



**SERVIZIO SANITARIO REGIONALE
EMILIA - ROMAGNA**
Istituto Ortopedico Rizzoli di Bologna
Istituto di Ricovero e Cura a Carattere Scientifico



ORTHOWATCH

Integrating Outcome Registers, Retrieval Analysis Programs and Preclinical Validation Methods into a Synergistic Post-Marketing Surveillance Program for Orthopedic Devices

It is widely appreciated that optimal medical care occurs when clinical decisions are based on information derived from rigorous scientific study. This concept is the foundation of evidence-based medicine. In the past two decades, orthopaedic medicine increasingly has derived benefits from joint arthroplasty registers, such as the Register of Orthopaedic Prosthetic Implants (RIPO) in Italy. RIPO documents approximately 128,000 arthroplasty surgeries, including the clinical outcomes of patients treated with more than 150 different types of joint prostheses. ORTHOWATCH aims to supplement such clinical evidence by systematically evaluating explanted prostheses after they have endured a finite duration of function in patients. Explanted prostheses were made available through the Register of Orthopaedic Prosthetic Explants (REPO) at the Istituto Ortopedico Rizzoli, which includes all prostheses retrieved during revision joint arthroplasty. There are more than 2700 explanted prostheses in REPO, including 665 explants added during ORTHOWATCH.

ORTHOWATCH encompasses three objectives executed by a multi-disciplinary project team. Objective 1 implements a screening protocol for categorizing the explanted prostheses obtained through REPO. Objective 2 implements measurement technologies to assess the performance of explanted prostheses. Objective 3 uses the metrics gained from the explant assessments to verify that pre-clinical simulations represent the *in vivo* performance. Through successful completion of these objectives, ORTHOWATCH provides a unique source of explant information and a standardized framework for developing predictive pre-clinical evaluations.

ORTHOWATCH contributes to knowledge transfer and enhanced scientific excellence by bringing together a large multi-disciplinary team (28 direct participants) of clinical scientists and biomedical researchers, including collaborators and orthopaedic device manufacturers in the EU and abroad. The advantage of this approach is that different methodologies were combined synergistically to achieve a level of understanding of joint replacement performance that is greater than the individual parts. Fostering such collaboration in the EU encourages innovation and ensures that the newest technologies address the needs of European patients. Training opportunities in ORTHOWATCH were provided to students within the framework of EU-funded mobility programs, producing a foundation for continued work in orthopaedic biomedical technology.

ORTHOWATCH demonstrates the utility of explants for understanding the biomechanical environment in which joint prostheses function and wear, providing useful inputs into an overall post-marketing surveillance program. The approach complements the current CE marking and provides an explicit mechanism addressing safety and efficacy monitoring for joint prostheses. ORTHOWATCH encourages technology development to improve the performance and longevity of joint prostheses, helping to drive changes in surgical techniques and prosthesis designs.

ORTHOWATCH is a structured post-marketing surveillance model that integrates a clinical outcome register (RIPO) with a systematic prosthesis retrieval program (REPO). It provides a mechanism for continuous feedback to both the healthcare service and technical sectors. Outputs from ORTHOWATCH have been widely disseminated through publication of original research in medical and scientific journals and public presentations at international forums. Using these communication channels to target the clinical and biotechnology communities, ORTHOWATCH provides essential input into the product development lifecycle and ultimately aids the development of the next generation of joint prostheses.

For additional information regarding ORTHOWATCH, please contact Marco Viceconti, PhD.

Laboratorio di Tecnologia Medica
Istituto Ortopedico Rizzoli
via di Barbiano 1/10
40136 Bologna, Italy

e-mail: viceconti@tecno.ior.it
telephone: +39-051-6366865
fax: +39-051-6366863
<http://www.tecno.ior.it>

Laboratorio di Tecnologia Medica
Via di Barbiano, 1/10 – 40136 Bologna, Italy
tel. +39-051-6366864 / fax. +39-051-6366863
e-mail: tecno@tecno.ior.it
www: <http://www.ior.it/tecno/>

Istituto Ortopedico Rizzoli di Bologna - IRCCS
Sede legale Via Di Barbiano, 1/10 - 40136 Bologna
Ospedale Via G. C. Pupilli, 1 - 40136 Bologna
Centro di Ricerca Via Di Barbiano, 1/10 - 40136 Bologna
Tel. 051/6366111 - Fax 051/580453 www.ior.it
Codice Fiscale e Partita IVA 00302030374