EFORT
*1st European Consensus*
on Medical & Scientific Research Requirements for the Clinical Introduction of Orthopaedic Joint Replacement Devices

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**EFORT Implant & Patient Safety Initiative**

# PROGRAMME | 1st European Consensus on "Medical & Scientific Research Requirements for the Clinical Introduction of Orthopaedic Joint Replacement Devices"

## DAY 1 | Tuesday, 22 June 2021 | Group I: Introduction of innovations

*Link to connect to Virtual Conference: to follow*

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| **08:30-09:00** | **Welcome**<br>Process and aims | *K.P. Günther, T. Grupp, S. Overgaard* |

### 1 | BIOLOGICAL SAFETY / BIOCOMPATIBILITY & STERILITY

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| **09:00-09:10** | **Question 1A** \| How can the biological safety of a final finished medical device with limited, prolonged, and long-term implantation be established (including potential degradation products and novel materials/indications)? | *R. Mayer, D. Bergadano, I. Wüstefeld, M. Bohner* |
| *Not addressed* | **Question 1B** \| How can the used materials as well as their degradation products in a clinical setup? | |

### 2 | MRI SAFETY AND RADIOLOGICAL VISIBILITY

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| **09:10-09:20** | **Question 2A** \| How can be established that no risks for the patient emanates from the implant during postoperative imaging and that assessability of relevant aspects (e.g. implant position) is possible, e.g. is not impaired by undue artefacts? | *F. Kainberger, V. Carbone*<br>*Draft statement due* |

### 3 | PRE-CLINICAL METHODS

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| **09:20-09:30** | **Question 3A and B** \| What are potentials and what are limitations of pre-clinical testing in the field of arthroplasty?<br>Which demands must the test methodology of pre-clinical testing in the field of arthroplasty meet? | *L. Cristofolini, T. Grupp, C. Kaddick, M. Morlock, D. Janssen* |

## 4 | INTERFACE COMPATIBILITY / INTERFACE GEOMETRY

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| **09:30-09:40** | **Question 4A** \| How can be confirmed that all interfaces (implant – instrument only) are geometrically / dimensionally compatible and fulfil the intended purpose, i.e. the interface is functional in clinical practice? | *C. Rieker, M. Bernardoni, C. Schilling, M. Woiczinski, J. Bridgens* |

## 5 | MECHANICAL COMPONENT TESTING (static/dynamic)

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| **09:40-09:50** | **Question 5AB THA** \| 5A Are there standard methods to establish that the implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)?<br>5B Are there additional test methods to establish that an implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)? | *M. Bernardoni, L. Cristofolini, J.P. Kretzer* |
| **09:50-10:00** | **Question 5A TKA** \| Are there standard methods to establish that the implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)? | *C. Kaddick, C. Schilling, D. Janssen, J.P. Kretzer* |
| **10:00-10:10** | **Question 5B TKA (1&2)** \| Are there additional test methods to establish that an implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)? | *C. Kaddick, C. Schilling, D. Janssen* |
| **10:10-10:20** | **Question 5B TKA (3&4)** \| Are there additional test methods to establish that an implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)? | *C. Kaddick, C. Schilling, D. Janssen* |
| **10:20-10:30** | **Question 5C** \| How can be established from a clinical perspective that the implant will withstand the endurance habitual and peak loads that must reasonably be expected (i.e. single implant parts as well as complete arthroplasty combination)? | *M. Morlock, J.P. Kretzer, R. Schierjott, F. Traina, R. Larrainzar-Garijo, G. Duda, C Kaddick* |

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| **10:30-11:00** | **Coffee break** |

## 6 | BIOTRIBOLOGY (wear simulation, wear debris release and biological response)

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| **11:00-11:10** | **Question 6A** \| Can standard test methods in total hip and knee arthroplasty (THA, TKA) show that the planned articulations enable the function of the joint replacement throughout the expected implant lifetime without producing a critical amount of wear? | *T. Grupp, J. Fisher, C. Kaddick, P. Kretzer, C. Rieker* |
| **11:10-11:20** | **Question 6B** \| What kind of proof apart from traditional standard test methods (each for TKA and THA) can be applied to show that the planned articulations (i.e. also including patella-trochlea) enable the function of the implant / the joint throughout the expected implant lifetime without producing a critical amount of wear? | *T. Grupp, J. Fisher, C. Kaddick, P. Kretzer, C. Rieker* |
| **11:20-11:30** | **Question 6C \|** From a clinical point of view, what kind of proof can show that the planned articulations (i.e. also including patella-trochlea) enable the function of the implant / the joint throughout the expected implant lifetime without producing a critical amount of wear? | M. Jäger, M. Dreischarf, T. Grupp, C. Rieker *Draft statement due* |
| **11:30-11:40** | **Question 6D** \| How can we detect wear/debris complications at an early follow-up? | *E. Garcia-Rey, J. Cordero-Ampuero, G. Babis, F. Benazzo, M. Morlock* |

## 7 | SIZE RANGE AND ANATOMICAL DESIGN OF THE IMPLANTS

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| **11:20-11:30** | **Question 7A** \| How can the appropriateness of the implant geometry, sizing range and increments be assessed with respect to the reconstruction of anatomical structures? | *D. Janssen, M. Bernardoni, R. Schierjott* |
| **11:30-11:40** | **Question 7B** \| How can it be clinically assessed that provided implant sizes can cover the majority of the patients' characteristics in terms of size increments and range and that the implant's geometry allows appropriate reconstruction of the anatomical structures? | *F. Benazzo, B. Grimm, C. Mazza, F. Mancino, R. Schierjott* |

## 8 | MODULARITIES / INTERFACES

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| **11:50-12:00** | **Question 8A** \| How can the in vivo behaviour of interfaces between implant components (e.g. head-conus-connection, not articulation partners) be assessed pre-clinically, for example concerning the consequences of micro motion or corrosion processes? | *J. P. Kretzer, M. Morlock, T. Grupp, C. Kaddick, R. Mayer* |
| **12:00-12:10** | **Question 8B** \| How can the in vivo behaviour of interfaces between implant components (e.g. head-conus-connection, not articulation partners) be assessed clinically, for example concerning the consequences of micro motion or corrosion processes? | *F. Traina, M. Morlock, A. Hart, R. Mayer* |

## 9 | IMPLANT FIXATION

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| **12:10-12:20** | **Question 9A** \| How can be assessed if a reasonable primary and secondary stability, as well as a physiological application of force / force transmission into the underlying bone can be achieved when using a cemented implant? | *L. Cristofolini, T. Grupp, V. Jansson, R. Mayer* |
| **12:20-12:30** | **Question 9B** \| How can the primary and secondary stability and physiological load transfer to the peri-prosthetic bone of cementless implants be assessed in a pre-clinical stage? | *D. Janssen, C. Schilling, J. P. Kretzer, R. Mayer* |
| **12:30-12:40** | **Question 9C** \| How to assess primary and secondary stability of orthopaedic joint replacement devices in a clinical setting. How to apply/obtain/ensure optimal force / force transmission into the underlying bone (probably some comments on the place for telemetrised examinations of implants is expected?) | *J. Kärrholm, R. Nelissen, M. Dreischarf, R. Mayer* |
| **12:40-12:50** | **Question 9D** \| What are the radiologic methods and parameters to estimate primary stability of implant fixation to the bone?<br>What are recommended time points for evaluating subsidence/loosening of implant components?<br>How can be decided which method for clinical examination is best for evaluating implant fixation depending on the implant and fixation material? | *J. Kärrholm, R. Nelissen, M. Dreischarf, J. Cordero-Ampuero, P. Heesterbeek, R. Mayer* |

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| **12:50-13:30** | **Lunch break** |

## 10 | JOINT STABILITY AND KINEMATICS

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| **13:30-13:40** | **Question 10A** \| How can one prove in a pre-clinical setting that an implant enables the reconstruction of a functionally satisfying and stable joint, including an appropriate range of motion and best possible preservation / restoration of kinematics? | *W. Taylor, B. Innocenti, G. Duda, T. Grupp, M. Woiczinski*<br>*Draft statement due* |
| *Not addressed* | **Question 10B \|** How can one prove from a clinical perspective that an implant enables the reconstruction of a functionally satisfying and stable joint, including an appropriate range of motion and best possible preservation / restoration of kinematics? | |

## 11 | TRANSFERABILITY OF RESULTS

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| **13:40-13:50** | **Question 11A** \| To what extent can pre-clinical/clinical results of a specific product be transferred to another device? | *D. Bergadano, J. Bridgens, T. Grupp, A.-P. Schulz* |
| **13:50-14:00** | **Question 11B** \| To what extent can pre-clinical test results of a product be transferred into the clinical setting? | *M. Jäger, F. Traina, A. Giurea, T.Grupp, S. Rusch*<br>*Draft statement due* |

## 12 | EVALUATION OF INSTRUMENTS AND USABILITY

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| **14:00-14:10** | **Question 12A** \| How can be assessed from a pre-clinical point of view if the handling of an implant including the implant-specific instruments is uncomplicated and if the workflow runs smoothly, achieves the desired results and does not lead to undue stress for patient and surgeon? | *A. Giurea, F. Benazzo, A. Blom, M. Bernardoni, C. Schilling, S. Overgaard, F. Traina, R. Mayer* |
| **14:10-14:20** | **Question 12B** \| How can be assessed from a clinical point of view if the handling of an implant including the implant-specific instruments is uncomplicated and if the workflow runs smoothly, achieves the desired result and does not lead to undue stress for patient and surgeon? | *A. Giurea, F. Benazzo, A. Blom, M. Bernardoni, C. Schilling, S. Overgaard, F. Traina, R. Mayer* |

## 13 | MODIFICATIONS / ADJUSTMENTS

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| **14:20-14:30** | **Question 13A and B** \| What are additional requirements to implement function-relevant modifications/ adjustments during the PMCF phase of a device?<br>What are additional requirements to implement non-function-relevant modifications/ adjustments during the PMCF phase of a device? | *J. Bridgens, M. Bernadoni, C. Schilling, S. Rusch, P. Massin, R. Larrainzar-Garijo, F. Traina, V. Jansson* |

## 14 | PRE-CE STUDIES / SAFETY STUDIES

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| **14:30-14:40** | **Question 14A** \| What are potentials and what are limitations of a pre-CE study (or safety study) in the field of arthroplasty? | *A. Blom, D. Bergadano, I. Wüstefeld, J. Cobb, F. Haddad, M. Jäger, H. Achakri, M. Fink, A.-P. Schulz* |
| **14:40-14:50** | **Question 14B** \| Which requirements to the study design of pre-CE studies/safety studies exist? | *A. Blom, D. Bergadano, I. Wüstefeld, J. Cobb, F. Haddad, M. Jäger, H. Achakri, M. Fink, A.-P. Schulz* |

## 15 | PERIOPERATIVE AND SHORT-TERM POSTOPERATIVE (SERIOUS) ADVERSE EVENTS

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| **14:50-15:00** | **Question 15A** \| Is it possible to prove pre-clinically that the implantation procedure and the implants do not induce unreasonably high rates of adverse events or complications (directly implant-related, e.g. inter-operative periprosthetic fractures, substantial bleeding, substantial migration, and generally related to the surgery / procedure, e.g. fast track, modified surgical approaches)? | *F. Siccardi, S. Rusch, S. Overgaard, A. Giurea, T. Grupp, A.-P. Schulz* |
| **15:00-15:10** | **Question 15B** \| How can be proven clinically, that the implantation procedure and the implants do not induce unreasonably high rates of adverse events or complications (directly implant-related, e.g. inter-operative periprosthetic fractures, substantial bleeding, substantial migration, and generally related to the surgery / procedure, e.g. fast track, modified surgical approaches)? | *F. Siccardi, S. Rusch, S. Overgaard, A. Giurea, T. Grupp, A.-P. Schulz* |

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| **15:10-15:30** | **Coffee break** |

## 16 | FUNCTIONAL RESULT / CLINICAL OUTCOME

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| *Not addressed* | **Question 16A** \| How can be proven that the functional results / the clinical outcome of the implant (including radiological alignment) meets the expectations on a modern endoprosthesis? | |
| *Not addressed* | **Question 16B** \| Besides standard radiologic and clinical evaluation, what gives us information about patient satisfaction for daily life activity and quality of life of patients treated by joint replacement? | |

## 17 | REVISION RATE / SURVIVAL TIME

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| **15:30-15:40** | **Question 17A and B** \| A. Revision rate / survival time<br>B. How can different factors regarding patients, at short or long-term, be considered in survival analysis? | *V. Jansson, A. Blom, B. Bordini, A. Lübbeke-Wolf* |

## 18 | PMCF (post-market clinical follow-up) STUDIES

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| **15:40-15:50** | **Question 18A** \| What are potentials and limitations of PMCF studies in the field of arthroplasty? | *A. Lübbeke-Wolf, H. Achakri, D. Bergadano, I. Wüstefeld, J. Bridgens, M. Jäger, H. Windhagen, P. Massin, E. Garcia-Rey, R. Larrainzar-Garijo* |

## 19 | REGISTRY STUDIES

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| **15:50-16:00** | **Question 19A** \| What are potentials of registry studies in the field of arthroplasty?<br>*Draft statement due* | *V. Jansson, A. Blom, S. Overgaard, R. Nelisson, B. Bordini* |

## 20 | FUNCTIONALIZED IMPLANTS / BIOMATERIALS / SURFACES / INNOVATIONS

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| **16:00-16:10** | **Question 20A** \| How is it possible to evaluate functionalized surfaces or novel aspects of implants for which no standardized / established test methods yet exist and where no proof of function is yet defined? | *G. Duda, B. Masson, M. Jäger, E. Garcia-Rey, M.A. Pérez Ansón, R. Schierjott, G. Reilly* |

## 21 | IN SILICO TRIALS (Big Data Analytics, Machine Learning, System Biology models, system physiology models)

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| **16:10-16:20** | **Question 21A** \| In what ways can In Silico Trials methodologies (whether mechanistic like Finite Element Analysis or data-based like machine learning) contribute to the assessment and evaluation of implants? | *M. Viceconti, B. Grimm, W. Van der Weegen, F. Traina, I. Wüstefeld, C. Mazza, M. Dreischarf, C. Lohmann* |
| **16:20-16:30** | **Question 21B** \| How is it possible to use elements of in silico pre-clinical and clinical trials (i.e. FEA, multi-body simulations), AI/ML & Big Data as basis for implants, instruments, procedure (e.g. pre-op planning, pre-op positioning)? | *M. Viceconti, B. Grimm, W. Van der Weegen, F. Traina, I. Wüstefeld, C. Mazza, M. Dreischarf, C. Lohmann* |

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| **16:30-17:00** | **Discussions & questions** | *All* |

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| **From 19:00** | **Informal dinner**<br>**Place: SchillerGarten Dresden** | *Onsite attendees* |

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# DAY 2 | Wednesday, 23 June 2021 | Group I: Introduction of innovations

*Link to connect to Virtual Conference: to follow*

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| **08:30-09:00** | **Introduction to the Consensus voting process** | *T. Grupp, S. Overgaard* |
| **09:00-10:30** | **Virtual Consensus voting \|** Part 1 | *All* |
| **10:30-10:40** | **Short break** | |
| **10:40-12:30** | **Virtual Consensus voting \|** Part 2 | *All* |
| **12:30** | **Conclusions & End of meeting of Group I** | *T. Grupp, S. Overgaard* |