Carefully planned and well conducted prospective clinical studies provide the best evidence about efficacy and safety of orthopedic surgical treatments. Case series, registries, and retrospective data are less valid sources of evidence.

Beate Hanson

The new role of AOCID as a partner in clinical research

The AO Foundation has placed prospective clinical research at the top of its strategic priorities. This new strategic orientation requires development of many important methodological, logistical and regulatory skills. Good study design, sufficient sample sizes, high follow-up rates, multicenter and multinational participating sites, advanced statistical methods combined with the highest standards in protecting safety and privacy of the patients who volunteer to participate in the studies are but a few key elements to success.

New requirements
The AO Registry of clinical cases based on the Müller AO Classification of fractures was the mainstream clinical research approach in the nineties. With the emergence of evidence-based orthopedic surgery in the late nineties, the focus of clinicians, patients and policy makers has shifted towards patient relevant outcomes such as function, pain, and quality of life. Parallel to that, in the light of ever increasing health care costs, demand for evidence about cost-effectiveness of new and competing therapies, devices and diagnostic equipment has emerged. Registry-based information became insufficient to provide the level of evidence required to provide answers to these important clinical and policy issues. Registration was discontinued and the focus was then transferred to prospective clinical research. The goal is to provide high quality data from clinical studies that will lead to scientific publications in clinical journals and contribute to advance science and the practice of orthopedic surgery.

New organization and skills
The new focus required new skills and approaches. To meet these new challenges, AO Clinical Investigation and Documentation (AOCID) has undergone a significant internal reorganization.

The work focus has shifted toward skills and knowledge of importance to design, conduct and report good quality clinical trials. Our services focus on close collaboration with AO surgeons. Ideas are brainstormed and sharpened by combining clinical experience and expertise, public health relevance and literature overviews. Study methodologies are at the apex of new developments in study epidemiologic and statistical design. Studies are conducted in international environments with challenging regulatory and language requirements.

AOCID is currently focusing on high quality prospective multicenter clinical studies, randomized controlled trials and observational studies. Significant internal growth has occurred. Expertise has been strengthened in all relevant professional areas: systematic review of literature, study planning, advanced statistical planning, regulatory preparations, monitoring, data management, along with technical and scientific reporting.
In addition to the core business of clinical studies, AOCID has engaged in development of advanced computer-assisted fracture classifications and, most recently, new computer-aided patient outcome instruments.

A range of services is offered to assist clinicians, researchers and device manufactures with study design, study methodology, statistical planning and analysis, literature overviews and assistance with scientific reporting.

**Current AOCID**

Currently, AOCID has 25 permanent staff and a number of external subcontractors and investigators are engaged in clinical studies conducted across 150 different clinical sites on four continents. Studies are performed for various elements of the AO Foundation and involve all three specialties (trauma, craniomaxillofacial and spine). In addition, industry sponsors are using AOCID services to conduct scientific and regulatory studies.

The future of AOCID is to evolve into a leading global clinical research organization for orthopedic surgical trials thus helping clinicians, organizations and, ultimately, patients to achieve better clinical results by use of evidence-based clinical approaches.

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Good level of evidence arises from well designed and conducted observational studies (eg, cohort and case-control studies). The gold standard remains a randomized controlled trial (RCT).

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![Diagram of Level of Evidence](chart.png)