.de/regionalzentren-karte/)) or, in the case of non-CHIR-Net associated centers, by a responsible resident or attending surgeon (SIGMA coordinator; Figure 2). This structure provides for the recruitment of a high number of patients while warranting quality control and continuous coordination on a local and a national level. A SIGMA national trial committee is responsible for the design of a given SIGMA study, setup of the necessary infrastructure (e.g. CRF and databases), training of participants, acquisition of funding, analyses of data, and publication. The members of the SIGMA national trial committee therefore

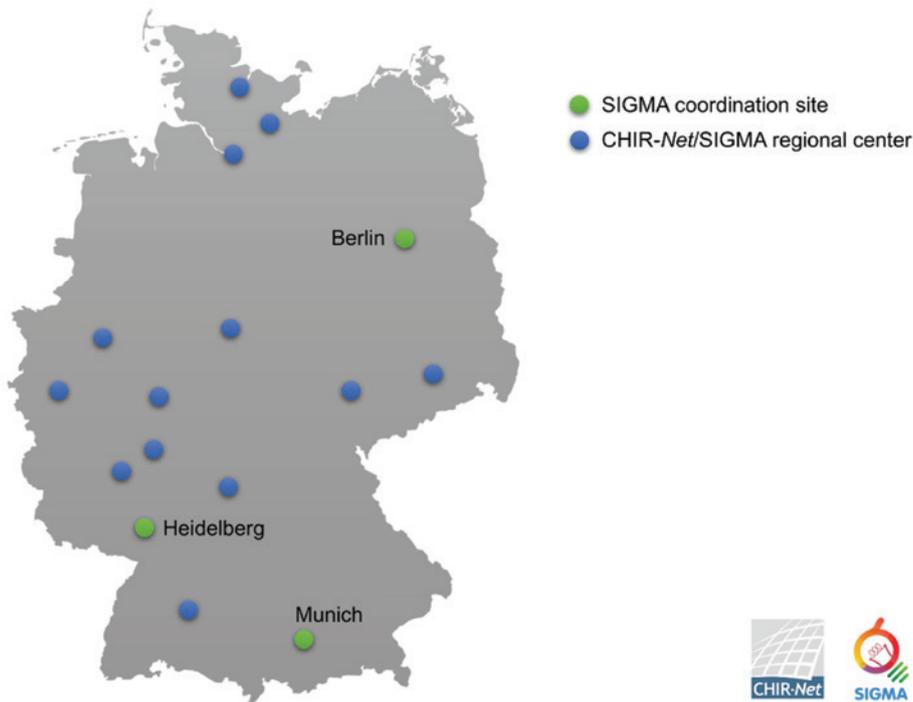


Figure 1: CHIR-Net network and SIGMA coordination sites.

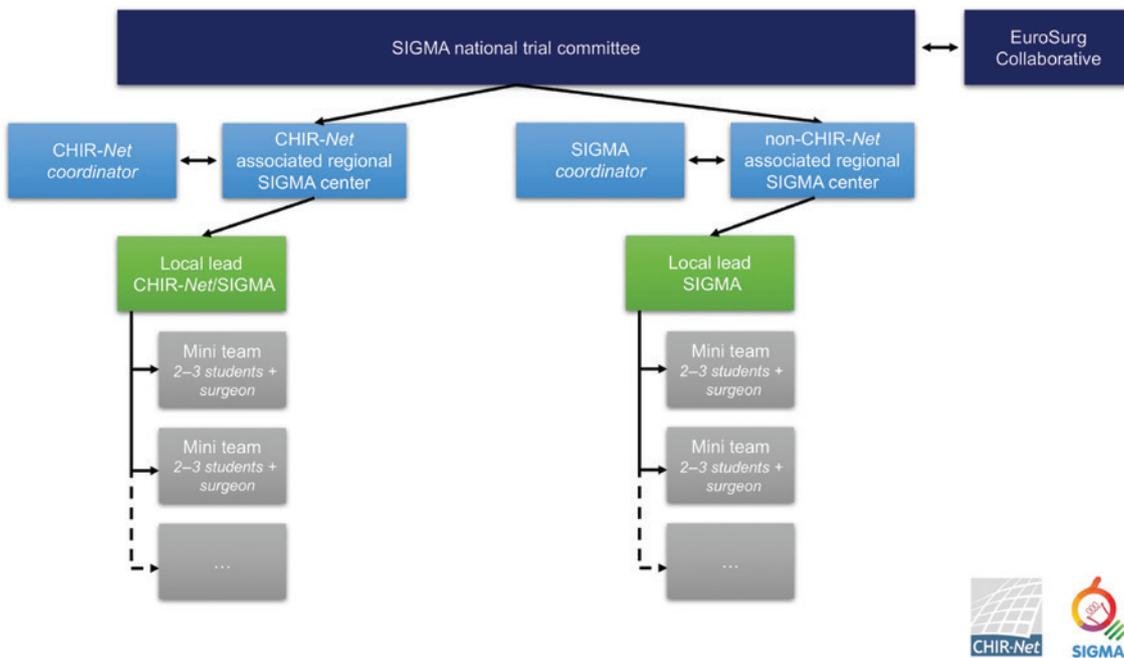


Figure 2: CHIR-Net SIGMA organigram.

vary according to the study but comprise medical students as well as associated clinical scientists, methodologists, and associated study personnel.

SIGMA is benefitting from a tight collaboration with CHIR-Net, the surgical trial network of the German

Surgical Society ([www.chir-net.de](http://www.chir-net.de)). CHIR-Net has succeeded in creating a nationwide research infrastructure comprising university and non-university centers that provides the basis for SIGMA collaboration projects [3]. Since its foundation in 2006, CHIR-Net has recruited more

than 10,800 patients in RCTs and consists of 16 regional centers and more than 390 partner hospitals. SIGMA mini-teams and local leads are associated with their local CHIR-Net regional center, and future CHIR-Net and SIGMA-led trials are reciprocally fostered by additional resources and manpower.

Similar to its UK-based predecessor STARSurg, SIGMA will collaborate on a pan-European and international level as part of EuroSurg. EuroSurg is a network of medical students and surgeons from Europe and Oceania who cooperate to run high-quality, multicenter, international studies. SIGMA will appoint a national committee carrying out EuroSurg-led collaboration efforts in Germany. Through EuroSurg, SIGMA students will take part in an international exchange that is thriving from discourse and the connection of medical professionals with highly diverse backgrounds. This allows for the continuous development of CHIR-Net SIGMA projects and individual skills alike.

Finally, SIGMA offers complimentary visits of surgical conferences and networking events and encourages students and supervising physicians to interact closely even outside data collection through the concept of local mini-teams.

## CHIR-Net SIGMA infrastructure

In line with CHIR-Net quality requirements, SIGMA aims to deliver high-quality clinical trials in agreement with national and international standards including good clinical practice (GCP) guidelines. To this end, CHIR-Net SIGMA strives for the training and education of medical students in the fundamental principles of clinical trial design and conduct (see section below) as well as providing an open, cost-efficient, and transparent infrastructure for the implementation of prospective clinical trials. For this purpose, CHIR-Net SIGMA has established a secure, REDCap™-based ([www.project-redcap.org](http://www.project-redcap.org)) database. REDCap™ is an open, secure web application for building and managing online surveys and database and can be used online and offline to create electronic case report forms (eCRFs). By establishing a REDCap™-based secure server environment at the University of Heidelberg, SIGMA teams can access the eCRF forms from virtually everywhere. Furthermore, data entry is not only restricted to local mini-teams but can also be done directly by patients via digital surveys. This allows the widespread use of patient-reported outcome measures (PROMs) such as quality of life or symptom scores.

Another pivotal characteristic of SIGMA is its dissemination by a social media strategy developed by the

STARSurg collaborative that already proved successful in recruiting students from multiple countries to become involved in STARSurg and EuroSurg trials. SIGMA makes use of established platforms such as CHIR-Net and university mailing lists, websites ([www.sigma.university](http://www.sigma.university)), as well as social media platforms such as Facebook ([www.facebook.com/sigmastudynetwork](http://www.facebook.com/sigmastudynetwork)), Twitter (@sigmastudies), and Instagram ([www.instagram.com/sigmastudynetwork](http://www.instagram.com/sigmastudynetwork)) and national conferences to attract today's medical students and broadcast progress updates [21]. For project coordination, the SIGMA national trial committee, local leads, mini-teams, and CHIR-Net coordinators use the app-based application Slack (<https://slack.com/>) to allow for real-time project management and communication. SIGMA's social media strategy thus aims at making comprehensive clinical research accessible and student oriented.

## Training of medical students

Training and education are essential components to ensure ethical clinical trial conduct in line with national and international standards such as the Declaration of Helsinki or GCP guidelines [22]. CHIR-Net SIGMA is therefore currently developing a SIGMA clinical trials curriculum (SIGMA CTC; Prüf-Studierenden-Kurs) based on the extensive experiences from the CHIR-Net Rotational Program [23] and Prüfarzt-Kursen organized by the Coordination Centre for Clinical Studies (KKS). It is a hands-on training program giving an introduction to EbM, biostatistics, clinical trial conduct, and meetings with research-active surgeons. Coursework includes rationales and key steps for the conduction of clinical trials and advanced protocol discussions. Courses will be constantly evaluated and adjusted to create a solid theoretical foundation for collaborating students.

The first SIGMA CTC will be held in Heidelberg from February 2 to 4, 2018. Enrollment is possible for all medical students interested in the upcoming CHIR-Net SIGMA studies (see below) at [www.sigma.university](http://www.sigma.university). The application deadline is January 1, 2018.

## Planned clinical trials

PATRONUS (prospective multicenter cohort study of patient-reported outcomes and complications following major abdominal neoplastic surgery; DRKS number DRKS00013035 Universal Trial Number U1111-1202-8863)



**Figure 3:** At a glance: the CHIR-Net SIGMA network.

will be the first clinical trial initiated and led by the CHIR-Net SIGMA network Figure 3. Its objectives include determining the association between short-term (postoperative) complications and long-term clinical outcomes (survival) and PROMs. Two sets of PROMs will be used in the PATRONUS trial: (a) a core set of 12 cancer-associated symptoms measured via the newly developed Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) [24] and (b) cancer-specific quality of life (measured via the computer adaptive testing version of the EORTC QLQ-C30). These will be adjusted for patient-specific factors, the type of malignancy, and its associated surgical procedure. The study is designed as a prospective multicenter observational cohort study across Germany. The study will recruit from all active SIGMA sites at that time, and the inclusion of first patient (FPI) is planned for February 2018.

SIGMA mini-teams will also contribute to Ileus Management International (IMAGINE), an international, observational study of postoperative ileus and provision of management after colorectal surgery. This trial is sponsored by the European Society of Coloproctology (ESCP). The aim of this study is to elucidate the incidence of postoperative ileus, its clinical management after elective colorectal surgery in an international cohort, and the assessment of the effects of NSAIDs on postoperative ileus. The study protocol is available at <http://euro-surg.org/ imagine-hub/>. Data collection is due to start in January 2018. SIGMA is the national network committee for Germany responsible for disseminating and running the study. Attending surgeons act as a link between participating students and SIGMA as their national surgical

research association. As part of IMAGINE, SIGMA students and physicians are interacting with similar research initiatives in the United Kingdom, Italy, Australia, and New Zealand, among others, on an international level.

## Conclusion

SIGMA is a recently founded research network that enables medical students to participate in high-quality clinical trials and benefit from broad training opportunities. It was established by CHIR-Net as a student-driven multicenter research network in Germany, with tight connection to the national CHIR-Net as well as pan-European and international frameworks, such as the EuroSurg initiative. The main objectives of SIGMA include the design, initiation, conduction, analysis, and publication of prospective multicenter clinical trials initiated and led by medical students as well as implementation of EbM in everyday surgical education.

With SIGMA, we believe to address both the lack of clinical research training for medical students and the growing need of academic institutions for research-competent trainees, thereby ensuring patient-oriented surgical research in the future. Thus, the feasibility of such initiatives needs to be rigorously evaluated and adequate training is a vital prerequisite for the performance of successful student-led clinical trials.

Starting in 2018, SIGMA will perform its first multicenter observational study (PATRONUS) in Germany. We invite all interested students, residents, and surgeons to participate in SIGMA trials.

### Author Statement

Research funding: Authors state no funding involved.  
 Conflict of interest: Authors state no conflict of interest.  
 Informed consent: Informed consent is not applicable.  
 Ethical approval: The conducted research is not related to either human or animals use.

### Author Contributions

Pia-Elena Frey: Conceptualization; Data curation; Project administration; Writing – review and editing. Mirco Friedrich: Conceptualization; Data curation; Project administration; Writing – original draft. Lukas Rädiker: Conceptualization; Data curation; Project administration; Writing – review and editing. Christoph A. Fink: Conceptualization; Data curation; Project administration; Writing – review and editing. Alexander Leuck: Conceptualization; Data curation; Project administration; Writing – review and editing. Solveig Tenckhoff: Data curation; Resources; Writing – review and editing. Jens Neudecker: Supervision; Writing – review and editing. André L. Mihaljevic: Conceptualization; Project administration; Supervision; Writing – original draft; Writing – review and editing.

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**Supplemental Material:** The article (<https://doi.org/10.1515/iss-2017-0038>) offers reviewer assessments as supplementary material.



## Reviewer Assessment

Pia-Elena Frey<sup>a</sup>, Mirco Friedrich<sup>a</sup>, Lukas Rädeler<sup>a</sup>, Christoph A. Fink<sup>a</sup>, Alexander Leuck, Solveig Tenckhoff, Jens Neudecker and André L. Mihaljevic\*

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## Reviewers' Comments to Original Submission

### Reviewer 1: anonymous

Oct 24, 2017

<b>Reviewer Recommendation Term:</b>	Accept
<b>Overall Reviewer Manuscript Rating:</b>	100
<b>Custom Review Questions</b>	<b>Response</b>
Is the subject area appropriate for you?	5 - High/Yes
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	5 - High/Yes
Do the keywords clearly reflect the paper's content?	5 - High/Yes
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	5 - High/Yes
How comprehensive and up-to-date is the subject matter presented?	5 - High/Yes
How adequate is the data presentation?	5 - High/Yes
Are units and terminology used correctly?	5 - High/Yes
Is the number of cases adequate?	5 - High/Yes
Are the experimental methods/clinical studies adequate?	5 - High/Yes
Is the length appropriate in relation to the content?	5 - High/Yes
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	5 - High/Yes
Please rate the accuracy of methods.	5 - High/Yes
Please rate the statistical evaluation and quality control.	5 - High/Yes
Please rate the appropriateness of the figures and tables.	5 - High/Yes
Please rate the appropriateness of the references.	5 - High/Yes
Please evaluate the writing style and use of language.	5 - High/Yes
Please judge the overall scientific quality of the manuscript.	5 - High/Yes
Are you willing to review the revision of this manuscript?	Yes

### Comments to Authors:

In this well-written article, the authors describe the objectives and the infrastructure of CHIR-NET Sigma as a student-driven multicenter research network, enabling medical students to contribute to clinical trials.

This initiative is highly appreciated, urgently needed and just timely. Congratulations to all being responsible for this new structure.

**Reviewer 2: anonymous**

Nov 02, 2017

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<b>Reviewer Recommendation Term:</b>	Accept
<b>Overall Reviewer Manuscript Rating:</b>	80
<b>Custom Review Questions</b>	<b>Response</b>
Is the subject area appropriate for you?	5 - High/Yes
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	4
Do the keywords clearly reflect the paper's content?	4
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	5 - High/Yes
How comprehensive and up-to-date is the subject matter presented?	4
How adequate is the data presentation?	4
Are units and terminology used correctly?	4
Is the number of cases adequate?	N/A
Are the experimental methods/clinical studies adequate?	N/A
Is the length appropriate in relation to the content?	4
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	5 - High/Yes
Please rate the accuracy of methods.	N/A
Please rate the statistical evaluation and quality control.	N/A
Please rate the appropriateness of the figures and tables.	5 - High/Yes
Please rate the appropriateness of the references.	4
Please evaluate the writing style and use of language.	4
Please judge the overall scientific quality of the manuscript.	4
Are you willing to review the revision of this manuscript?	Yes

**Comments to Authors:**

This is a really nice paper which clearly reflects the importance of teaching students and young residents in performing clinical trials. Clinical trials are a very important part of our every day work. So it is a good practice to build up a network for training and education of medical students in important principals of clinical trials as well it is a good and easy way to perform prospective clinical trials with a large number of patients included in the trial.

The paper is well structured and the reader gets a good overview of the structure and organisation of SIGMA and CHIR-net SIGMA.

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