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Standard Guide for Clinical Outcomes for Clinical Trials and/or Clinical Registries for Hip Reconstructive Surgery¹

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1. Scope

1.1 This guide is intended as a resource for individuals and organizations when designing clinical trials and/or clinical registries and addresses the selection of patient-reported outcomes, safety outcomes, imaging outcomes, and other topics related to hip reconstructive surgery (HRS) including: (1) hip replacement systems, (2) hip fracture surgery, (3) acetabular fracture surgery, (4) hip arthroscopy and/or labrum repairs, and (5) peri-acetabular osteotomies, or other hip surgeries.

1.2 In this guide, methods to measure the efficacy, effectiveness, and safety of HRS devices through standardizing clinical outcome measures are provided for designing, reviewing, and accepting human clinical trial protocols.

1.3 This guide is intended to provide consistency in study design, review, regulatory approval, and health insurance coverage approval for hip reconstructive surgery to the health care market.

1.4 For the purpose of this guide, HRS pertains to any device or tissue-engineered medical product (TEMP) that is intended to replace, resurface, reconstruct, and/or provide fixation of the hip joint, in part or in total, as a treatment for joint disease, trauma, or dysfunction, where long-term improvement in function and pain relief without major adverse events are the desired outcomes.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.39 on Human Clinical Trials.

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2. Referenced Documents

2.1 ASTM Standards:²

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F2809 Terminology Relating to Medical and Surgical Materials and Devices (Withdrawn 2019)³

F2979 Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses

2.2 ISO Standards:⁴

ISO 12891-1 Retrieval and analysis of surgical implants—Part 1: Retrieval and handling

ISO 12891-2:2014 Retrieval and analysis of surgical implants—Part 2: Analysis of retrieved surgical implants

3. Terminology

3.1 Definitions:

3.1.1 *level of evidence, n*—strength of clinical evidence for evidence-based medicine (**1**).⁵

3.1.2 *safety, n*—the condition of being protected from or unlikely to cause risk or injury.

3.2 Acronyms:

3.2.1 **AAHKS**—American Association of Hip and Knee Surgeons

3.2.2 **AAOS**—American Academy of Orthopaedic Surgeons

3.2.3 **AJRR**—American Joint Replacement Registry

3.2.4 **ANCHOR**—Academic Network of Conservational Hip Outcomes Research

3.2.5 **ASA**—American Society of Anesthesiologists

3.2.6 **CAT**—Computer Adaptive Testing

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁵ The boldface numbers in parentheses refer to the list of references at the end of this standard.

- 3.2.7 *CDRH*—Center for Devices and Radiologic Health
- 3.2.8 *CMS*—Centers for Medicare and Medicaid Services
- 3.2.9 *EQ-5D*—European Quality of Life – 5 Domains
- 3.2.10 *FDA*—Food and Drug Administration
- 3.2.11 *HHS*—Harris Hip Score
- 3.2.12 *HOOS*—Hip dysfunction and Osteoarthritis Outcome Score
- 3.2.13 *HOOS JR*—Hip dysfunction and Osteoarthritis Outcome Score Joint Replacement
- 3.2.14 *HRQL*—Health-related quality of life
- 3.2.15 *HRS*—Hip Reconstructive Surgery
- 3.2.16 *HSAS*—Hip Sports Activity Scale
- 3.2.17 *ICD*—International Classification of Diseases
- 3.2.18 *iHOT-12*—international Hip Outcome Tool (12 questions)
- 3.2.19 *iHOT-33*—international Hip Outcome Tool (33 questions)
- 3.2.20 *LEAS*—Lower Extremity Activity Scale
- 3.2.21 *MCID*—Minimal clinically important difference
- 3.2.22 *MDC*—Minimum detectable change
- 3.2.23 *MRI*—Magnetic Resonance Imaging
- 3.2.24 *NPRS*—Numeric Pain Rating Scale
- 3.2.25 *OHS*—Oxford Hip Score
- 3.2.26 *PRO*—Patient-reported outcome
- 3.2.27 *PROMIS*—Patient-Reported Outcomes Measurement Information System
- 3.2.28 *QALY*—Quality Adjusted Life Year
- 3.2.29 *RSA*—Radiostereometric analysis
- 3.2.30 *SAE*—Serious adverse event
- 3.2.31 *SD*—Standard deviation
- 3.2.32 *SEM*—Standard error of the measurement
- 3.2.33 *SF-6D*—Short Form (6 dimensions)
- 3.2.34 *SF-12*—Short Form (12 questions)
- 3.2.35 *SF-36*—Short Form (36 questions)
- 3.2.36 *SMFA*—Short Musculoskeletal Functional Assessment
- 3.2.37 *TEMP*—Tissue Engineered Medical Products (ASTM Subcommittee F04.40)
- 3.2.38 *THA*—Total Hip Arthroplasty
- 3.2.39 *TUG*—Timed Up and Go
- 3.2.40 *UCLA*—University of California Los Angeles
- 3.2.41 *VAS*—Visual Analog Scale
- 3.2.42 *VR-6D*—Veterans Rand (6 dimensions)
- 3.2.43 *VR-12*—Veterans Rand (12 questions)
- 3.2.44 *VR-36*—Veterans Rand (36 questions)
- 3.2.45 *WOMAC*—Western Ontario and McMaster Universities Osteoarthritis Index

4. Summary of Guide

4.1 It is the intent of this guide to provide an overview of appropriate outcomes that are to be addressed in human clinical trials of hip reconstructive surgery (HRS). Depending on the requirements of the clinical trial, the outcomes to be addressed include hip-specific patient-reported outcomes, health-related quality-of-life patient-reported outcomes, activity level scales, pain relief (that is, VAS, NPRS), patient preference data, and adverse events collection and reporting.

4.2 Because of the broad range of indications for HRS, patient comorbidities, and functional/activity levels, it is impossible to identify or specify a single instrument score that measures the “success” of HRS. Instead, a clinically significant improvement (minimum clinically important difference [MCID]) in a joint-specific, disease-specific, or quality-of-life instrument should be used as a measure of clinical “success” (2). Clinical success measured with patient-reported outcomes may be defined through clinical improvement in terms of MCIDs and/or achieving a clinical success threshold value defined and justified in the study protocol or literature. The MCID can be calculated using consensus methods (also known as Delphi methods), anchor-based methods, and distribution methods.

4.2.1 Consensus methods use clinical and domain experts to define the MCID (3). Anchor-based approaches compare the change in the patient-reported outcome (PRO) score to some other measure of change, considered an anchor or external criterion, to determine whether or not a magnitude of change is significant. The anchor may consist of a clinical measure or a Global Assessment Rating in which the patients rate themselves to some extent as “better,” “unchanged,” or “worse.” Distribution-based approaches compare the change in PRO scores to some measure of variability such as the standard error of measurement (SEM), the standard deviation (SD), the effect size, or the minimum detectable change (MDC) (4). Although there is no consensus as to the superior method to determine the MCID, it is recommended that the MCID be based primarily on relevant patient-based and clinical anchors. Distribution-based methods should be used to support the estimates from anchor-based approaches and can be used in situations in which anchor-based estimates are unavailable (5). Whenever possible, investigators should use validated scores with established MCID values.

4.3 The application of this guide does not guarantee clinical success of a finished product but will help to ensure consistency and adequacy of the data collected based on the clinical trial protocol.

4.4 The insurance coverage criteria for medical treatments include: (1) that a net health outcome is achieved, (2) the clinical trial results are applicable (generalizable) to the patient population, and (3) the clinical trial results are applicable (generalizable) to medical providers. Therefore, subgroup analyses based on patient characteristics (age, sex) and provider characteristics (academic medical center practice versus community orthopedic practice setting, high versus low surgical volume centers, urban versus rural geographic practice locations) should be included. Financial disclosures of clinical