
CONTRACT

CONSENT IN A TRIAL & CARE ENVIRONMENT

# D2.1 – Finalised questionnaire ready for distribution

| *COVER AND CONTROL PAGE OF DOCUMENT* | |
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| Project Acronym: | CONTRACT |
| Project Full Name: | Consent in a trial and care environment |
| Document id: | D 2.1 |
| Document name: | Finalised questionnaire ready for distribution |
| Document type (PU, INT, RE) | PU |
| Version: | 1.0 |
| Date: | 26.2.2011 |
| Editor:<br>Organisation:<br>Address: | Norbert Graf<br>Saarland University<br>Dep. Paediatric Oncology<br>Campus Homburg, 66421 Homburg, Germany |

Document type PU = public, INT = internal, RE = restricted

**ABSTRACT:**

The present deliverable is a report on the finalised questionnaire ready for distribution. This questionnaire will be made available via the CONTRACT website to different types of stakeholders. The intention is to analyse the current situation concerning the legal, ethical, technical and clinical handling of consent in European projects dealing with vulnerable patient groups. The results of the questionnaire will serve as the necessary input for WP3 (Evaluation of the status in Europe).

**KEYWORD LIST:** Questionnaire, Stakeholders, consent

| ***MODIFICATION CONTROL*** | | | |
|---|---|---|---|
| Version | Date | Status | Author |
| 0.1 | 29.12.2010 | Draft | Norbert Graf |
| 0.2 | 10.01.2011 | Draft | Norbert Graf |
| 0.3 | 20.01.2011 | Draft | Norbert Graf |
| 0.4 | 27.01.2011 | Draft | Norbert Graf |
| 0.5 | 08.02.2011 | Draft | Norbert Graf |
| 1.0 | 27.02.2011 | prefinal | Norbert Graf |
| 2.0 | 03.03.2011 | Final | Norbert Graf |

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# Contents

# Executive Summary

Work Package 2 (Problem Analysis) of CONTRACT will analyse the current situation concerning the legal, ethical, technical and clinical handling of the issues of consent in European projects dealing with vulnerable patient groups. The proposed methodology is a project-based questionnaire to identify existing practices and problems encountered in translational research throughout Europe.

The present deliverable is a report on the finalised questionnaire to be distributed to identified stakeholders. This questionnaire will be made available via the CONTRACT website to different types of stakeholders. The main stakeholders that were identified are:

- Clinicians / Care providers
- Chairpersons of research projects / trials
- Basic Researcher / Molecular biologists
- Computer Scientists
- Legal Experts
- Ethicists
- Data Manager / Statisticians
- European Policymakers

Patients or Patient groups are not the target of this questionnaire. They will be addressed in other EU-projects like ENCCA, the Network of Excellence for Paediatric Oncology.

The questionnaire will be available in English and is structured in a way that there are common questions for all stakeholders and stakeholder specific questions.

In parallel to the development of the questionnaire, the final identification of the target projects to be surveyed and relevant stakeholders within these projects was carried out.

The results of the questionnaire will serve as the necessary input for WP3 (Evaluation of the status in Europe).

# 1 Introduction

## 1.1 Purpose, context and scope of this deliverable

The present document is the narrative description of the finalised questionnaire prior to distribution. The questionnaire will be made available online via the website of the CONTRACT project. The main stakeholders will be identified and informed about the project in advance and asked to participate in the survey.

## 1.2 Background

CONTRACT focuses on informed consent as a fundamental precondition for the legal processing of personal data. Data flow between care and research or between different clinical disciplines and research groups is fundamental for translational research. As the data to be exchanged are in most cases personal data, data protection is of utmost importance. Regulations on data protection require that the data are only collected for specified, explicit and legitimate purposes and not further processed in any other way. Obtaining informed consent to the processing of data from patients is part of a data protection framework. Physicians are aware that they need to ask for prior consent when treating a patient and when asking a patient to participate in a trial.

One problem in obtaining consent is the heterogeneity of requirements depending on what the patient is being asked to consent to. "They differ in scope, necessity and in the conditions they need to comply with in order to be valid. They differ in their legal basis, in their doctrine and in the consequences a breach of consent might have. Those differences cause a tremendous legal and ethical complexity which becomes even more prevalent when the patient belongs to a vulnerable group. This complexity produces uncertainty and doubt among researchers and clinicians. Due to this complexity, IT-systems set up for care and for trials are frequently seen as different worlds. They lack the interfaces needed to make the data transferable. Doubt and complexity in relation to the legal, ethical and technical side of a framework for a trial can cause the end of translational research before it has even begun and this effect has a dramatic impact on patient groups already disadvantaged by their specific vulnerability."[1]

Another problem of consent is the number of different consent forms and the increasing load of information provided by these forms. This poses the question of whether patients become 'overloaded' with information when giving consent. "Informed consent is not designed to protect the legal interests of the research team – rather to protect participants by providing essential information about the trial and informing them about their rights as participants. But investigators should realise that the written document alone may not ensure that participants fully understand the consequences of trial participation."[2]

The aim of the survey is to show how ongoing and upcoming European and national translational projects deal differently with consent issues. This will be the basis for delivering

[1] CONTRACT – Annex I – Description of work. Page 5

[2] Karlberg J-PE, Speers MA: Reviewing Clinical Trials: A Guide for the Ethics Committee. Hong Kong, PR China, 2010, page 71. ISBN 978-988-19041-1-9

concrete policy recommendations as to how the European Union could jointly protect patient's rights and support translational research by a better structured approach towards consent issues.

# 2 Target Projects and Stakeholders

## 2.1 Introduction

The CONSENT project has chosen to focus on projects and stakeholders dealing with consent issues in clinical trials involving vulnerable patient groups in particular.

We have identified the following main stakeholder groups for the survey:

- Clinicians / Care providers
- Chairpersons of research projects / trials
- Basic Researcher / Molecular biologists
- Computer Scientists
- Legal Experts
- Ethicists
- Data Manager / Statisticians
- European Policymakers

The difficulty for the CONTRACT project is the fact that the number of potential stakeholders is vast and it would not be possible to cover this scope within the project lifetime. Patients or patient groups are not the target of this questionnaire. Due to limited resources, it is not possible to provide the questionnaire in different languages, which is a prerequisite for surveys addressing patients or patient groups. These groups will be addressed in other EU projects such as ENCCA, the Network of Excellence for Paediatric Oncology, where patients are the main focus in their analysis of the same task. Close cooperation with ENCCA in this topic will add additional value to the work undertaken by CONTRACT.

## 2.2 Targeted projects

We have identified 221 projects to be actively contacted and asked to participate in the survey. The selection criteria were projects with a clinical research dimension and ideally with a clear link to vulnerable patient groups and/or consent issues. A search based on these criteria was done via the Cordis webpage using the “projects search” tool. Additional projects were added via connections through CONTRACT consortium members. The majority of the projects selected are European projects (184; 83%).

***Table 1. European projects***

| Project Name | Institution | Contact Person | Function | Phone Number | email |
|---|---|---|---|---|---|
| Mitotarget - Mitochondrial dysfunction in neurodegenerative diseases: towards new therapeutics | | Valérie Cuvier | Clinical Study Manager | +33 4 91 82 82 82 | vcuvier@trophos.com |
| CHILD-INNOVAC - Nasal vaccination against respiratory infections in | INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE | Christine MAZINGUE (Ms.) | | | |

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| young children | MEDICALE (INSERM) | | | | |
| DEVANI - Design of a vaccine to immunize neonates against GBS infections through a durable maternal immune response | NOVARTIS VACCINES AND DIAGNOSTICS S.R.L. | Francesco GULLI (Dr) | | | |
| IBDASE - Mucosal protease and their inhibitors in inflammatory bowel disease: From etiopathogenetic insight to innovative therapy | UNIVERSITAET BERN | Daniel LOTTAZ (Dr) | | | |
| CAREPNEUMO - Combating antibiotics resistant pneumococci by novel strategies based on in vivo and in vitro host pathogen interactions | HELMHOLTZ-ZENTRUM FUER INFEKTIONSFORSCHUNG GMBH Braunschweig | Michael STRÄTZ (Dr.) | | | |
| EPOC - European paediatric oncology off-patent medicines consortium | UNIVERSITY OF NEWCASTLE UPON TYNE | Nicola PLACE ( Ms) | | | |
| DIABIMMUNE - Pathogenesis of type 1 Diabetes - testing the hygiene hypothesis | Helsingin Yliopisto | Katariina VAINIO-MATTILA (Ms.) | | +358 9 191 25043 | |
| SOS - Safety of non-steroidal anti-inflammatory drugs | ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM | Sander WOERDEMAN (Mr.) | | +31 10 7043049 | |
| GIPIO - Gastro-intestinal peptides in obesity | UNIVERSITAET LEIPZIG | Frank NOLDEN (Dr) | | +49 34197 30100 0 | |
| EUROTRAPS - Natural course, pathophysiology, models for early diagnosis, prevention and innovative treatment of TNF Receptor Associated Periodic Syndrome TRAPS with application for all hereditary recurrent fevers | CENTRE HOSPITALIER UNIVERSITAIRE DE MONTPELLIER | Valérie THORIN (Ms) | | +33 467339643 | |
| EURADRENAL - Pathophysiology and natural course of autoimmune adrenal failure in Europe | UNIVERSITETET I BERGEN | Inger GJESDAHL (Ms.) | | +47-55584998 | |
| CUREHLH - European initiative to improve knowledge, treatment and survival of haemophagocytic syndromes in children | UNIVERSITÄTSKLINIKUM HAMBURG-EPPENDORF | Kai LEHMBERG (Dr) | | +49-40741054209 | |
| SAGHE - Safety and appropriateness of Growth hormone treatments in Europe | ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS | Christophe MISSE (Mr) | | +33-144841770 | |

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| EUNEFRON – European network for the study of orphan nephropathies | UNIVERSITE CATHOLIQUE DE LOUVAIN | Olivier DEVUYS T (Professor) | | +32-2-7645453 | |
| PEDDOSE.NET – Dosimetry and Health Effects of Diagnostic Applications of Radiopharmaceuticals with particular emphasis on the use in children and adolescents | EIBIR GEMEINNUETZIG E GMBH ZUR FOERDERUNG DER ERFORSCHUNG DER BIOMEDIZINISCH EN BILDGEBUNG | Monika HIERAT H (Ms.) | | +43-15334064-20 | |
| NIMBL – Nuclease Immune Mediated Brain and Lupus-like conditions (NIMBL): natural history, pathophysiology, diagnostic and therapeutic modalities with application to other disorders of autoimmunity | THE UNIVERSITY OF MANCHESTER | Liz FAY (Ms.) | | +44-1612757114 | |
| EURO-PADNET – The pathophysiology and natural course of patients with Primary Antibody Deficiencies (PA | UNIVERSITY COLLEGE LONDON | Greta BORG-CARBOTT (Ms.) | | +44-2031083033 | |
| 03K – Oral off-patent oncology drugs for kids | INSTITUT GUSTAVE ROUSSY | Arnauld FORES T (Mr) | | +33-142116604 | |
| CHERISH - Improving diagnoses of mental retardation in children in Central Eastern Europe and Central Asia through genetic characterisation and bioinformatics/-statistics | ALMA MATER STUDIORUM-UNIVERSITA DI BOLOGNA | Verdiana BANDI NI (Ms.) | | +39-0512099764 | |
| PERS – Paediatric European Risperidone Studies | STICHTING KATHOLIEKE UNIVERSITEIT | Maarten VAN LANGEN (Mr) | | +31-24-3619791 | |
| NEOMERO – European 10ulticentre network to evaluate pharmacokinetics, safety and efficacy of Meropenem in neonatal sepsis and meningitis | FONDAZIONE PENTA-FOR THE TREATMENT AND CARE OF CHILDREN WITH HIV-ONLUS | Silvia FAGGION (Dr) | | +39-049-8213585 | |
| TREATRUSH – Fighting blindness of Usher syndrome: diagnosis, pathogenesis and retinal treatment (TreatRetUsher) | UNIVERSITE PIERRE ET MARIE CURIE – PARIS 6 | Christine PETIT (Professor) | | +33-145688890 | |
| PENTA LABNET Paediatric European network treatment AIDS laboratory network | FONDAZIONE PENTA-FOR THE TREATMENT AND CARE OF CHILDREN WITH HIV-ONLUS | Silvia FAGGION (Dr) | | +39-049-8213585 | |
| PLASTICISE - Promotion of plasticity as a treatment for | THE CHANCELLOR, | Edna MURPHY | | +44-1223- | |

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| neurodegenerative conditions | MASTERS AND SCHOLARS OF THE UNIVERSITY OF CAMBRIDGE | (Ms.) | | 333543 | |
| CHEARTED - Gene-environment interactions in heart development | ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM | :Ruth VAN DER GAAG (Dr) | | +31-20-5664647 | |
| LIFEVALVE - Living autologous heart valves for minimally invasive implantable procedures | UNIVERSITAET ZUERICH | Simon Philipp HOERSTRUP (Professor) | | +41-44-2553801 | |
| REBORNE - Regenerating bone defects using new biomedical engineering approaches | INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) | Marianne DESMEDT (Ms.) | | +33-240350669 | |
| ALPHA-MAN - Clinical development of Enzyme Replacement Therapy in alpha-Mannosidosis patients using recombinant human enzyme. | CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL | Paul SAFTIG (Professor) | | +49-4318802216 | |
| PREDICTA - Post-infectious immune reprogramming and its association with persistence and chronicity of respiratory allergic diseases | NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS | Efstathia KAFENTZI (Ms.) | | +30-2103689194 | |
| PHARMACHILD - Long-term PHARMacovigilance for Adverse effects in Childhood arthritis focussing on Immune modulatory drugs | UNIVERSITAIR MEDISCH CENTRUM UTRECHT | Efdokia CHATZOUDI (Ms.) | | +31-887554579 | |
| TINN2 - Treat Infections in NeoNates 2 - Evaluation of an infective agent (azithromycin) for the treatment of infections in preterm and term neonates | INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM) | Isabelle PIRES ( Ms.) | | +33-143622716 | |
| LOULLA&PHILLA - Development of 6-mercaptopurine and Methotrexate oral liquid formulations for the maintenance treatment of Acute Lymphoblastic Leukemia in children | ONLY FOR CHILDREN PHARMACEUTICALS | Vincent GREK ( Dr.) | | +33-6-62889643 | |
| ADDUCE - Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects | THE SCHOOL OF PHARMACY, UNIVERSITY OF LONDON | Ian Chi Kei WONG (Professor) | | +44-2078741544 | |
| PSYCHCNVS - Copy number variations conferring risk of psychiatric | ISLENSK ERFDAGREINING EHF | Bjorgvin RICHARDSSON (Mr) | | +354-5701821 | |

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| disorders in children | | | | | |
| p-medicine | University of the Saarland | Norbert Graf (Prof.) | | +49 6841 1628397 | |

***Table 2. Further European projects***

| Project Name | Institution | Contact Person | Function | Phone Number | email |
|---|---|---|---|---|---|
| HIV Indicator Diseases Survey Across Europe - UK Arm | Chelsea and Westminster NHS Foundation Trust | Ann K Sullivan, MBBS FRCP | | +44 (0)208 746 8000 ext 56199 | ann.sullivan@chelwest.nhs.uk |
| | | Michael Rayment, MBBS MA MRCP | | +44 (0)208 746 8000 ext 56529 | michaelrayment@nhs.net |
| 6xFU/Epirubicin/Cyclophosphamide (FEC) Compared to 3xFEC-3xDocetaxel in High-risk Node-negative Breast Cancer Patients (NNBC3-Europe) | Martin-Luther-Universität Halle-Wittenberg | Christoph Thomssen, MD | | | *christoph.thomssen*@medizin.uni-*halle*.de |
| Malnutrition and Outcome in Hospitalized Children in Europe | Ludwig-Maximilians - University of Munich | Christina B Hecht, PhD candidate | | 01149891607904 | christina.hecht@med.uni-muenchen.de |
| | | Astrid AM Rauh, MD,MPH | | 01149895160 7934 | astrid.rau-pfeiffer@med.uni-muenchen.de |
| Association of Multiple CardiOvascular Risk Factors and Erectile Function Across Europe (AMORE-Eur) | University Hospital, Saarland | Michael Böhm, MD | | 0049-6841-16- ext 23000 | michael.boehm@uniklinikum-saarland.de |
| | | Magnus Baumhäkel, MD | | 0049-6841-16- ext 23000 | magnus@baumhaekel.de |
| Saving and Empowering Young Lives in Europe (SEYLE) | Rabin Medical Center | Alan Stanley Apter, MD | | 9723925323 2 | eapter@clalit.org.il |
| | | Keren non Tochterman, BA | | 9723925345 2 | kerento@clalit.org.il |
| Persistent Lyme Empiric Antibiotic Study Europe (PLEASE) | Radboud University | Anneleen Berende, M.D. | | +31 24-3618819 | AIG-secretariaat@AIG.umcn.nl |
| PREVAIL EU: Transfemoral Placement of Aortic Balloon Expandable Transcatheter Valves Trial (Europe) | Edwards Lifesciences | Jodi Akin | | 949 250 2730 | jodi_akin@edwards.com |
| Utilisation of Angiox® in European Practice (EURO-vision) | The Medicines Company | Diana Schuette, PhD | | +44 (0)1235 448500 | Diana.Schuette@themedco.com |

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| The TRAfermin in Neuropathic Diabetic Foot Ulcer Study - Northern Europe The TRANS-North Study | Olympus France SAS | Corentin Le Camus, PhD | | 33 1 45 60 35 32 | corentin.lecamus@olympus.fr |
| | | Bruyère Mahuzier, PharmD | | 33 1 45 60 34 98 | bruyere.mahuzier@olympus.fr |
| Combination Chemotherapy With or Without Filgrastim Before Surgery, High-Dose Chemotherapy, and Radiation Therapy Followed by Isotretinoin With or Without Monoclonal Antibody in Treating Patients With Neuroblastoma | University Hospitals, Leicester | Ruth Ladenstein, MD, Protocol chair | | 43-1-404-700 | |
| A Migration and Bone Density Study Comparing 2 Types of Bone Cement in the OptiPac Bone Cement Mixing System | University of Aarhus | Kjeld Soballe, MD, Prof. | | | *kjeld@soballe.com* |
| Hull Early Walking Aids for Transtibial Amputees - Randomised Control Trial (HEART) | | Ian C Chetter, MB ChB, FRCS | | +44 1482 674212 | ian.chetter@hey.nhs.uk |
| Europe-Africa Research Network for Evaluation of Second-line Therapy (EARNEST) | Medical Research Council | Justine Boles | | +44 (0)207 670 4918 | jvb@ctu.mrc.ac.uk |
| | | Nicholas Paton | | +44 (0) 207 670 4808 | nip@ctu.mrc.ac.uk |
| The Effect of Teenage Maternity on Obstetrical and Perinatal Outcomes | University of Luebeck | Daniel A Beyer, M.D. | | + 49 451 500´2141 | daniel.beyer@uk-sh.de |
| Genetics of Women With Lobular Carcinoma in Situ of the Breast | National Cancer Research Network | Elinor Sawyer, MD | | | *elinor.sawyer@cancer.org.uk* |
| International Transtar Registry | Ethicon Endo-Surgery (Europe) GmbH | Goran Ribaric, MD, MSc | | | gribaric@its.jnj.com |
| | | Birgit Temiz, CRA | | | btemiz@its.jnj.com |
| Adherence to PTH(1-84) Treatment (FP-002-IM) | Nycomed | | | +45 4677 1111 | clinicaltrials@nycomed.com |
| Treatment of Predominant Central Sleep Apnoea by Adaptive Servo Ventilation in Patients With Heart Failure (Serve-HF) | ResMed | Andrea Ballentin, MD | | +49 89 54 88 44 255 | serve-hf@ikkf.de |
| | | Simone Knabl | | +49 89 54 88 44 274 | serve-hf@ikkf.de |
| Multi-Centre European | NHS Tayside | James | | +44 (0) 1382 | j.ferguson@dunde |

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| Photopatch Test Study | | Ferguson, FRCP | | 632240 | e.ac.uk |
| | | Alastair C Kerr, MRCP | | +44 (0) 1382 632240 | alikerr01@yahoo.co.uk |
| European Surgical Outcomes Study (EuSOS) | Queen Mary University of London | Ahsun Khan, MBBS FRCA MD | | +44 207 377 7299 | ahsun.khan@bartsandthelondon.nhs.uk |
| | | Amanda Vivian-Smith, RGN | | +44 207 377 7299 | amanda.smith@bartsandthelondon.nhs.uk |
| Comparison of Laparoscopic Colectomy Versus Open Colectomy for Colorectal Cancer: … A Prospective Randomized Trial | National Taiwan University Hospital | Jin-Tung Liang, M.D., Ph.D. | | 886-2-23562068 | jintung@ha.mc.ntu.edu.tw |
| A Phase II, Open Label Trial of a Vaccine (FSME-IMMUN 0.5 mL Baxter) Against Tick-borne Encephalitis (TBE) for NIAID Workers Manipulating Tick Borne Encephalitis Virus (TBEV) | National Institute of Allergy and Infectious Diseases (NIAID) | Patient Recruitment and Public Liaison Office | | (800) 411-1222 | prpl@mail.cc.nih.gov |
| Safety and Efficacy Study of Kaname Coronary Stent System for the Treatment of Patients With Coronary Artery Disease (KARE) | Terumo Europe N.V. | Dragica Paunovic, MD | | +3216381405 | dragica.paunovic@terumo-europe.com |
| | | Danny Detiege, RN | | +3216381380 | danny.detiege@terumo-europe.com |
| Study of CH5132799 Administered Orally in Patients With Advanced Solid Tumors | Chugai Pharma Europe Ltd. | Chugai Pharma Europe | | +44 208 987 5600 | web_info@chugai-pharm.co.uk |
| A Study to Investigate the Benefits of the Early Detection and Intensive Treatment of Type 2 Diabetes | University Hospitals, Leicester | Melanie J Davies, MD | | +44 0116 2586798 | melanie.davies@uhl-tr.nhs.uk |
| | | Emma L Healey, PhD | | +44 0116 2586798 | emma.healey@uhl-tr.nhs.uk |
| Swedish Adjustable Gastric Banding Observational Cohort Study | Ethicon Endo-Surgery (Europe) GmbH | Goran Ribaric, MD | | +49-40-5297 ext 3125 | gribaric@its.jnj.com |
| Safety, Tolerability, Pharmacodynamic and Pharmacokinetics of a Single Rectal Application of 10 mg NRL001 in Elderly Subjects | Norgine | David Bell, MRCGP MFPM | | +44 (0) 28 9081 8381 | |

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| International Survey of Acute Coronary Syndromes in Transitional Countries (ISACS-TC) | University of Bologna | Raffaele Bugiardini, MD | | +39 335 5612962 | raffaele.bugiardini@unibo.it |

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| | | Lina Badimon, MD | | +34 670296741 | badimon@csic-iccc.org |
| A Study of the Safety and Pharmacokinetics of PRO283698 in Patients With Rheumatoid Arthritis | Genentech | Ellen Ashley | | | ashley.ellen@gene.com |
| Observational Study on Safety of Room Temperature Stable NovoSeven® in Patients With Haemophilia A or B | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Observational Study to Investigate the Occurrence of Bleeding in Postmenopausal Women Treated With 0.5 mg Estradiol and 0.1 mg Norethisterone Acetate for 12 Months | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Comparison of NN1250 Plus Insulin Aspart With Insulin Detemir Plus Insulin Aspart in Type 1 Diabetes: An Extension Trial to NN1250-3585 (BEGIN™) | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Clinical Management of Argatroban in Patients With Heparin Induced Thrombocytopenia Type II | Mitsubishi Tanabe Pharma Corporation | Mitsubishi Pharma Europe | | +44 (0)20 7065-5000 | information@mitsubishi-pharma.eu |
| Efficacy and Safety of Basal-bolus Therapy, Comparing Stepwise Addition of Insulin Aspart Versus Complete Basal-bolus Regimen (Full STEP™) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| A Study to Evaluate Pre-emptive Treatment for Invasive Candidiasis in High Risk Surgical Subjects (INTENSE) | Astellas Pharma Inc | Medical Affairs Europe | | 44 (0)1784 419400 | |
| Liver Transplant European Study Into the Prevention of Fungal Infection (TENPIN) | Astellas Pharma Inc | Medical Affairs Europe | | 44 (0) 1784 419 713 | |
| Ibuprofen Suppositories Administration in Infants and Children | Soroka University Medical Center | EUGENE LEIBOVITZ, MD | | 972-8-6244065 | eugenel@bgu.ac.il |
| Multi-national Study Investigating the Effect and Safety of rFXIII on Transfusion Needs in Patients Undergoing Heart Surgery | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Efficacy of NNC 0142-0000-0002 in Subjects With Rheumatoid Arthritis | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | - | clinicaltrials@novonordisk.com |

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| Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results – A Long Term Evaluation (LEADER) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Comparing Safety and Efficacy of NN5401 With Insulin Glargine in Subjects With Type 2 Diabetes: An Extension to Trial NN5401-3590 (BOOST™) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7179 | |
| Observational Study on Efficacy and Safety of Liraglutide in Subjects With Type 2 Diabetes (EVIDENCE) | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | - | clinicaltrials@novonordisk.com |
| Safety and Efficacy of NNC 0142-0000-0002 in Subjects With Moderately to Severely Active Crohn's Disease | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Safety and Efficacy of Recombinant Factor VIII (N8) in Male Children Previously Treated With Haemophilia A | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Safety and Efficacy of N8 in Prevention and On-demand Treatment of Bleeding Episodes in Subjects With Haemophilia A: An Extension to Trials NN7008-3543 and NN7008-3545 | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7179 | |
| Efficacy and Safety of Liraglutide in Subjects With Type 1 Diabetes Undergoing Islet Cell Transplantation | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7180 | |
| Observational Study of NovoPen Echo® on Safety and Treatment Satisfaction in Children and Adolescents With Type 1 Diabetes (REMIND™) | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Terlipressin Administration in Septic Shock Refractory to Catecholamines | Assaf-Harofeh Medical Center | Tal Mann, Dr | | 97257345789 | tal_mb@hotmail.com |
| A Multiple Dose Trial of NNC 0151-0000-0000 in Subjects With Rheumatoid Arthritis | Novo Nordisk | Public Access to Clinical Trials – Novo Nordisk | | | clinicaltrials@novonordisk.com |

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| A Study to Compare Two Medications With an Inactive Medication and Look at the Effect on a Person's Mental Ability | Astellas Pharma Inc | Medical Affairs Europe Limited | | +44 (0) 1784 419 400 | |

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| (SENIOR) | | | | | |
| Study of 2 Doses of Solifenacin Succinate in Female Subjects With Overactive Bladder. (SHRINK) | Astellas Pharma Inc | Medical Affairs Europe Ltd | | + 44 (0)1784 419 400 | contact.gb@eu.astellas.com |
| Safety and Performance of the Automated Fluid Shunt in Patients With Ascites and Diuretic Resistance (PIONEER) | NovaShunt AG | | | | |
| A Study Evaluating Safety and Tolerability of YM150 Compared to Warfarin in Subjects With Atrial Fibrillation (OPAL-2) | Astellas Pharma Inc | Astellas Pharma Europe BV Medical Clinical Development Department | | + 31 (0)71 54 55878 | |
| Safety and Pregnancy Outcomes in Thrombocythemia Patients Exposed to Xagrid Compared to Other Treatments | Shire Pharmaceutical Development | Shire Call Center | | 866-842-5335 | |
| First-in-man Trial of NNC 0142-0000-0002 in Patients With Rheumatoid Arthritis | Novo Nordisk | Public Access to Clinical Trials - Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Pharmacokinetics of a Single Intravenous Dose of Recombinant Factor XIII in Children With Congenital FXIII A-subunit Deficiency | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| A Study to Evaluate the Safety and Efficacy of Denosumab and Ibandronate in Postmenopausal Women Sub-Optimally Treated With Daily or Weekly Bisphosphonates | Amgen | Amgen Call Center | | 866-572-6436 | |
| International Registry for Severe Chronic Neutropenia | National Center for Research Resources (NCRR) | | | | |
| Clinical- and Immunological Activity, Safety and Tolerability of Different Doses / Formulations of AFFITOPE AD02 in Early Alzheimer's Disease | Affiris AG | Vera Buerger, MSc | | - | vera.buerger@affiris.com |

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| PRIMARA: A Prospective Descriptive Observational Study to Review Mimpara (Cinacalcet) Use in Patients With Primary Hyperparathyroidism in | Amgen | Amgen Call Center | | 866-572-6436 | |

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| Clinical Practice | | | | | |
| Human Anaplasmosis in Eastern France | University Hospital, Strasbourg, France | Yves HANSMANN, MD | | 33.3.69.55.05.45 | yves.hansmann@chru-strasbourg.fr |
| Safety and Efficacy of N8 in Haemophilia A Subjects | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| A Trial to Assess the Effect of Liraglutide on Gastric Emptying in Healthy Obese Volunteers | Novo Nordisk | Public Access to Clinical Trials - Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Comparison of NN1250 Versus Insulin Glargine in Subjects With Type 2 Diabetes: An Extension Trial to NN1250-3579 (BEGIN™) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Comparison of NN1250 Plus Insulin Aspart With Insulin Glargine Plus Insulin Aspart in Type 1 Diabetes: An Extention Trial to NN1250-3583 (BEGIN™) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7179 | |
| Double-Lumen Tube With or Without a Carinal Hook | Hopital Foch | Marc Fischler, MD | | 46252442 ext 00331 | m.fischler@hopital-foch.org |
| Effects Of Exenatide On Liver Biochemistry, Liver Histology And Lipid Metabolism In Patients With Fatty Liver Disease | University of California, Davis | Marilyn Robinson | | 916-703-5501 | marilyn.robinson@ucdmc.ucdavis.edu |
| Comparison of NN1250 With Insulin Glargine Plus Insulin Aspart With or Without Metformin and With/Without Pioglitazone in Type 2 Diabetes: An Extension Trial to NN1250-3582 (BEGIN™) | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Efficacy of Zinc Sulfate With Probiotics for the Treatment of Acute Diarrhea in Children | University Hospital No 1 Wroclaw | Leszek Szenborn, Prof | | +48717703151 | szenborn@zak.am.wroc.pl |
| | | Ernest P. Kuchar, MD | | +48717703156 | kuchar@zak.am.wroc.pl |
| First-in-Man Trial of NNC114-0005 in Healthy Subjects and Subjects With Rheumatoid Arthritis | Novo Nordisk | Public Access to Clinical Trials - Novo Nordisk | | | clinicaltrials@novonordisk.com |
| Use of Phenoxybenzamine [PBZ] IV to Assist High Flow Low Pressure Perfusion [HFLPP] on Cardio-Pulmonary Bypass | The Cleveland Clinic | Muhammad A Mumtaz, MD | | 2164449125 | mumtazm@ccf.org |
| | | Brian W Duncan, MD | | 2164449365 | duncanb@ccf.org |

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| Phase 2 Safety & Efficacy of FOLFIRI in Combination With AMG 479 or AMG 655 vs FOLFIRI in KRAS-mutant Metastatic Colorectal Carcinoma | Amgen | Amgen Call Center | | 866-572-6436 | |
| Evaluation of HumIRA® in Patients With Active Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis in EASTern European Countries (EviraEAST) | Abbott | Vanesa Cinotti Klepac, B.Sc. | | +385 1 2350 538 | vanesa.klepac@abbott.com |
| Use of Sodium Stibogluconate as a Treatment for Leishmaniasis | U.S. Army Medical Research and Materiel Command | Glenn Wortmann, MD | | | glenn.wortmann@amedd.army.mil |
| UMPIRE – Use of a Multidrug Pill In Reducing Cardiovascular Events | Imperial College London | Contact: Simon A McG Thom, MD, FRCP | | 4,42076E+11 | s.thom@imperial.ac.uk |
| Observational Study on the Long Term Safety of Kuvan® Treatment in Patients With Hyperphenylalaninemia (HPA) Due to Phenylketonuria (PKU) or BH4 Deficiency (KAMPER) | Merck KgaA | Agnès Champigneulle, MD, PhD | | +41 22 414 3000 | agnes.champigneulle@merckserono.net |
| Transdermal Absorption of Dimercaptopropane-1-Sulfonate (DMPS) and Effect on Urinary Mercury Excretion | Banner Health | Anne-Michelle Ruha, M.D. | | 602-839-2342 | michelle.ruha@bannerhealth.com |
| Oxidative Stress and Cardiac Arrest | Institut d'Anesthesiologie des Alpes Maritimes | Jean-Christophe Orban, MD | | 33611947008 | orban.j@chu-nice.fr |
| | | Carole Ichai, MD, PhD | | | carole.ichai@unice.fr |
| Evaluation of Middle Ear Implantation | Assistance Publique – Hôpitaux de Paris | Olivier STERKERS, MD,PhD | | +33(0) 1 40 87 56 29 | olivier.sterkers@bjn.aphp.fr |
| | | Sophie Williams, BSc | | 27-11-276-8800 | swilliams@witshealth.co.za |
| Sublingual Buprenorphine for Chronic Pain | National Institute on Drug Abuse (NIDA) | Russell K Portenoy, MD | | 212-844-1505 | Rportenoy@bethisrael.org |
| Ribavirin for Hemorrhagic Fever With Renal Syndrome in Germany (HFRS) | : U.S. Army Medical Research and Materiel Command | MAJ Nicholas Conger, MD | | DSN 314-486-8870 | nicholas.conger@amedd.army.mil |
| | | LTC Stephen Silvey, MD | | DSN 314-486-8156 | stephen.silvey@amedd.army.mil |
| Bendamustine HCL in Relapsed and Primary Refractory Hodgkin | Memorial Sloan-Kettering Cancer | Craig Moskowitz, MD | | 212-639-2696 | |

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| Lymphoma | Center | | | | |
| | | Paul Hamlin, MD | | 212-639-6143 | |
| Oral Fluid Screening Devices | National Institute for Health and Welfare, Finland | Pirjo Lillsunde, Dr | | +358947448342 | pirjo.lillsunde@ktl.fi |
| | | Charlotta Engblom, M.Sc.(Tech.) | | +358947448546 | charlotta.engblom@ktl.fi |
| Bevacizumab in Advanced Hepatocellular Carcinoma | Institut Gustave Roussy | Valerie Boige, MD | | 00 33 014-211-4308 | boige@igr.fr |
| | | Jean-Pierre Pignon, MD, PhD | | 00 33 014-211-4565 | jppignon@igr.fr |
| Borrelia Species in Cutaneous Lyme Borreliosis | University Hospital, Strasbourg, France | Dan LIPSKER, MD | | 33.3.88.11.61.79 | dan.lipsker@chru-strasbourg.fr |
| Safety of Liraglutide in Pediatric Patients With Type 2 Diabetes | Novo Nordisk | Novo Nordisk Clinical Trial Call Center | | 866-867-7178 | |
| Mistletoe as Complementary Treatment in Patients With Advanced Non-Small-Cell Lung Cancer (NSCLC), Treated With Carboplatin/Gemcitabine Chemotherapy Combination: Randomized Phase II Study (Iscador) | Rambam Health Care Campus | Gil --- Bar-Sela, Dr. MD | | +972-4-854-3810 ext | g_barsela@rambam.health.gov.il |
| Pilot Study of Raltegravir/Truvada Versus Efavirenz/Truvada for Adults With Acute IV-1 Infection | University of Alabama at Birmingham | Kerry Upton, RN | | 205-975-9128 | |
| Host Responses in Kidney-transplant Recipients With Chronic Hepatitis E Virus Infection | Assistance Publique Hopitaux De Marseille | Valerie MOAL | | | valerie.moal@ap-hm.fr |
| Study of Glutamine as Prophylaxis for Irinotecan Induced Diarrhea | Alberta Health Services | Michael Sawyer, MD | | 780-432-8726 | michsawy@cancerboard.ab.ca |
| French Evaluation Group Avastin Versus Lucentis (GEFAL) | Hospices Civils de Lyon | Laurent KODJIKIAN | | 0472071718 ext +33 | laurent.kodjikian@chu-lyon.fr |
| | | Jérôme MOLLARD | | 0472115439 ext +33 | jerome.mollard@chu-lyon.fr |
| The Role of Patient Expectations in Traumatic Orthopedic Outcomes-TEFTOM EURASIA | AO Clinical Investigation and Documentation | No Contacts or Locations Provided | | | |
| Cerebral Toxoplasmosis | University | Daniel AJZENBERG, | | 33 5 55 05 | ajz@unilim.fr |

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| and AIDS (TOXODFA) | Hospital, Limoges | PharmD, PhD | | 61 60. | |
| Study of XL147 in Advanced or Recurrent Endometrial Cancer | Exelixis | PRA Contact Line | | 1-800-251-8124 | |
| Convection Enhanced Localized Administration of PRX321 With Real-Time Imaging for Therapy of Recurrent Glioblastoma (CLARITY-1) | Protox Therapeutics | Patrick M Rossi, MD | | 609-744-3880 | prossi@protoxtherapeutics.com |
| Assessing the OAB-8 Questionnaire as a Tool to Measure Treatment Outcome | Rambam Health Care Campus | Ilan Gruenwald, MD | | 00972-4-8542882 | I_gruenwald@rambam.health.gov.il |
| | | Yoram Vardi, Prof | | 00972-4-8542819 | yvardi@rambam.health.gov.il |
| TF2- Small Cell Lung Cancer Radio Immunotherapy | Centre René Gauducheau | Please refer to this study by its ClinicalTrials.gov identifier: NCT01221675 | | | |
| Clopidogrel and Aspirin for the Treatment of Polycythemia Vera (ISCLAP) | Myeloproliferative Disorders-Research Consortium | Raffaele Landolfi, MD | | +309630154335 | rlandolfi@rm.unicatt.it |
| | | Ronald Hoffman, MD | | 212-241-1948 | ronald.hoffman@mssm.edu |
| Gliogene: Brain Tumor Linkage Study | M.D. Anderson Cancer Center | Melissa Bondy, PhD | | 713-794-5264 | |
| Clinical Evaluation of the Needleless® Sling | Samsung Medical Center | Kyu-Sung Lee, Ph.D | | 82-2-3410-3554 | ksleedr@skku.edu |
| SPATAX: Clinical and Genetic Analysis of Cerebellar Ataxias and Spastic Paraplegias (Spatax) | Institut National de la Santé Et de la Recherche Médicale, France | Alexandra Dürr, MD, PhD | | 0033142162182 | alexandra.durr@upmc.fr |
| Use of the Hansen Medical System in Patients With Atrial Fibrillation (ARTISAN AF) | Hansen Medical | Please refer to this study by its ClinicalTrials.gov identifier: NCT01122173 | | | |
| | | Deb Cardinal | | 512-458-9410 | dscardinal@austinheartbeat.com |
| An Effectiveness Trial of Maintenance Therapy for Nicotine Dependence | University of Pennsylvania | Elisa Martinez, MPH | | 215-746-3109 | emart@mail.med.upenn.edu |
| Lymphomyosot for Ankle Edema Following Fracture | Shaare Zedek Medical Center | Menachem Oberbaum, MD | | 972-2-6666395 | oberbaum@szmc.org.il |
| Case Analysis on Real Life Incidence of Photodynamic Therapy (PDT) Safety Outcomes (CALIPSO) | Axcan Pharma | Michelle Depot, Ph.D | | 450 467 5138 ext 2190 | mdepot@axcan.com |

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| | | Valérie Ratheau, M.Sc. | | 450 467 5138 ext 2096 | vratheau@axcan.com |
| Second Generation" Drug-Eluting Stents Implantation Followed by Six Versus Twelve-Month - Dual Antiplatelet Therapy | Fondazione Mediolanum per Attività e Ricerche Cardiovascolari Onlus | Monica Repetto, Dr. | | 02.34535088 ext 29 | repetto@mcr-med.com |
| Medico-Economic Comparison of Four Strategies of Radioiodine Ablation in Thyroid Carcinoma Patients (Estimabl) | National Cancer Institute, France | Martin SHCLUMBERGER, PhD | | 00 33 014-211-6095 | schlumbg@igr.fr |
| Community-acquired Methicillin-Resistant Staphylococcus Aureus Carriage Among Athletes (PSARM-S) | University Hospital, Limoges | Marie-Cécile PLOY, Professor | | (+33)(0)555 056166 | *marie-cecile.ploy*@unilim.fr |
| Stenting Versus Best Medical Treatment of Asymptomatic High Grade Carotid Artery Stenosis | Vienna General Hospital | Martin Schillinger, Prof. Dr. | | 0043/14040 0/4671 | martin.schillinger@meduniwien.ac.at |
| National Cohort of Uncomplicated Alcoholic Cirrhosis (CIRRAL) | Assistance Publique - Hôpitaux de Paris | Nathalie GANNE, MD PH | | +33(0)1 48 02 62 94 | nathalie.ganne@jvr.aphp.fr |
| Safety of Photodynamic Therapy (PDT) in the Ablation of High-grade Dysplasia (HGD) in Barrett's Esophagus (BE) (Oedisse) | Axcan Pharma | Michelle Depot, Ph.D. | | 450 467 5138 ext 2190 | mdepot@axcan.com |
| | | Valérie Ratheau, M.Sc. | | 450 467 5138 ext 2096 | vratheau@axcan.com |
| eRehab: Can Information and Communication Technology (ICT) Enhance Self-management of Cardiovascular Disease? | University Hospital of North Norwa | Konstantinos Antypas, MSc | | 4797613265 | Konstantinos.Antypas@telemed.no |
| Early Goal-Directed Volume Resuscitation in Severe Acute Pancreatitis (EAGLE) | Technische Universität München | Wolfgang Huber, MD | | 0049 89 4140 2265 | Wolfgang.Huber@lrz.tum.de |
| Utility of Antibiotic Treatment in Non-purulent Exacerbations of Chronic Obstructive Pulmonary Disease: a Double Blinded, Randomized, Placebo-controlled Trial of Security and Efficacy (AEPOC-ATB) | Fundacion Clinic per a la Recerca Biomédica | Nestor Soler, MD, PhD | | +34 932.275.400 ext 2280 | nsoler@clinic.ub.es |
| | | Arturo Huerta, MD | | +34 932.275.400 ext 5549 | ahuerta@clinic.ub.es |
| Quantitative Requirements of Docosahexaenoic Acid for Neural Function in Children With | Ludwig-Maximilians - University of | Fabienne Faber, MD | | 49 89 5160 ext 7813 | Fabienne.Faber@med.uni-muenchen.de |

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| Phenylketonuria | Munich | | | | |
| | | Hans Demmelmair, PhD | | 49 89 5160 ext 3692 | Hans.Demmelmair@med.uni-muenchen.de |
| SCOPE-Study: Salzburg Chronic Obstructive Pulmonary Disease-Exercise and Oxygen Study | Paracelsus Medical University | Josef Niebauer, MD, PhD, MBA | | 0043 (0)662 4482 ext 4270 | j.niebauer@salk.at |
| | | Sanz Miguel Angel, Dr | | 34 (96) 197 3057 | msanz@uv.es |
| Treatment of Relapsed Promyelocytic Leukemia With Arsenic Trioxide (ATO) | PETHEMA Foundation | : Priego Miguel, Data manager | | 34 635 964 539 | miguepriego@gmail.com |
| Failure and Cardiovascular Events in Community-acquired Pneumonia (FAILCAP) | University of Milan | Stefano Aliberti, M.D. | | | stefano.aliberti@unimi.it |
| | | Francesco Blasi, M.D., PhD | | 0039 0250320627 | francesco.blasi@unimi.it |
| PI or NNRTI as First-line Treatment of HIV in West Africa - the PIONA Trial | University of Aarhus | Sanne Jespersen, MD | | 89498491 ext 0045 | sanne.jespersen@ki.au.dk |
| | | Alex L Laursen, MD, DMSc | | 89498305 ext 0045 | alexlaur@rm.dk |
| Atrial Fibrillation Registry for Ankle-brachial Index Prevalence Assessment: Collaborative Italian Study. (ARAPACIS | University of Roma La Sapienza | Francesco Violi, MD | | 39 06-4461933 | francesco.violi@uniroma1.it |
| | | Giovanni Davì, MD | | 39-0871-541312 | gdavi@unich.it |
| Quality of Life Among Children With Congenital Heart Disease | University Hospital, Montpellier | AMEDRO Pascal, MD | | 467336635 | p-amedro@chu-montpellier.fr |
| Filling of Tooth Sockets With MBCP Gel TM Versus Technical Without Filling | Nantes University Hospital | Yves Amouriq | | 06 08 76 64 45 | yves.amouriq@univ-nantes.fr |
| Extracorporeal Shockwave Treatment for Chronic Soft Tissue Wounds | AUVA | Michael PUSCH, MD | | 43-128-802 | michael.pusch@gmx.at |
| The Effect of Inhaled N-Acetylcysteine Compared to Normal Saline on Sputum Rheology and Lung Function | University Hospital, Ghent | Sabine Van Daele, MD, PhD | | | sabine.vandaele@ugent.be |
| Influence of DPP-4 on Inflammatory Parameters in Diabetics: Gender Aspects | Medical University of Vienna | Jeanette Strametz-Juranek, MD | | 0140400 ext 4816 | jeanette.strametz-juranek@meduniwien.ac.at |
| | | Alexandra Kautzky-Willer, MD | | 0140400 ext 4314 | alexandra.kautzky-willer@meduniwien.ac.at |

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| Non-Micturation Bladder Activity in Relation to Self-Consciousness During Filling Phase and Sensation Measurement During the Filling Phase | Maastricht University Medical Center | Sajjad Rahnama'i, MD | | | sajjad_r@yahoo.com |
| Treatment Protocol for Relapsed Acute Promyelocytic Leukemia (APL) With Arsenic | German AML Cooperative Group | Eva Lengfelder, MD, PhD | | 0049 621 3834110 | eva.lengfelder@med3.ma.uni-heidelberg.de |
| Efficacy Study of the Octapolar Lead in Patients With Failed Back Surgery Syndrome (FBSS) With Chronic Pain | Medtronic Neuromodulation Europe | Rik Buschman, PhD | | 31 6 209 101 85 | rik.buschman@medtronic.com |
| Endomicroscopy in Ulcerative Colitis | PENTAX Europe GmbH | Ralf Kiesslich, Prof. Dr | | 49-613-117-7299 | info@ralf-kiesslich.de |
| BeneMACS is to Show That HeartMate 2 (HM2) Left Ventricular Assist Device (LVAD) Survival in Non Transplant Patients is Equal/Better Than Results in Medical Literature (BeneMACs) | Thoratec Europe Ltd | Luc-Marie Jacquet | | 3227642712 | Luc-Marie.Jacquet@uclouvain.be |
| Dexamethasone, Ofatumumab and Bendamustine (DOT) First-line in Mantle-cell Lymphoma(MCL) | Southern Europe New Drug Organization | Michele Magni, MD | | | michele.magni@istitutotumori.mi.it |
| Lenalidomide and Paclitaxel in Advanced Solid Tumors | Southern Europe New Drug Organization | Monica Miani, Pharm.D. | | +39 02764204(1) ext 33 | mianim@sendo-org.it |
| | | Laura Dal Zotto, Biol.Sc. | | +39 02764204(1) ext 21 | dalzottol@sendo-org.it |
| Sorafenib in Combination With RAD001 in Advanced Solid Tumors Selected on Molecular Targets | Southern Europe New Drug Organization | Filippo De Braud, MD | | 39 0257489482 | filippo.debraud@ieo.it |
| Comparative Study of Ologen Collagen Matrix Versus Mitomycin-C in Trabeculectomy: A Study in Germany | Aeon Astron Europe B.V. | Thomas Dietlein, MD | | +49-221-478-5862 ext 4300 | thomas.dietlein@uk-koeln.de |
| Hyperthermia Treatment in Conjunction With Mitomycin C Versus BCG for Superficial Bladder Cancer | Medical Enterprises Europe B.V. | Yagel E Koren, MD | | 972-3-9244830 | yagel@mel.co.il |
| | | Naama Reich, MSc | | | naamar@mel.co.il |
| Prolonged Adjuvant Temozolomide vs "Stop & Go" in Glioblastoma Patients (PATSGO) | Cliniques universitaires Saint-Luc-Université Catholique de | Jean-Francois BAURAIN, MD, Ph | | +32 2 764 54 71 | jean-francois.baurain@@uclouvain.be |

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|---|---|---|---|---|---|
| | Louvain | | | | |
| | | Albert FOURNIER, Pr | | +33 3 22 45 58 41 | Fournier.Albert@chu-amiens.fr |
| | | Ziad MASSY, Pr | | + 33 3 22 45 57 85 | Massy.ziad@chu-amiens.fr |
| Nicotinamide Versus Sevelamer Hydrochloride on Phosphatemia Control on Chronic Hemodialysed Patients (NICOREN) | Centre Hospitalier Universitaire, Amiens | | | | |
| Clinical Investigation to Assess the Safety and Feasibility of the Crestal, Minimal-invasive Sinus Floor Augmentation With the Pressure Chamber Drill (DKK) and the Sinus Vibration Pump (SVP) (DKK SVP) | Jeder GmbH | Michaela Bayerle-Eder, Prof., | | | michaela.bayerle-eder@meduniwien.ac.at |
| Neurogenic Intermittent Claudication Evaluation Study (NICE) | Medtronic Spinal & Biologics ECA | Gino Mariën | | +32 2 609 22 73 | gino.marien@medtronic.com |
| | | Attila Mihalyi, Ph. | | +32 2 609 45 23 | attila.mihalyi@medtronic.com |
| A Prospective, Randomized Clinical Study on the Effects of Casein Phosphopeptide-amorphous Calcium Phosphate (CPP-ACP) Paste on Plaque, Gingivitis and White Spot Lesions in Orthodontic Patients - Part 2 | University Hospital, Ghent | Silvia Dauwe | | | silvia.dauwe@ugent.be |
| Effect of Protein Composition on Gastric Emptying | Ullevaal University Hospital | Groa B Johannesdottir, MD | | | groh@uus.no |
| | | Charlotte Brun, MD | | | brap@uus.no |
| A Prospective, Randomized Clinical Study on the Effects of Casein Phosphopeptide-amorphous Calcium Phosphate (CPP-ACP) Paste on Plaque, Gingivitis and White Spot Lesions in Orthodontic Patients - Part 1 | University Hospital, Ghent | Veronique Noens | | | veronique.noens@ugent.be |
| Prasugrel Versus Clopidogrel in Acute Coronary Syndrome (ACS) Undergoing Percutaneous Coronary Intervention (PCI) | University of Heidelberg | Evangelos Giannitsis, Prof. Dr. | | +49 (0)6221-56-8611 | Evangelos_Giannitsis@med.uni-heidelberg.de |
| Incidence of Acute Cerebrovascular Events Using Either Minimized or Standard Cardiopulmonary Bypass Circuit (ROCsafeTM) | Hannover Medical School | Ingo Kutschka, PD Dr. med. | | 0049-511-532-2154 | kutschka.ingo@mh-hannover.de |

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|---|---|---|---|---|---|
| Monopolar Electrosurgery Versus Ultrasound Scissors in Thoracoscopic Ventral Spondylodesis (Harmonic) | University of Cologne | Christina Otto, MD | | +49 221 478 86973 | christina.otto@uk-koeln.de |

## 2.3 Main Stakeholders

We have identified the following main stakeholders:

- Clinicians / Care providers
- Chairpersons of research projects / trials
- Basic Researchers / Molecular biologists
- Computer Scientists
- Legal Experts / Ethicists
- Data Manager / Statisticians
- European Policymakers

The following tables list stakeholders related to Basic Researchers, Computer Scientists Ethics groups, Patient Organisations, Registries, Data Protection authorities, National authorities, Data Managers and Controllers and personal contacts. Those persons will actively be invited to participate in the survey.

***Table 3. Basic Researchers***

| Institution | Contact Person | Function | Phone Number | email |
|---|---|---|---|---|
| University Würzburg<br>Department of Biochemistry | Manfred Gessler (Prof.) | Director | +49 931 31 84160 | gessler@biozentrum.uni-wuerzburg.de |
| Saarland University, Medical Faculty,<br>Department óf Human Genetics | Eckart Meese | Director | +49 6841 1626038 | eckart.meese@uks.eu |
| University Kiel<br>Department of Paediatrics | Martin Stanulla | | | *martin.stanulla@uk-sh.de* |

***Table 4. Ethics Groups***

| Institution | Contact Person | Function | Phone Number | email |
|---|---|---|---|---|
| Austrian Commission on Bioethics | Mag. Dr. Doris Wolfslehner<br>Mag. Pia Paola Huber<br>Gabriela Schwehla<br>Birgit Berger | | +43 1 531 15-2987<br>+43 1 531 15-2967<br>+43 1 531 15-4116<br>+43 1 531 15-2932 | doris.wolfslehner@bka.gv.at<br>pia-paola.huber@bka.gv.at<br>gabriela.schwehla@bka.gv.at<br>birgit.berger@bka. |

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|---|---|---|---|---|
| | | | | gv.at |
| Le Comité consultatif de Bioéthique de Belgique | | | | |
| Bioetická komise Czech | | | | rvv@vlada.cz |
| University Centre for Bioethics Czech | | | ´+420 549 494 913 | ucb@med.muni.cz |
| The Danish Council of Ethics | Lise Wied Kirkegaard, cand.jur., MPK.<br>Anne Lykkeskov, cand.comm. | Director of Secretariat<br>Project Manager | +45 3524 0681<br>+45 3524 0651 | lwk@etiskraad.dk<br>al@etiskraad.dk |
| The Estonian Genome Foundation | Andres Metspalu M.D., Ph.D.<br>Annely Allik<br>Ene Mölder | Director<br>Marketing and Communications Manager<br>Contracts and Assets Administrator | (+372) 7440 242<br>+372 7 440 241<br>+372 7 440 240 | andres.metspalu@geenivaramu.ee<br>annely.allik@geenivaramu.ee<br>ene.molder@geenivaramu.ee |
| National Advisory Board on Health Care Ethics (ETENE), Ministry of Social Affairs and Health (Finland) | | | ´+358 9 16001 | etene@stm.fi |
| National Advisory Board on Research Ethics (Finland) | Sanna Kaisa Spoof<br>Heidi Laine<br>Aino Alatal | Secretary General<br>Assistant Project Assistant | ´+358-9-228 69 234<br>´+358-9-228 69 235<br>´+58-44-346 9990 | sanna-kaisa.spoof@tsv.fi<br>heidi.laine@tsv.fi<br>aino.alatalo@tsv.fi |
| Finnish National Advisory Board on Biotechnology | Kimmo Pitkänen<br>Jyrki Pitkäjärvi<br>Karoliina Niemi | Chairman & Research Coordinate<br>Vice-Chariman & Senior Adviser<br>Secretary & Senior Researcher | ´+358 9 191 25734<br>´+358 9 16001<br>´+358 9 160 52323 | kimmo.pitkönen@helsinki.fi<br>jyrki.pitkäjärvi@ymparisto.fi<br>karoliina.niemi@mmm.fi |
| Board for Gene Technology | | | ´+358 9 16001 | gtlk.stm@stm.fi |
| Comité Consultatif National d'Ethique (CCNE) (France) | | | ´+ 33 01 42 75 66 42 | Contact: http://www.ccne-ethique.fr/contact.php |
| Nationaler Ethikrat Deutschland | Dr. Joachim Vetter<br>Dr. Katrin Bentele<br>Petra Hohmann | Leiter der Geschäftsstelle<br>Wissentschaftliche Referentin<br>Sekretatiat | ´+49/30/203 70-242<br>´+49/30/203 70-524<br>+49/30/203 70-242 | vetter@ethikrat.org<br>bentele@ethikrat.org<br>hohmann@ethikrat.org |
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| Kinder-Krebs-Hilfe | Mrs Anita Kienesberger | Chariwoman | +43 1 402 88 99 | *oesterreichische@kinderkrebshilfe.at* |
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|---|---|---|---|---|
| | | Contact person to ECRIN | | |
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| BBMRI | Prof. Dr. Jan-Eric Litton, Stockholm | deputy director of BBMRI.se | 070-836 6810 | Jan-Eric.Litton@ki.se |
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| I-BFM | Prof. Dr. Martin Schrappe | Scientific Chairman of I-BMF | | martin.schrappe@uk-sh.de |
| SIOP Europe | Fr. Prof. Dr. Ladenstein | Chairwoman of SIOP Europe | +43 (1) 404 70-0 | ruth.ladenstein@ccri.at |

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| Ireland - Data Protection Commissioner<br>Canal House<br>Station Road<br>Portarlington<br>Co. Laois<br>Ireland | Stewart Fennell | Information Officer | 057 868 4800 | info@dataprotection.ie |
| Slovenia - Information Commissioner | Urban Brulc | | 00386 (0) 1 230 97 78 | Urban.Brulc@ip-rs.si |
| Sweden - Swedish Data Inspection Board | Erik Janzon | Legal advisor & Team leader | +46 70 728 64 32 | Erik.Janzon@datainspektionen.se |
| Austria - DPA | Mag. Georg LECHNER | | Tel: ++43 (1) 531 15 / 2946 | Georg.LECHNER@dsk.gv.at |

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| LBNL, USA | Paul Spellman | | | |
| University College London, UK | Bernadette Modell | | | |
| University Medical Center Groningen,NL | Alexandros Kanterakis | | | |
| Ontario Institute for Cancer Research, Canada | Vincent Ferretti | | | |
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| Norwegian Institute of Public Health, Norway | Astanand Jugessur | | | |
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| Professor of Health Informatics and Director of the Centre for Health Informatics and Multiprofessional Education, University College London | David Ingram | | | d.ingram@ucl.ac.uk |

# 3 Description of Questionnaire

## *3.1 Introduction to the questionnaire*

An introduction by explaining the questionnaire to the different stakeholders and to provide information about data security and confidentiality issues related to the survey will be given at the beginning of the questionnaire. The participants will also be asked if they want to receive a summary of the results of the survey.

The opening paragraph of the questionnaire is as follows (in brown-red):

**PLEASE READ BEFORE STARTING**

This survey is part of a European Collaborative Project called **CONTRACT** (COnsent in a TRiAl and Care environment) funded in the 7th Framework Programme (Grant agreement 261412). **CONTRACT** will support translational research projects – both ongoing and upcoming. It will develop a multidisciplinary approach in delivering facts and figures on different approaches to informed consent both in European projects and in European Member States. **CONTRACT** will analyze the IT-related representation of these different understandings and the outcome of these differences in the daily clinical and/or research routine. For more information about the project please visit our website: http://www.contract-fp7.eu/.

This **questionnaire** will analyse the current situation concerning the legal, ethical, technical and clinical handling of consent, mainly in European projects dealing with vulnerable patient groups. The purpose is to identify existing practices and problems encountered in translational research throughout Europe.

By participating in this survey **you will help us** to advise translational research projects in all issues of informed consent and to deliver concrete policy recommendations as to how the European Union could jointly protect patient's rights and support translational research by a better structured approach towards consent issues. In addition you will be able to access to the prelaunch version of the CONTRACT helpdesk which will provide advice on aspects of informed consent in a research setting. (please see http://www.contract-fp7.eu/ for further details).

The survey is addressed to

- Clinicians / Care providers,
- Chairpersons of research projects / trials,
- Researchers / Molecular biologists,
- Computer Scientists,
- Legal Experts
- Ethicists,
- Data Manager / Statisticians and
- European Policymakers.

The questionnaire takes approximately 30 minutes to complete and we would be very grateful if you could take this time to fully complete all questions.

The data is raised and processed for this survey only. The data will be anonymised wherever possible before processing and destroyed **after two years**. You may revoke your consent to the processing of your personal data at any time. In this case, all your personal data will be deleted immediately. Please contact us if you have any questions or if you would like to get more information about the survey. If you would like to receive the results of this questionnaire by email, please provide us with your email address:

- o Yes, I want to be notified about the results of this survey and for that purpose provide you with my email address: _____@_____

For any questions regarding this survey please send an e-mail to:

**Institut für Rechtsinformatik / Gottfried Wilhelm Leibniz Universität Hannover**
Prof. Dr Nikolaus Forgó - forgo@iri.uni-hannover.de
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Many thanks for your contribution.

The survey team

## *3.2 Sections of the questionnaire*

The questionnaire is divided into 6 different sections. These sections are listed in the below table showing the number of questions and which stakeholders have to answer them.

| | Section | number of questions | to be answered by |
|---|---|---|---|
| 1 | General | 35 | all |
| 2 | Clinical care | 11 | all |
| 3 | Research | 3 | researchers |
| 4 | IT related<br>Clinical care context<br>Clinical trial context | <br>21<br>11 | <br>IT experts<br>IT experts |
| 5 | Legal and ethical issues | 31 | all |
| 6 | Handling | 6 | all |

## *3.3 Development of the questionnaire*

The questionnaire was developed in an iterative process between all members of the consortium of CONTRACT. This was done via email, telephone conferences and meetings. The last meeting took place in Homburg on the 14th of February 2011.

A prefinal version was sent to different stakeholder groups (GPOH, I-BFM and SIOP Europe) to obtain feedback on the questionnaire which provided valuable feedback in particular for section 2 (clinical care) of the questionnaire.

Griet Verhenneman and Magdalena Góralczyk presented the questionnaire at the ENCCA Meeting in Brussels on the 10th of February 2011. The participants of the meeting showed a high level of interest in participating and clearly acknowledged that consent is a problematic issue especially in clinical trials.

# 4 The proposed dissemination of the questionnaire

The questionnaire will be made available via the website of CONTRACT. People who have already given their consent in taking part in the survey will be notified by email with the link to the questionnaire.

The link to the questionnaire will also be sent to the targeted projects and other stakeholders as given in tables 1-11 for distribution to their members. Some of the targeted projects also agreed to link to the questionnaire through their website, like GPOH, SIOP Europe.

To avoid double entry or spam entries each respondent needs to register and will receive immediately a token which allows him to enter the questionnaire.

# 5 Technical implementation

The technical implementation will be done by Custodix.

# 6 Appendix – The questionnaire

The following pages list the whole questionnaire.

Questions highlighted in green are not mandatory to answer.

Text highlighted in yellow gives explanations to the following questions.

Questions with green bars will have 6 discrete possibilities to answer.

# Final Questionnaire

## 1. General [questions 1.1 to 1.24 are to be answered by everybody]

**1.1 How old are you?** [ ] years

**1.2. What is your gender?** [ ] male [ ] female

**1.3 What is your highest professional degree/diploma?**

- Primary school
- High school
- Bachelor
- Master or equivalent
- State Exam
- MD
- PhD or other
- Professor at a University
- Other

**1.4 In which country do you work?**

- European Countries
  - Albania
  - Andorra
  - Armenia
  - Austria
  - Azerbaijan
  - Belarus
  - Belgium
  - Bosnia and Herzegovina
  - Bulgaria
  - Croatia
  - Cyprus
  - Czechia
  - Denmark
  - Estonia
  - Finland
  - France
  - Georgia
  - Germany
  - Greece
  - Hungary
  - Iceland
  - Ireland
  - Italy

- Kazakhstan
- Latvia
- Lichtenstein
- Lithuania
- Luxembourg
- Macedonia
- Malta
- Moldova
- Monaco
- Montenegro
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- San Marino
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom
- Vatican City

- Non-European Countries
  - Africa
  - Asia
  - Australia
  - North America
  - South America

**1.5 What is your profession?**

- Physician
- .Molecular biologist
- Bioinformatician
- Computer Scientist
- Statistician
- Lawyer
- Ethicist
- Auditor for clinical trials
- Manager
- Politician
- Other

**1.6 Where are you employed?**

- o University
- o Large Industry
- o SME (small medium enterprise)
- o Government (public) service
- o Self-employed
- o Other

- o **1.7 Can you please specify the role in which you are answering this questionnaire?**
- o Clinician / Care provider
- o Chairperson of an international pharmaceutical Trial
- o Chairperson of an international investigator initiated trial
- o Chairperson of a national pharmaceutical Trial
- o Chairperson of a national investigator initiated trial
- o Coordinator of a European research project
- o Coordinator of a National research project
- o Scientist
- o Medical Society member
- o Member of an Ethics Committee
- o Computer scientist
- o Legal practitioner
- o Data manager / Statistician
- o Auditor of clinical trials
- o Data protection officer
- o Data protection Authority official
- o Patient association/organisation member
- o Registry employee
- o Politician
- o Regulatory Authority official
- o Other

**1.7a In case of 'other', please specify other:** _____

**1.8 For how many years have you been dealing with issues of obtaining consent in your work?**

____ years

**1.9 Did you ever sign a consent form as a patient or for someone else?**

- o **Yes**
- o **No**

(if no, continue with question 1.10)

**1.9.1 If yes, for whom did you sign:**

- o Myself

- o My child
- o For someone else as a legal guardian

**1.9.2 Have you retained a copy of the consent form?**

- o Yes
- o No, I did not receive a copyNo

**1.9.3 How comfortable were you in general with the process of obtaining consent?**

not at all — perfectly satisfied

0 +5

**1.9.4 Did you feel that the consent form you filled in together with written information explained the medical information sufficiently?**

too detailed — not at all

0 +5

**1.9.5 Did you feel that the consent form you filled in together with written information explained the legal information sufficiently?**

too detailed — not at all

0 +5

**1.9.6 How did the process of giving consent influence your concerns related to the subject of the consent?**

**a) with respect to the medical procedures to be undertaken**

increase to maximal concern — decrease to no concern

0 +5

**b) with respect to the sensitivity and handling of your data**

increase to maximal concern — decrease to no concern

0 +5

**1.10 Are you familiar with legal requirements regarding the content of consent procedures?**


**1.11 In how much detail should a consent form/procedure explain medical information?**


**1.12 In how much detail should a consent form/procedure explain legal information?**


**1.13 Should there be different practices of obtaining consent for care and research environments?**

- o **Yes**
- o **No**

**1.14 Which of the following aspects do you consider should be included in consent forms for clinical trials?**
**Please mark every item that is needed.**

- o The trial is always research
- o Purpose of the trial
- o Trial treatment(s)
- o Trial procedures
- o Data protection
- o The participant's responsibilities
- o Experimental trial aspects
- o Foreseeable risks or inconveniences
- o Expected benefits for patients
- o Expected benefits for general public

- o Alternative procedure(s) or treatment(s)
- o Compensation and/or treatment available in the event of trial-related injury
- o Payment to participants
- o Expenses for participants
- o Information about liability issues
- o Participation is voluntary, and the participant may refuse to participate or withdraw from the trial at any time
- o The monitor(s), the Ethical Committee, and the regulatory authority(ies) will be granted direct access to the participant's medical records
- o Records identifying the participant will be kept confidential to all parties with the exception of those specified before
- o The participant or representative will be informed if information becomes available that may be relevant to their willingness to continue participating in the trial
- o Person(s) to contact for further information regarding the trial, rights of trial participants, and in the event of trial-related injury
- o Circumstances and/or reasons under which participation on the trial may be terminated by the sponsor
- o Expected duration of trial participation
- o Approximate number of participants involved in the trial

**1.15 Which of the following aspects do you consider should be included in consent forms for clinical care?**
**Please mark every item that is needed.**

- o Purpose of the treatment or diagnostic procedure
- o Data protection
- o The participant's responsibilities
- o Foreseeable risks or inconveniences
- o Expected benefits for patients
- o Alternative procedure(s) or treatment(s)
- o Treatment available in the event of side effects
- o Information about liability issues
- o Participation is voluntary, and the participant may refuse to participate or withdraw at any time
- o Records identifying the participant will be kept confidential
- o Person(s) to contact for further information
- o Expected duration of the treatment or diagnostic procedure
- o Approximate number of patients undergoing the diagnostic procedure by the specific physician doing the procedure
- o Approximate number of patients with this disease being treated by the specific physician

**1.16 Are you familiar with the re-consent procedure?**

- o **Yes**
- o **No**

(if no, continue with question 1.17)

**1.16.1 How important is obtaining re-consent from a legal point of view?**

very important  not at all

0 +5

**1.16.2 In your opinion should such a procedure be obligatory?**

- o no
- o yes, for under-aged patients
- o yes, for all the patients

**1.16.3 When should a re-consent be obtained to your opinion? (More than 1 point in time can be marked)**

- o Never
- o Once a patient turns 14
- o Once a patient turns 16
- o 4 weeks after the begin of a trial treatment
- o At the end of a trial
- o Every time data or biological material is needed for a new research topic
- o Every time biological material is used
- o After every amendment of a trial

**1.17 How important is the role of physician when obtaining consent?**

very important  not at all

0 +5

**1.18 How important is the attitude of the physician to the project when obtaining consent?**

very important  not at all

0 +5

**1.19 How much previous experience in clinical care should a physician obtaining consent have?**


**1.20 Is it possible in your opinion to obtain informed consent without speaking to the patient, e.g. Using only paper based or electronic mailing methods?**

- o **Yes**
- o **No**

**1.21 How important is it to provide an information sheet for the patient to allow him/her inform him/herself about the project?**


**1.21.1 Should this information sheet be accompanied by a face to face consultation in any case?**

- o **Yes**
- o **No**

**1.22 Do you think that patients have difficulties *in general* to understand consent forms and procedures?**

- o **Yes**
- o **No**

**1.23 How many patients do you think understand all items addressed in consents forms and procedures?**


**1.24 To what extent do the requirements to obtain informed consent restrain research in general?**


**[The questions 1.25 to 1.35 are only for chairpersons of trials and coordinators of projects]**

**1.25 If you are a chairperson of a project or a trial that needs to obtain consent(s) would it be possible to receive the templates used for consent procedures for analysis?**
**Would you be willing to upload your templates for obtaining consent for analysis here?**

If yes, can you please upload here:
If yes, is it possible to receive the project or trial protocol to analyse the completeness of your consent:
If yes, can you please upload here:

If it is not possible to upload, can you send these documents by postal service to:

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30167 Hannover

**1.26 What kind of project are you running?**

- o Prospective clinical trial
- o Retrospective clinical trial
- o An epidemiological project
- o A research project where only retrospective data are used which does not influence the diagnosis or treatment of current patients
- o Other

**1.26a If you are running a prospective clinical trial, is this** (*multiple answers possible*):

- o Randomised
- o Multicentre
- o International inside Europe
- o International outside Europe

**1.27 Did you compile the consent forms for your project/trial by yourself?**

- o **Yes**
- o **No**

**1.27.1 If yes, how difficult was it for you to compile the consent forms for your project?**

very difficult  not at all

0 +5

**1.28.2 if no, who compiled it?**_____

**1.28 Did you use a template to write the consent forms for your project?**

- o **Yes**
- o **No**

**1.28.1 if no, would a template have been helpful?**

- o **Yes**
- o **No**

- o **1.28.2 If yes, would you be willing to pay for such a template/service? Yes**
- o **No**

**1.29 Did you need to change the consent forms/procedures after an ethical review of your project?**

- o **Yes**
- o **No**

**1.30 Do you think you have addressed all items that are legally and ethically needed in terms of informed consent in your project?**

- o **Yes**
- o **No**

**1.31 Do you know whether patients have difficulties to understand *your* consent forms and procedures?**

- o **Yes**
- o **No**

**1.32 How many patients do you believe understand all items addressed in the consent procedures of your project?**


**1.33 In how many languages do you provide the consent forms and procedures in your project?** [ ]

**1.34 Do you provide an information sheet to patients to inform themselves about the project?**

- o **Yes**
- o **No**

**1.35 Please specify the minimal and maximal number of different consents forms that you provide for a single patient?**

- o Minimal _____
- o Maximal_____

## 2. Clinical Care [questions 2.1 to 2.11 have to be answered by everybody]

**2.1 Do you see a discrepancy between actual clinical practice and the legal and ethical regulations for clinical practice?**

very huge  Not at all

0 +5

**2.2 What is the maximal number of different consent forms that should be provided for a patient taking part in a trial?** _____

**2.3 Should there be a maximum number of pages of written information given to a patient at once?**

- o **Yes**
- o **No**

**2.3.1 If yes, how many pages of written information for patients do you think are acceptable?** _____

**2.4 Should there be a maximum number of pages of written information given to a patient for one disease, treatment or diagnostic procedure?**

- o **Yes**
- o **No**

**2.4.1 If yes, how many pages of written information for patients do you think are acceptable?** _____

**2.5 In your experience, how useful is this information for patients to understand what is happening?**

very useful  not at all

0 +5

**2.6 As far as you know such written information, how useful is this information for patients to agree with what is happening?**

very useful  not at all

0 +5

**2.7 How much time should a patient be given to reflect before he is asked to sign a consent form for any kind of procedure or treatment according to your opinion?**

- o < 1 hour
- o
- o 1 - 6 hours
- o 6 - 12 hours
- o 12 - 24 hours or including one night
- o 24 – 48 hours
- o 3 to 5 days
- o > 5 days

**2.7.1 Should there be more time given as stated above in case of a prospective randomized trial?**

- o **Yes**
- o **No**

**2.7.2 Does this match with the legal / ethical requirements of informed consent?**

- o Yes
- o No
- o There are no legal requirements

**2.8 Can you estimate the average time period between diagnosis to the time at which consent is given by patients/parents/legal guardians in general today?**

_____

**2.9 What is the time frame in which consent forms need to be signed by patients/legal guardians?**

_____

- o There is no legally binding timeframe
- o I do not know

**2.10 What are your suggestions for improvement of obtaining informed consent in clinical care?**

_____

_____

_____

_____

**2.11 To what extent would such improvements influence the future of clinical trials?**

very much  not at all

0 +5

## 3. Research [questions 3.1 to 3.3 have to be answered by clinical and basic researchers]

**3.1 Did you experience barriers in any of your research projects as a consequence of unclear or lack of informed consent?**

- o **Yes**
- o **No**

**3.2 To what extent did these barriers affect the research?**

a large extent  not at all

0 +5

**3.3 How easy is it to overcome these barriers?**

very easy  not at all

0 +5

## 4. IT related – Clinical Care Context

***[questions 4.1 to 4.22 relate to the clinical care context. They are targeted towards people working with or familiar with the Electronic Health Record System (EHR) /Electronical Medical Record (EMR) used in their organization]***

**4.1 Does your Electronic Health Record System (HER)/Electronical Medical Record (EMR) serve as access point to the majority of medical data (excluding administrative data and appointment scheduling) that is available on a patient in the hospital?**

- O Yes, our Hospital Information System (HIS) comes from single vendor
- O Although the HIS is segmented over the hospital, cross department data access is possible
- O No, different information silos exist in the hospital

**4.2 Do you use a commercial EHR/EMR solution?**

- O No
- O Yes, Vendor

**4.2.1 In case of 'yes, Vendor', please specify Vendor:**

_____

**4.3 Do patients give care-related consent by signing paper forms?**

- O Yes
- O No

**4.3.1 If yes, do you archive the paper consent forms electronically? (e.g. signed paper consent forms)**

- O Yes
- O No

**4.4 If consent is archived, is that done centrally?**

- O Yes
- O No

**4.5 Is the patient consent (also) recorded electronically? (if yes, check all that apply)**

- O Yes, the patient can give consent using an electronic signature
- O Yes, the data management application requests the physician to record electronically in the application that the patient has given consent (and signed a form)
- O Yes, other
- O No, there is no electronic recording or archiving whatsoever

**4.5.1 In case of yes, other, please specify other:**

_____

*[All further questions in this section are only relevant in case there is electronic patient consent recording (i.e. more than archiving alone)]*

**4.6 Is consent to care-related procedures (e.g. agreement surgical procedures ...) recorded separately from data processing consent?**

- O Yes, actually all different types of consent are recorded separately
- O Yes, a distinction is made between medical and research related procedures on the one side and data processing consent on the other

- O No

**4.7 Is electronic consent handled by an eConsent system that is separate/independent from the IT infrastructure of the hospital information system and/or of the trial?**

- O Yes
- O No

**4.8 Does your EHR/EMR access control system enforce the recorded patient consent with respect to data protection?**

- O Yes
- O No

If yes, please give some detail about the EMR/EHR Patient Consent Directives privacy functionality. (Questions 4.10, 4.11, 4.12)

**4.9 Consent means "opting-in", allowing something additional to the standard policy. However, "Consent Directives" can also be specified as rules for restricting use with respect to the standard policy (rather "opting out").** Does your EHR/EMR support recording of patients preferences regarding data sharing that limit sharing with respect to the default access policies**?**

- O Yes
- O No

**4.10 This question addresses the consent directive specification granularity. With respect to the data that can be referred to in a Patient Consent Directive, a Patient Consent Directive can apply to... (check all that apply)**

- O All data for a patient that is associated with treatment in a particular department
- O All data associated to a particular care episode for a patient
- O All data of a patient of which has been attributed a certain confidentiality level in the EMR/EHR
- O Specific pre-defined result sets or datasets (e.g. mental health data, HIV results and data, ...)
- O Patient Directives always cover the complete medical dataset (all data in the hospital)

**4.11 Can a patient express Consent Directives about sharing medical data for care environment (e.g. refuse or enable data sharing outside of the local episode, for example by giving feedback to a general practitioner)**

- O Yes
- O No

**4.12 Can a patient express consent about secondary use of his EHR/EMR data in specific research projects?**

- O Yes
- O No

**4.13 Can a patient express consent about being contacted for possible inclusion into a clinical trial (i.e. consenting to having his medical data scanned for that purpose)?**

- O Yes
- O No

**4.14 Can Patient Consent directives specify "conditions" under which they are valid (e.g. only valid in emergency situations, only for non-commercial research)?**

- O Yes
- O No

**4.15 When consent is given by a legal guardian, is his identity recorded and will be identifiable?**

- O Yes
- O No

**4.16 Does the system automatically initiate re-consent or remind the physician to initiate reconsent when a minor patient becomes legally adult or even at an earlier age defined before?**

- O Yes
- O No

**4.17 Does the system support functionality for consent life-time limiting (other than age-related time-limiting)? (e.g. expiration of consent possibly followed by automated request for reconsent)**

- O Yes
- O No

**4.18 Is the system capable of recording that consent has been revoked?**

- O Yes
- O No

**4.19 Can a patient easily obtain a (complete) overview of what he has consented to?**

- O Yes
- O No

**4.20 If possible, please describe the procedures and ICT technologies that guarantee the secure process of personal data in your institution?**

_____

_____

_____

_____

**4.21 Please note down any relevant remarks not covered by the above questions:**

_____

_____

_____

_____

_____

## IT related – Clinical Trial Context

**[*questions 4.22 to 4.26 relate to the clinical trial context and are to be answered by people involved in development or management of clinical trail IT systems*]**

**4.22 Is there an electronic system to manage consent related documents (information leaflets, templates, ...)?**

- O Yes, this functionality is provided by the Clinical Trial Data Management System (CTMS) we use
- O Yes, we use a generic document management system
- O Yes, other

O No

**4.22.1 In case of 'yes, other', please specify other:**

_____

**4.23 Do patients give trial related consent by signing paper forms?**

O Yes
O No

**4.24 Do you archive signed paper consent forms electronically? (e.g. scanned signed paper forms)**

O Patients are not asked to sign paper consent forms
O Yes
O No

**4.25 If consent is archived, is that done centrally?**

O Yes, in the clinic
O Yes, in the department only
O Yes, nationwide
O No

**4.26 Is the patient consent (also) recorded electronically? (if yes, check all that apply)**

O Yes, the patient can give consent using an electronic signature
O Yes, the data management application requests the physician to record electronically in the application that the patient has given consent (and signed a form)
O Yes, other
O No, there is no electronic recording or archiving whatsoever

**4.26.1 In case of 'yes, other', please specify other:**

_____

***(All further questions (4.27 – 4.37) in this section are only relevant in case there is electronic patient consent recording (i.e. more than archiving alone))***

**4.27 Is consent to medical related procedures (e.g. agreement surgical procedures ...) recorded separately from data processing consent?**

- O Yes, actually all different types of consent are recorded separately
- O Yes, a distinction is made between medical and research related procedures on the one side and data processing consent on the other
- O No

**4.28 Is there an electronic system that provides functionality for managing consent given by individual patients (i.e. more functionality than document management as referred to in 4.22) in a more or less generic way?**

- O Yes, consent management is provided by the CTMS we use
- O Yes, we use an independent system for consent management
- O Yes, other
- O No

**4.28.1 In case of 'yes, other', please specify other:**

_____

**4.29 Does the consent management system offer an overview of the required and obtained consent(s) for each enrolled patient?**

- O Yes
- O No

**4.30 Is the consent management system capable of dealing with trial workflow dependent consent? (e.g. different treatment trajectories might require different consent)**

- O Yes
- O No

**4.31 Does the consent management system offer support for obtaining re-consent after a study amendment?**

- O Yes
- O No

**4.32 Does the consent management system offer support for initiating a re-consent procedure when the patient becomes legally adult or even at a younger age? (e.g. reminder)**

- O Yes
- O No

**4.33 Is the recorded consent "integrated" in the investigator trial workflow? (e.g. data entry is prevented as long as no consent is registered, the investigator is presented with a warning when new consent is needed, etc)**

- O Yes
- O No

**4.34 When consent is given by a legal guardian, is his identity recorded and will be identifiable?**

- O Yes
- O No

**4.35 Does the system allow consent to be revoked?**

- O Yes
- O No

**4.36 Can a patient easily obtain a (complete) overview of the consent he/she has given?**

- O Yes
- O No

**4.37 Please note down any relevant remarks not covered by the questions:**

_____

_____

_____

_____

## 5. Legal and ethical issues *[questions to all, if not otherwise specified]*

**5.1 Do you have to deal with different legal sources when organizing the consent procedure?**

- o No -> go to 5.3
- o Yes, because different national sources are applicable to my project -> go to 5.2
- o Yes, because multi national sources are applicable to my project-> go to 5.2

**5.2 Do you use one or more forms to obtain consent?**

- o [ ] yes
- o [ ] no

**5.2.1 If you use several, how many then:** [ ]

**5.3 European regulations require for different types of consent. At least three of them might be relevant: the patient's consent to treatment, consent to participate in a clinical trial and consent to allow the processing of personal data. Are you aware that by law you might be required to acquire three separate types of consent?**

- o Yes, I am aware of these regulations and my institution fulfills these requirements
- o Yes, I am aware of these regulations but my institution does not fulfill these requirements
- o No, I am not aware of these regulations

**5.4 Are there any specific data security or data protection policies concerning patients' data at your institution?**

- o Yes
- o I am not aware of any
- o No

**5.5 Does your institution have a Data Protection Officer (a person in charge of monitoring data protection issues in your institution)?**

- o Yes
- o No
- o I do not know

**5.5 In case of clinical trial with participating centres outside of your country do you then also apply foreign legislation to your consent?**

- o Yes
- o No

**5.7 To what extent have you experienced difficulties within European projects arising from differing national implementations of EU legislation?**

Significant difficulties  not at all

0 +5

[ ] I do not know

**5.8 Has this had a negative impact on your project / research?**

- o Yes
- o No

**5.8.1 If yes, what are the difficulties have caused negative impact?**

_____

_____

_____

**5.8.2 If yes, would a harmonized one-for-all approach help you in your research?**

a lot  not at all

0 +5

**5.9 Does your organization conduct retrospective studies?**

- o Yes
- o No

**5.9.1 If yes, how is consent regulated in these cases?**

- o Only data of patients who previously consented to additional studies is admitted to the study
- o Former patients are asked for consent for the use of the data which was previously collected
- o All the previously collected data is being used for the study and additional consent of the data subject is not sought

**5.10 In case of vulnerable patients (i.e. subjects possibly not capable of giving legally valid informed consent, such as minors) which of the following is fulfilled:**

- o A legal representative needs to sign the consent form;
- o A vulnerable patient needs to assent
- o Any other specific measures, please describe?

_____

_____

**5.11 Are there any measures taken to measure the vulnerable patient's capability to understand the implications of the assent given?**

- o Yes
- o No

**5.12 In case of conflict between the consent of the legal representative and assent of the vulnerable patient what further steps are taken?**

- o The opinion of the legal representative is binding
- o Vulnerable patient is not admitted to the trial
- o A ruling of the court is needed,
- o Other
- o Such a situation has never occurred in my practice

**5.12.1 In case of 'other', please specify other:**

_____

**5.13 Do you also perform trials on healthy children?**

- O Yes
- O No

**5.13.1 If yes, what is the procedure of obtaining consent and assent in the case of healthy children?**

_____

_____

_____

**5.14 Do you also perform trials on mentally ill patients?**

- O Yes
- O No

**5.14.1 If yes, what is the procedure of obtaining consent and assent in the case of mentally ill patients?**

_____

_____

_____

**5.15 Are there any additional good practices, or guidelines you follow in drafting your consent forms?**

- O Yes
- O No

**5.15.1 If yes, please provide a link or upload the guidelines here:**

***[questions to all]***

**5.16 Should consent be negotiable or predetermined by one side?**

- o Negotiable
- o Predetermined

**5.17 How long do you store the consent forms?**

until the end of the trial / project

indefinite

0 +5

**5.18 Is this legally required or is this done for other reasons?**

- o Legally required
- o I do not know
- o Other reasons:

**5.18a In case of 'other reasons', please specify reasons:**

_____

_____

**5.19 Are you required to obtain accreditation of a governmental or non-governmental institution for your consent forms and procedures?**

- O Yes
- O No

**5.19.1 If yes, by what institution?**

_____

_____

_____

**5.19.2 If yes, can you please describe the accreditation procedure?**

_____

_____

_____

_____

_____

**5.20 Do the consent forms require approval by an ethics committee?**

- o Yes, by my local ethical committee
- o Yes, by my local and other national ethical committees
- o No

**5.21 Do any additional institutions review your consent forms?**

O Yes

O No

**5.23.1 If yes, please name the institutions**

_____

_____

_____

**5.22 Do you inform patients about the rights they have concerning informed consent?**

| | | |
|---|---|---|
| Their rights as a patient | [ ] Yes | [ ] No |
| Their rights as a clinical trials subject | [ ] Yes | [ ] No |
| Their rights as a data subject | [ ] Yes | [ ] No |

**How do you provide this information?**

_____

_____

_____

_____

_____

_____

O **5.23 Do you direct the patient to a non-involved institute/specialist to explain the dangers and aims of the therapy /study?** Yes

O No

**5.24 Can the data subject/patient access their personal data after signing the consent form?**

O Yes

O No

**5.24.1 If yes, how is this organized? e.g. direct or indirect access, on paper or electronically?**

_____

_____

**5.25 Do you share non-personal data about trial participants with other institutions?**

| | | |
|---|---|---|
| in the same country | [ ] Yes | [ ] No |
| abroad, within Europe | [ ] Yes | [ ] No |
| abroad, outside of Europe | [ ] Yes | [ ] No |

**5.25.1 If yes, is the participant informed about this?**

- o Yes
- o No

**5.26 Do you create the same level of data security for collected information in all your trial centres**?

- O Yes
- O No

**5.27 Are you aware of any legal complaints in your professional or personal environment due to the possible inappropriate handling of consent?**

- O Yes
- O No

**5.27.1 If yes, what legal actions were taken?**

- o Alternative dispute resolution /Mediation
- o Other complaint procedure
- o Lawsuit against the hospital or clinician

***[The next questions are only for the National data authorities]***

**5.28 Does your institution have a unit which provides specific legal support concerning:**

| | | |
|---|---|---|
| medical law | [ ] Yes | [ ] No |
| scientific research, patents | [ ] Yes | [ ] No |
| clinical trials | [ ] Yes | [ ] No |

**5.29 Does your institution offer advice about obtaining valid informed consent?**

- O Yes
- O No

**5.29.1 If yes, does it offer specific advice for medical data?**

- o Yes
- o **No**

**5.29.2 If yes, please describe what kind of advice and in what form it is offered**

| | | |
|---|---|---|
| Online | [ ] Yes | [ ] No |

| | | |
|---|---|---|
| Phone | [ ] Yes | [ ] No |
| Mail | [ ] Yes | [ ] No |
| eye to eye | [ ] Yes | [ ] No |
| flyers | [ ] Yes | [ ] No |
| guidelines | [ ] Yes | [ ] No |
| Others | [ ] Yes | [ ] No |

**5.29.2.1 In case of 'Others', please specify:**

_____

_____

_____

_____

_____

**5.29.3 If you offer such advice: is there an interest from the clinical trials organizers in it?**

- o **Yes**
- o **No**

**5.30 Does your institution have any procedure of control (audit) over the collection of consent and corresponding data?**

- o **Yes**
- o **No**

**5.31 Is there a procedure for data subjects to submit a complaint?**

- o **Yes**
- o **No**

**5.31.1 If yes, are clinical trials included in such a procedure?**

- o **Yes**
- o **No**

**5.31.2 If yes, how is such a complaint handled?**

_____

_____

_____

_____

_____

## 6. Handling *[questions to all]*

**6.1 Should the consent process be paper based?**

- o **Yes**
- o **No**

**6.2 Should the consent form be signed electronically?**

- o **Yes**
- o **No**

**6.2.1 If yes, how many patients will be able to give consent electronically?**

None  all

0 +5

**6.3 Should there always be an alternative between paper based and electronic consent**

- o **Yes**
- o **No**

**6.4 How should a patient be able to withdraw consent?**

- o Electronically, via Web [ ]
- o Only by telling the treating physician [ ]
- o By writing to the treating physician [ ]
- o Other way [ ]

***[The next questions are only for chairpersons of trials and coordinators of projects]***

**6.5 Do you use paper based consent forms or electronic means?** paper based only [ ]

- o Paper based, but they are later stored electronically [ ]
- o Electronic means only [ ]

**6.6 Should an electronic consent form be based on modules, so that a specific template can be build?**

- o **Yes**
- o **No**

**6.6.1 If yes, what kind of consent modules would be needed:**

- o for care
- o for trial
- o for research
- o for biobanking
- o for data storage
- o for data transfer
- o for other

**6.6.1.1 In case of 'other', please specify other:**

_____

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