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BORN IN BRIXEN / BRESSANONE (ITALY) ON FEBRUARY 23RD, 1964

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EDUCATION

Degree in Pharmacy, 1994

UNIVERSITA' DEGLI STUDI DI BOLOGNA, BOLOGNA (ITALY)

PROFESSIONAL EXPERIENCE

1989 – 1994: teacher for Italian at German professional school in Brixen / Bressanone (Italy)

1995: chemist at “Aquila Nera” pharmacy in Bozen / Bolzano (Italy)

1996 - ongoing: co-operation with several Sponsors and Contract Research Organisations. Main experience:

- Quintiles (now IQVIA) from 2005 to 2016 and in 2020
- Factory-CRO (now Avania) from 2005 to 2017
- PPD from 2005 to 2006
- Pharmtrace from 2012 to 2017
- Clementia Pharma (now Ipsen) from 2013 to 2019
- CartiHeal from 2013 to 2022
- Cardialysis from 2014 to 2018
- Parexel, occasional co-operations
- Syneos Health, occasional co-operations
- ABX-CRO from 2015 to 2021
- Worldwide Clinical Trials from 2020 to 2021

Clinical Trials-related activity:

- submission to Competent Authorities (until 2012 this activity was personally done; starting from 2013 this activity has been delegated to regulatory experts I co-work with)

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- submission to Ethic Committees (until 2012 this activity was personally done; starting from 2013 this activity has been delegated to regulatory experts I co-work with)
- contract negotiation
- site selection visits
- initiation visits
- monitoring visits
- trials followed as blinded CRA
- trials followed as un-blinded CRA
- close-out visits
- remote monitoring
- for-cause visits for non-enrolling sites
- Key Performance Indicators' (KPI) analysis: operational timelines, participants' recruitment, CRA performance (adherence to timelines set-up by the Monitoring Plan, quality of the reports, correspondence to the investigational sites), data quality/compliance, overall and specific financial co-monitoring and CRA evaluation

THERAPEUTIC EXPERIENCE

THERAPEUTIC AREA	PATHOLOGY	AMOUNT OF TRIALS	PHASE(S) (amount of trials)
<i>Circulatory / Cardio-vascular (15)</i>	Aortic Valve Replacement and Degenerative Mitral Regurgitation	2	III (1), Post-marketing (1)
	Atrial Fibrillation	1	II
	Coronary Artery Disease	1	III
	Heart failure	1	III
	Hypertension	7	III (1), IV (6)
	Stroke and TIA (treatment and prevention)	1	IV
	Venous Thromboembolism	2	III
	Percutaneous Coronary Implant	1	III
<i>Dermatologic (3)</i>	1 st and 2 nd degree burns	1	III
	Pemphigus vulgaris	1	I
	Anti-fungal therapy	1	IV
<i>Emergency Medicine (5)</i>	Blunt and Overt Traumas	1	III
	Intracranial Haemorrhage	1	IV
	Surgery Bleeding	1	IV
	Urgency Anti-coagulation Therapy during Ambulance or Helicopter transportation	2	III
<i>Endocrine and Metabolic (6; + 1 Paediatric)</i>	Diabetes Mellitus	2	III (1), IV (1)
	Dyslipidaemia	1	IV
	Growth Factor Hormone (Paediatric)	1	Observational
	Obesity	2	IV
	Paediatric Diabetes	1	IV
<i>Gastroenterology (4; + 1 Paediatric)</i>	Crohn Disease	1	III
	Crohn Disease (Paediatric)	1	Post-marketing
	Gastro-oesophageal reflux	1	IV
	<i>Helicobacter pylori</i> eradication	1	III
	Primary biliary cholangitis	1	II
<i>Genito-urinary (10)</i>	Assisted Procreation	1	III
	Female Contraception	2	III
	Male Contraception	1	III
	Prostatic Benign Hypertrophy (PBH)	2	III
	Prostate Tumor Prevention	2	III
	Vaginal Atrophy	1	III

	Vaginal Dryness	1	III
<i>Immunology (6; 3 paediatric too)</i>	<i>Lupus Eritematosus</i>	1	II
	Peanuts Allergy	3 (Adults and Paediatric)	III
	Pollen Allergy	2	III
<i>Infectious Diseases (12)</i>	Hepatitis C	5	III (3), IV (2)
	HIV	4	II (1), III (4), IV (4), observational (1)
	COVID-19	2	II (1), III (1)
	Opioid-replacement treatment	1	IV
<i>Medical Devices (22 in total: 2 aesthetic surgery, 10 orthopedics, 1 dental, 3 genitourinary, 2 gastroenterology - 1; + 1 paediatric-, 4 cardio-vascular)</i>	Benign Prostatic Hyperthrophy	2	Post-marketing/Observational
	Breast Aesthetic Surgery	1	Post-marketing/Observational
	Dental Trabecolar Implant	1	Post-marketing/Observational
	Face Aesthetic Surgery	1	Interventional
	Hip Orthopedics	3	Post-marketing/Observational
	Knee Orthopedics	5	Interventional (2), post-marketing/observational (3)
	Heart failure	1	Interventional
	Lumbar Orthopedics	1	Post-marketing/Observational
	Male erectile dysfunction	1	Post-marketing/Observational
	Percutaneous Coronary Implant	2	Interventional
	Toe Orthopedics	1	Post-marketing/Observational
	Right ventricular outflow tract	1	Post-marketing/Observational
	Ulcerative Colitis	1	Interventional
	Ulcerative Colitis (Paediatric)	1	Interventional
<i>Musculoskeletal (1)</i>	Post-intervention Orthopedic Pain	1	IV
<i>Nefrology (6)</i>	Post-transplantation Renal Therapy	1	IV
	Pre-dialysis and Dialysis Therapy	2	III
	Renal Hypertension	1	III
	Renal Insufficiency	2	III
<i>Neurology (6)</i>	Epilepsy (Paediatric)	1	IV
	Multiple Sclerosis	2	III (1), IV (1)
	Alzheimer Disease	1	III
	Parkinson Disease	1	III
	Post-chemotherapy Neuropathy	1	III
<i>Onco-Haematology (14)</i>	Lymphomas	7	II (3), III (3), II/III (1)
	Leukemia	1	I/II (1)
	Multiple Myeloma	3	I/II (1), III (2)
	CD123-positive Malignancies (Acute Myeloid Leukemia and others)	1	I/II
	Several kinds of onco-hematologic diseases	2	I (1), III (1)
<i>Oncology (31)</i>	Breast	5	II (1), III (4)
	Colon	5	I (1), II (2), III (2)
	Head and neck	1	II/III

	Liver	2	II
	Lung	5	II (1), III (4)
	Microsphere Oncologic Therapy (Liver)	1	II
	Neuroendocrin Tumors of Gastroenteric and Pancreatic Origin (GEP-NET)	1	III
	Ovary	4	II (1), III (3)
	Pancreas	1	II
	Prostate	3	III (2), IV (1)
	Several kinds of tumor	1	I/II
	Locally advanced or metastatic solid tumors	1	I/II
	Rectum	1	II
<i>Ophthalmology (3)</i>	Glaucoma	2	III (1), post-marketing (1)
	Retinitis Pigmentosa	1	II/III
<i>Psychiatry/Psychology (5)</i>	Bipolar Disorder	1	III
	Major Depression	1	III
	Obsessive-compulsive Disorder	3	III
<i>Rare Diseases (5, 2 both adults and paediatric)</i>	Progressive Ossificans Fibrodysplasia (Adults and Paediatric)	1	Observational
	Paroxysmal Nocturnal Hemoglobinuria (PNH)	3	II
	C3 Glomerulopathy (C3G) or Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) (Adults and Paediatric)	1	II
<i>Respiratory (5)</i>	Asthma	2	II, IV
	Chronic Obstructive Pulmonar Disease (COPD)	1	III
	Idiopathic Pulmonary Fibrosis (IPF)	1	III
	Pneumonia	1	III
<i>Rheumatology (9)</i>	Arthrosis	3	III
	Psoriatic Arthritis	2	IV
	Rheumatoid Arthritis	3	III (2), IV (1)
	Rheumatoid arthritis + ankylosing spondylitis + psoriatic arthritis on psoriasis	1	Observational
<i>Other Pathologies (1)</i>	Hyperidrosis	1	IV

CLINICAL TRIALS (PHASES I, II, IIIA, IIIB, IV, DEVICES, POST-MARKETING, INTERVENTIONAL, NON-INTERVENTIONAL)

Only the most recent and important trials have been listed (*study drugs and study devices have been omitted because of secrecy reasons*):

1) ONCOLOGY TRIALS:

- A randomised, open clinical study with adjuvant therapy in post-menopausal women affected by breast cancer: **study drug** or **study drug** followed by **study drug**. **Interventional, phase III**
- A phase III study comparing **study drugs** versus **study drugs** in advanced breast cancer patients. **Interventional, phase III**
- An open label phase II study of **study drug** in combination with pre-operative standard radiotherapy in Rectal Cancer patients. **Interventional, phase II**

- Multi-centre phase III open label randomised trial comparing **study drug** in combination with a **study drug** infusional regimen to the same **study drug** infusional regimen alone as adjuvant treatment of stage II and III colon cancer. **Interventional, phase III**
- A randomised, double-blind, placebo-controlled, parallel group study of the efficacy and safety of **study drug** administered orally once daily for four years to reduce the risk of biopsy-detectable Prostate Cancer. **Interventional, phase III**
- Multi-centre phase III open label randomised trial comparing **study drug #1** in combination with a **study drug #2** infusional regimen to the same **study drug #2** infusional regimen alone as adjuvant treatment after resection of liver metastases for colorectal cancer. **Interventional, phase III**
- Multicentre phase III open label randomised trial comparing **study drug #1** in combination with a **study drug #2** infusional regimen to the same **study drug #2** infusional regimen alone as adjuvant treatment of stage II and III colon cancer. **Interventional, phase III**
- A single-arm phase II clinical study for the combination of **study drug #1** and weekly **study drug #2** plus **study drug #3** as first-line treatment in patients with epithelial ovarian cancer. **Interventional, phase II**
- Open label, phase II study of Whole Brain Radiotherapy (WBRT) and **study drug** for the treatment of brain metastases from HER-2 positive breast cancer. **Interventional, phase II**
- A multi-center, open-label clinical trial to evaluate the objective response rate of **study drug 1** in combination with modified **study drug #2** followed by one year of maintenance with **study drug #1** alone in patients with initially not or borderline resectable colorectal liver metastases. **Interventional, phase II**
- The **study device** use in Reconstruction Post-Market Study for Tissue Support and Repair in Direct-to-Implant Breast Reconstruction Surgery. **Interventional, device**
- Phase II randomized Study on **study drug #1** or intermittent administration of **study drug #1** and **study drug #2** in former smoking men affected by squamous non-small cells lung cancer (NSCLC) locally progressed or metastatic as second-line therapy after chemotherapy failure. **Interventional, phase II**
- Global study to assess the addition of **study drug #1** to **study drug #2** and **study drug #3** as front-line treatment of epithelial ovarian cancer, fallopian tube carcinoma or primary peritoneal carcinoma. **Interventional, phase IIIb**
- A randomized multicentre, double-blind, placebo-controlled comparison of chemotherapy plus **study drug #2** plus placebo versus chemotherapy plus **study drug #2** plus **study drug #1** as adjuvant therapy in patients with operable HER2-positive primary breast cancer. **Interventional, phase III**
- Evaluation of **study drug** in combination with local micro-therapy guided by **study device** enhanced MRI in patients with inoperable hepatocellular carcinoma. **Interventional, phase II**
- A two-cohort, open-label, multicenter, study of **study drug** in HER2 positive locally advanced or metastatic breast cancer patients who have received prior anti-HER2 and chemotherapy-based treatment. **Interventional, phase IIIb**
- A Phase 3, Randomized, Open Label Trial of **study drug 1** With or Without **study drug 2** in Subjects with Previously Untreated Multiple Myeloma. **Interventional, phase III**
- Phase I/II study to evaluate **study drug #1** in substitution of **study drug #2** or **study drug #3** in **infusion regimen** schedule as first line treatment in metastatic pancreatic cancer. **Interventional, phase I/II**
- An open-label, randomized phase III study of early switch maintenance vs. delayed second-line **study drug** in advanced stage squamous non-small cell lung cancer (NSCLC) patients after standard first-line platinum-based chemotherapy EDEN trial. **Interventional, phase III**
- A phase1/2 study of **study drug** monotherapy and in combination with other therapy in patients with advanced tumors. **Interventional, phase I/II**
- A phase III, prospective, double blind, placebo controlled, randomized study of adjuvant **study drug** in completely resected non-small cell lung cancer. **Interventional, phase III**
- A randomized open-label phase II study on the effect of **study drug #1** and **study drug #2** combined with personalized SIRT (P-SIRT), standard-dose SIRT (SD-SIRT) or immunotherapy followed by on-demand loco-regional SIRT (OD-SIRT) in non-resectable hepatocellular carcinoma (HCC) patients. **Interventional, phase II**
- A Phase 3 Study of **study drug #1** in Combination with **study drug #2** versus **study drug #2** Monotherapy in Advanced, Platinum-Resistant, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian-Tube Cancer. **Interventional, phase III**
- A Multicenter, Randomized, Double-blind, Phase 2/3 Study of **study drug 1** or Placebo in Combination with **study drug 2** for First Line Treatment of PD-L1-positive, Previously

Untreated Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma.

Interventional, phase II/III

- A Phase 1/2, Multicenter, Open-label, Dose Escalation and Dose Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of **study drug** in Adult Participants with Locally Advanced or Metastatic Solid Tumors. **Interventional, phase I/II**

2) ONCOHEMATOLOGY TRIALS:

- **Study drug** maintenance treatment versus no further therapy after a brief induction therapy with FDN + **study drug** in elderly patients with advanced stage previously untreated follicular lymphoma. **Interventional, phase II**
- Chemotherapy + **study drug** followed by **study drug** maintenance treatment in patients with advanced untreated Indolent B-cell non follicular lymphomas: phase II study. **Interventional, phase II**
- A phase IIIb study of **study drug** maintenance therapy in patients with follicular Non-Hodgkin's Lymphoma who have responded to induction therapy. **Interventional, phase IIIb**
- A double-blind, randomized, two-dose-arm, parallel group, international, multi-center trial of **study drug**, (**study drug characteristics**), in patients with Follicular Lymphoma who are refractory to **lymphoma traditional therapy** in combination with chemotherapy. **Interventional, phase III**
- A study of **study drug #1** plus **study drug #2** as induction therapy followed in responders by maintenance therapy versus observation on response rate in patients ≥ 60 years with previously untreated chronic lymphocytic leukemia. **Interventional, phase II**
- A randomized study comparing maintenance therapy with subcutaneous **study drug** continued until progression with observation only in patients with relapsed or refractory, indolent non-Hodgkin's lymphoma who completed and responded to **study drug**-based immunochemotherapy induction and initial 2-year **study drug** maintenance therapy administered subcutaneously. **Interventional, phase III**
- A Phase III, Randomized, Double-Blinded, Placebo-Controlled, Multi-Centre Study Evaluating the Safety, Tolerability and Efficacy of Combination Treatment of **study drug #1** and **study drug #2** as compared to Placebo and **study drug #2** for the Mobilization of Hematopoietic Stem Cells for Autologous Transplantation in Subjects with Multiple Myeloma. **Interventional, phase III**
- A Phase I/II open-label study to evaluate the safety and efficacy of **study drug** in patients with relapsed or refractory CD1d-positive chronic lymphocytic leukemia (CLL), multiple myeloma (MM) or acute myeloid leukemia (AML). **Interventional, phase I/II**
- A Phase III, Randomized, Double-Blinded, Placebo-Controlled, Multi-Centre Study Evaluating the Safety, Tolerability and Efficacy of Combination Treatment of **study drug #1** and **study drug #2** as compared to Placebo and **study drug #2** for the Mobilization of Hematopoietic Stem Cells for Autologous Transplantation in Subjects with Multiple Myeloma. **Interventional, phase III**
- A phase II/III, multicenter randomized study of **study drug #1 (X-XXX)** with or without **study drug #2** in patients with relapsed/refractory diffuse large B-cell lymphoma (RR DLBCL). **Interventional, phase II/III**
- A Phase 1/2, Multicenter, Open-label Study of **study drug** Monotherapy Administered Intravenously in Patients with CD123-positive Acute Myeloid Leukemia and Other CD-23-positive Hematologic Malignancies. **Interventional, phase I/II**
- A Phase 1, Dose Escalation, and Cohort Expansion Study Evaluating **study drug**, a Bruton's Tyrosine Kinase (BTK) Degradar, in Adults with Relapsed/Refractory B-cell Malignancies. **Interventional, phase I**
- A Phase 3, Open-Label, Randomized, Multicenter Study to Evaluate Antitumor Efficacy of **study drug** versus Investigator's Choice in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. **Interventional, phase III**

3) ONCOLOGY/RADIOLOGY/NUCLEAR MEDICINE TRIALS:

- A dose escalation study to evaluate safety, tolerability, pharmacokinetics, dosimetry, maximum tolerated dose and preliminary efficacy of intra-lesionally injected **study drug #1**, followed by systemic IV administration of escalating doses of **study drug #2** in patients with liver metastases from colorectal cancer. **Interventional, phase I**

- Prospective, randomized, Controlled, Open-label, Multicenter phase III study to evaluate efficacy and safety of **study drug #1** compared to targeted molecular therapy with **study drug #2** in patients with inoperable, progressive, somatostatin receptor-positive (SSTR⁺), neuroendocrine tumors of gastroenteric or pancreatic origin (GEP- NET). **Interventional, phase III**
- Prospective, Multi-Center Study to Assess the Diagnostic Performance of **study drug** in Patients with Newly-Diagnosed High-Risk or Very-High-Risk Prostate Cancer. **Interventional, phase III**

4) ONCOLOGY/GENITOURINARY TRIALS:

- Effectiveness of **study drug** treatment for the prevention of bone metastasis in high risk prostate cancer patients. A randomized, open-label, multicenter study of the **Sponsor name** in cooperation with the **Co-Sponsor #1 name** and the **Co-Sponsor #2 name**. **Interventional, phase IV**

5) CARDIOVASCULAR TRIALS:

- Efficacy and safety of **study drug**: reduction of blood pressure in the treatment of patients suffering from mild to moderate essential hypertension". **Non-interventional**
- **Study device** Verification Study. **Interventional, device**
- Global Registry on Long-Term Oral Anti-thrombotic Treatment in patients with Atrial Fibrillation. **Non-interventional**
- Comparative effectiveness of 1 month of **study drug #1** plus **study drug #2** followed by **study drug #1** monotherapy versus a current-day intensive dual antiplatelet therapy in all-comers patients undergoing percutaneous coronary intervention with **study drug #3** and **study device** family drug-eluting stent use. **Interventional, phase III**
- High and Intermediate Risk Degenerative Mitral Regurgitation Treatment: a Randomized Controlled Trial Comparing **study device** to Surgical Therapy. **Interventional, device**
- Global multicenter, open-label, randomized, event-driven, active-controlled study comparing a **study drug**-based antithrombotic strategy to an antiplatelet-based strategy after transcatheter aortic valve replacement (TAVR) to Optimize clinical outcomes. **Interventional, phase III**
- A prospective multicenter post market trial to assess the safety and effectiveness of the **study device** target eluting cobalt chromium coronary stent system (**study device** stent system) for the treatment of atherosclerotic lesion(s). **Interventional, device**
- **Study device** Vessel Preparation for Calcified Coronary Lesions using Orbital Atherectomy for Facilitating Bioresorbable Vascular Scaffold Implantation. **Interventional, device**
- A randomized clinical study utilising high-definition **study device #1** and **study device #2** Heart Team decision-making on the most optimal revascularization modality in patients with complex coronary artery disease. **Interventional, device**
- Evaluation of the Safety and Efficacy of and **study drug #1**-based compared to a **study drug #2**-based Antithrombotic Regimen in Subjects with Atrial Fibrillation following successful Percutaneous Coronary Intervention with Stent Placement (**study drug #1** Treatment versus **study drug #2** in Patients with AF undergoing PCI. **Interventional, phase III**
- The Clinical Evaluation of the **study device** in De Novo Native Coronary Artery Lesions. **Interventional, device**
- Prospective, randomized, 1:1 balanced, controlled, single-blind, multi-center study comparing clinical outcomes at 12 months between **study device #1** and **study device #2** in a "Real world, all comers" patient population (patients with symptomatic coronary artery disease including patients with chronic stable angina, silent ischemia, and acute coronary syndromes, who qualify for percutaneous coronary interventions). **Interventional, device**
- A randomized controlled trial to compare the safety and efficacy of **study device #1** and **study device #2** in treatment for three-vessel coronary artery disease. **Post-marketing randomized controlled device trial**
- A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of **study drug 1** relative to **study drug 2a** on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE. **Interventional, phase III**

- A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of **study drug 1** relative to **study drug 2b** on venous thromboembolism (VTE) recurrence and bleeding in patients with GI/GU cancer associated VTE. **Interventional, phase III**
- Randomized Clinical Evaluation of the **study device** Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF). **Interventional, device trial**

6) CARDIOVASCULAR/RADIOLOGY/NUCLEAR MEDICINE TRIALS:

- A randomized study to evaluate the feasibility of Heart-Team clinical decision making regarding the optimal (surgical or percutaneous based) revascularization strategy in patients with complex coronary artery disease, based on non-invasive coronary CT Angiography (CTA) imaging utilising high-definition **study procedure** compared to the current standard of care with conventional invasive coronary angiography (CA). **Interventional, phase III**
- **Study imaging procedure** for Risk Evaluation – A Multicentre trial to guide ICD implantation in NYHA class II & III heart failure patients with $25\% \leq \text{LVEF} \leq 35\%$. **Interventional, phase IIIb**

7) CARDIOVASCULAR/MUSCULOSKELETAL TRIALS:

- Evaluation of efficacy and safety of **study drug #1** vs. **study drug #2** in the treatment of pain and inflammation in Osteoarthritis (OA) patients with hypertension pharmacologically stabilized. **Interventional, phase III**

8) GASTROENTEROLOGY TRIALS:

- Randomized controlled multicenter investigation to compare the efficacy and safety of **study device** action mechanism, 5 versus 10 treatments, in patients with active ulcerative colitis. **Interventional, device**
- A randomized acceptability and safety study of **study drug** induction in heroin users. **Interventional, phase IV**
- Efficacy and safety of quadruple therapy by **study drug #1**, **study drug #2** and **study drug #3** given x 10 days with **study drug #4** in eradication of *helicobacter pylori*: a comparison to **study drug #4**, **study drug #5** and **study drug #6** given x 7 days. **Interventional, phase III**
- Open uncontrolled investigation to assess the efficacy and safety of **study device** granulocytes, monocytes/macrophage apheresis device in children and adolescents with active ulcerative colitis. **Interventional, device**
- **PEDIATRIC TRIAL**: A Multicenter, Prospective, Long-term Registry of Pediatric Patients with Crohn's Disease. **Non-interventional**
- Double-blind, randomized, placebo-controlled phase II dose-finding study comparing different doses of **study drug** tablets with placebo in the treatment of primary biliary cholangitis in patients with an inadequate response to ursodeoxycholic acid. **Interventional, phase II**
- **AS UN-BLINDED CRA**: A Phase 2b Randomized, Double-blind, Active and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with **study drug #1** and **study drug #2** in Participants with Moderately to Severely Active Ulcerative Colitis. **Interventional, IIb**
- **AS UN-BLINDED CRA**: A Phase 2b Randomized, Double-blind, Active-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of 48-weeks Combination Therapy with **study drug #1** and **study drug #2** in Participants with Moderately to Severely Active Crohn's Disease. **Interventional, IIb**

9) INFECTIOUS DISEASES' TRIALS:

- Randomised, controlled, phase IIIb/IV study with evaluation of supplemental treatment with **study drug** in multi-treated patients that are orally assuming a highly effective anti-retroviral therapy (HAART). **Interventional, phase IIIb/IV**
- A phase III, non-comparative, single arm, open label, multi-centre study comparing the antiviral efficacy and the tolerability of the scheme induction – maintenance (fourfold → threefold therapy) in anti-retroviral therapy naïve patients affected by HIV-1. A 72 weeks study with the therapeutic schema: induction with **study drug + study drug**, maintenance

- with **study drug** only by confirmed viral concentration's suppression. **Interventional, phase III**
- Expanded access to **study drug** in by HIV affected non-responding or intolerant to previous anti-retroviral therapies subjects. **Non-interventional**
- Observational, pharmacologic non-interventistic study about the induction and maintenance strategies: costs' analysis, quality of life related to general health conditions and to treatment's compliance. **Non-interventional**
- A randomized, open-label, multicenter, efficacy and safety study comparing **study drug #1** plus **study drug #2** to **study drug #1** plus **study drug #3** for the treatment of naive Patients with Chronic Hepatitis C. **Interventional, phase III**
- A phase II, randomized, double-blind, multicenter, immunogenicity, study of **study drug** versus placebo in patients infected with HIV-1 who have maintained an adequate response to ART. **Interventional, phase II**
- A phase III, randomized, partially double-blind and placebo controlled Study of **study drug #1** in combination with **study drug #2** and **study drug #3** in treatment-naïve patients with chronic genotype 1 HCV infection. **Interventional, phase III**
- A randomised, double-blind and placebo-controlled study to evaluate pharmacokinetics, safety and efficacy of **study drug #1** in combination with **study drug #2** and **study drug #3** in patients with hepatic impairment with genotype 1 chronic hepatitis C infection. **Interventional, phase III**
- A phase III, randomized, partially double-blind and placebo controlled Study of **study drug #1** in combination with **study drug #2** and **study drug #3** for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those ineligible to receive **standard treatment**. **Interventional, phase III**
- A phase III, randomised, open label, parallel group, active-controlled Study of an interferon-free regimen of **study drug #1** in combination with **study drug #2** and **study drug #3** compared to **study drug #4** in combination with **study drug #5** and **study drug #3** in treatment-naïve patients with chronic genotype 1b HCV infection. **Interventional, phase III**
- A Multicenter, Open Label, Pilot Study to Investigate Tolerability and Efficacy of **study drug #1** / **study drug #2** Without Ribavirin for 12 Weeks in Patients With Chronic HCV G1b Infection With Compensated Cirrhosis (Child-Pugh A5 to A6) and No Response to PR or Prior Failure to First Generation Protease Inhibitors (PIs). **Interventional, phase IIIb**
- A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel-Group Phase II Study to Evaluate the Efficacy and Safety of Intramuscular Injections of **study drug** for the Treatment of severe COVID-19
- A Phase III randomized, double-blind, placebo-controlled multicenter study in adults to determine the safety, efficacy and immunogenicity of **study drug**, a non-replicating ChAdOx1 vector vaccine, for the prevention of COVID-19. **Interventional, phase III**

10) NEUROLOGY TRIALS:

- A multi-centre, randomised, double-blind, controlled versus placebo study comparing the efficacy and tolerability of **study drug** in preventing or reducing the polyneuropathy induced by treatment with **study drug** alone or associated with other neurotoxic or no treatments. **Interventional, phase III**
- Single country study assessing cognition in Relapsing Remitting Multiple Sclerosis patients treated with **study drug**. **Interventional, phase IIIb**
- Multicenter, open-label, 12 weeks, phase IV prospective randomized study aimed at evaluating whether subcutaneous **study drug** administered in the morning may affect the severity of flu-like syndrome and patient-perceived invisible symptoms in subjects with relapsing multiple sclerosis. **Interventional, phase IV**
- AS UN-BLINDED CRA:** A Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study With an Open-Label Extension Phase to Confirm Safety and Efficacy of **study drug** in Subjects With Early Alzheimer's Disease. **Interventional, phase III**

11) (NEURO)ENDOCRINE:

- A randomised, double-blind study to compare the durability of glucose lowering and preservation of pancreatic beta-cell function of **study drug** monotherapy compared to **study drugs** in patients with drug-naïve, recently diagnosed type 2 Diabetes Mellitus. **Interventional, phase III**

12) GENITOURINARY TRIALS:

- A multi-centre, national, randomised, parallel groups, controlled study in order to identify a diagnostic – therapeutic strategy in outpatients affected by high PSA value. **Interventional, phase III**
- An open-label, multi-centre trial to evaluate the vaginal bleeding pattern of the combined contraceptive **study drug**. **Interventional, phase III**
- A randomised, double-blind, placebo-controlled, parallel group study investigating the effect of either 4 or 6 weeks **study drug** daily on peri-operative bleeding following transurethral resection of the prostate (TURP) in subjects with Benign Prostatic Hyperplasia (BPH). **Interventional, phase III**
- An open label, randomised study using **study drug** to improve achievement of K/DOQI targets in patients with ESRD". **Interventional, phase III**
- A prospective, randomised, investigator-blind, controlled, clinical study of phase III on the clinical efficacy and tolerability of **study drug** versus **study drug** administered subcutaneously in women undergoing controlled ovarian hyperstimulation (COH) in an ART programme (IVF). **Interventional, phase III**
- Sperm suppression and contraceptive protection provided by **study drug #1** combined with **study drug #2** in healthy men. **Interventional, phase IIb**
- A Prospective Multicenter Randomized Study Comparing Photoselective Vaporization of the Prostate with the **study device** and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Hyperplasia. **Interventional, device**
- Efficacy, tolerability and safety of a new medical device, **study device**, in the treatment of vaginal dryness in adult childbearing potential women. **Interventional, device**
- Efficacy, tolerability and safety of a new medical device, **study device**, in the treatment of vaginal dryness in post-menopausal women with vaginal atrophy. **Interventional, device**
- Post-market registry evaluating the safety and effectiveness of the **study device** in a real-world setting. **Interventional, device**
- Prospective registry for patients undergoing penile prosthesis implantation for male erectile dysfunction; observational trial. **Observational, device**

13) IMMUNOLOGIC/ALLERGIC REACTIONS' TRIALS:

- Observational, non-interventional one arm, global surveillance study of clinical outcomes in renal allograft recipients switched at least 6 months after renal transplantation to long-term immunosuppressive therapy with **study drug**. **Non-interventional**
- A double-blind, randomized, placebo controlled, multi-center trial of **study drug #1** and **study drug #2** in patients suffering from systemic lupus erythematosus (SLE) with WHO class V glomerulonephritis. **Interventional, phase IIb**
- **PEDIATRIC/ADULTS TRIAL:** Peanut allergy oral immunotherapy Study of **study drug** for desensitization in children and adults follow-on Study. **Interventional, phase III**
- A multicenter, open-label, long-term safety Study of **study drug** characterized oral desensitization immunotherapy in subjects who participated in a prior **study drug** Study. **Interventional, phase III**
- **PEDIATRIC TRIAL:** **Study drug** Trial in Europe measuring oral immunotherapy success in peanut allergic children. **Interventional, phase III**
- **AS BLINDED CRA:** A double-blind, randomized, placebo controlled, multi-center trial of **study drug #1** and **study drug #2** in patients suffering from systemic lupus erythematosus (SLE) with WHO class V glomerulonephritis. **Interventional, phase II**

14) RESPIRATORY TRIALS:

- **AS UN-BLINDED CRA:** A Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of **study drug** in Subjects with Idiopathic Pulmonary Fibrosis (IPF). **Interventional, phase III**
- A Phase 2, Randomized, Double-blind, Placebo-controlled, Multi center, Dose-ranging Study to Evaluate the Efficacy and Safety of **study drug** in Adult Participants with Severe Asthma. **Interventional, phase II**

15) DERMATOLOGY TRIALS:

- Double-blind, placebo controlled study on the efficacy and tolerability of **study drug** to speed up the healing of I and II grade superficial burns. **Interventional, phase III**
- An open-label, multi-centre, study of cross-linked **study device** in the treatment of Dermal Contour Deformities. **Interventional, device**
- A multi-centre, open-label, phase 1 study, Part A single ascending dose and Part B multiple dose, to evaluate the safety, tolerability and pharmacokinetics, and to explore early signs of effectiveness of induction of antigen-specific immune tolerance with **study drug** in pemphigus vulgaris patients. **Interventional, phase I**

16) MENTAL DISORDERS' TRIALS:

- Multi-centre, randomised, open study comparing the effects of **study drug** added to the mood stabilizer vs. the mood stabilizer alone. **Interventional, phase III**

17) EMERGENCY MEDICINE TRIALS:

- **AS BLINDED CRA:** A multi-center, randomized, double-blind, parallel group, placebo controlled trial to evaluate the efficacy and safety of **study drug** in severely injured trauma patients with bleeding refractory to standard treatment. **Interventional, phase III**
- A Phase 4 Randomized Clinical Trial of **study drug** [**study drug** for Injection] in Acute Intracranial Hemorrhage in Patients Receiving an Oral Factor Xa Inhibitor. **Interventional, phase IV**

18) MUSCOLOSKELETAL/ORTHOPEDIC TRIALS:

- Evaluation of the **study device** disc arthroplasty system. **Interventional, device**
- A perspective post-market surveillance of the **study device** in patients requiring reconstruction of lateral meniscus defect of the knee. **Interventional, device**
- Musculoskeletal: Observational study in order to evaluate the costs of the treatment of psoriatic arthritis refractory to traditional treatments. **Non-interventional**
- **Study device** cartilage system for filling a single full-thickness cartilage defect of the medial femoral condyle of the knee. **Interventional, device**
- Retrospective observational study with no title. **Non-interventional**
- Prospective observational study with no title. **Non-interventional**
- Open label, multicentric phase IIIb study to evaluate the effect of **study drug** in combination with **category of drugs** in the inhibition of progression of synovitis, bone marrow edema, and erosions evaluated by dedicated magnetic resonance imaging (MRI) in the hand of patients with rheumatoid arthritis (RA). **Interventional, phase IIIb**
- A single arm, open-label study of early improvement of anemia and fatigue during treatment with **study drug** in combination with non biologic **category of drugs**, in adult patients with moderate to severe active rheumatoid arthritis. **Interventional, phase IIIb**
- **Study device** Ceramic Bearing System in Total Hip Arthroplasty. **Interventional, device**
- Evaluation of the speed of action of **study drug #1** in comparison to **study drug #2** in the acute pain relief after mini invasive orthopaedic arthroscopic knee surgery in adults. **Interventional, phase IV**
- A Multicenter, Double-Blind, Randomized, Placebo-Controlled Pilot Study of a Single, Intra-Articular Injection of **study device** in Patients with Osteoarthritis of the Knee. **Interventional, device**
- **Study device** Implant Performance Evaluation in the Repair of Cartilage and OCD. **Interventional, device**
- **Study device** Implant Performance Evaluation in the Treatment of Osteoarthritis of the Great Toe. **Interventional, device**
- A Prospective Multicenter Open-label Randomized Controlled Trial of **study device** vs. Surgical Standard of Care (SSOC) for the Treatment of Joint Surface Lesions of the Knee. **Interventional, device**
- An observational prospective cohort study to evaluate safety of **study drug** subcutaneous in patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis on psoriasis. **Observational**

19) NEPHROLOGY TRIALS:

- An open label, randomised study using **study drug** to improve achievement of K/DOQI targets in patients with ESRD. **Interventional, phase III**
- A Randomized, Double-blind, placebo-controlled study to assess the efficacy and safety of **study drug** in chronic kidney disease subjects with secondary hyperparathyroidism not receiving dialysis. **Interventional, phase III**
- A randomised, double-blind, placebo-controlled study to assess the efficacy and safety of **study drug** in chronic kidney disease subjects with secondary hyperparathyroidism not receiving dialysis. **Interventional, phase III**
- A single arm, open label study to assess the efficacy, safety and tolerability of once-monthly administration of intravenous **study drug** for the maintenance of haemoglobin levels in haemodialysis patients with chronic renal anaemia. **Interventional, phase IIIb**
- A single arm, open label study to assess the efficacy, safety and tolerability of once-monthly administration of subcutaneous **study drug** for the maintenance of haemoglobin levels in pre-dialysis patients with chronic renal anaemia. **Interventional, phase IIIb**

20) METABOLIC TRIALS:

- An European randomized, parallel group, two-arm placebo-controlled, double-blind multicenter study of **study drug** once daily in the treatment of abdominally obese patients with dyslipidemia with or without other comorbidities. **Interventional, phase IIIb/IV**
- A pan-european randomized, parallel group, two-arm placebo-controlled, double-blind multicenter study of **study drug** once daily in the treatment of abdominally obese patients with impaired fasting blood glucose with or without other comorbidities. **Interventional, phase IIIb/IV**

21) RARE DISEASES' TRIALS:

- **PEDIATRIC/ADULTS TRIAL:** A Natural History, Non-Interventional, Two-Part Study in Subjects with Fibrodysplasia Ossificans Progressiva (FOP). **Non-interventional**
- A Phase 2 Open-label Study of **study drug** in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Who Have an Inadequate Response to Eculizumab Monotherapy. **Interventional, phase II**
- An Open-Label Study to Evaluate Efficacy and Safety of Long-term Treatment with **study drug** in Patients with PNH who Completed Clinical Study **trial name**. **Interventional, phase II**
- **PEDIATRIC/ADULTS TRIAL:** An Open-Label Phase 2 Proof-of-Concept Study in Patients with C3 Glomerulopathy (C3G) or Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) Treated with **study drug**. **Interventional, phase II**
- A Phase 2 Open-Label Proof of Concept Study to Assess the Efficacy, Safety, and Pharmacokinetics of the Oral Factor D (FD) Inhibitor **study drug** in Paroxysmal Nocturnal Hemoglobinuria (PNH) Patients as Monotherapy and with an Approved C5 Inhibitor as Background Therapy. **Interventional, phase II**

22) DENTISTRY TRIALS:

- A Multi-center, Prospective, Non-Randomized Postmarket Longitudinal Data Collection Program for Evaluating the **study device** Dental Implant. **Interventional, device**

23) OCULISTIC TRIALS:

- **Study device** for refractory open-angle glaucoma: a prospective, multicenter Clinical Trial. **Interventional, device**
- A double-masked, randomized, controlled, multiple-dose Study to evaluate the efficacy, safety and tolerability of **study drug** in subjects with retinitis pigmentosa (RP) due to mutations in Exon 13 of the USH2A gene with advanced vision loss. **Interventional, phase II/III**

The above mentioned Trials have been/are sponsored by: Abbott, ABX GmbH, Active Implants Corporation, Aimmune, Alexion, Alfa Wassermann, Alfasigma (former Sigma-Tau), Allergan Medical, American Medical Systems Inc., Amgen, Anthos Therapeutics, Astra Zeneca, Axcan Pharma, Bayer, Bicara Therapeutics,

Biocodex, Biogen Idec, BioLine Rx, Biomet Biologics, Bionor Immuno AS, Böhringer Ingelheim, Böhringer Mannheim, Bracco, Cardiovascular Systems Inc., CartiHeal, Cartilix, Bristol-Myers Squibb, Canadian Cancer Trials Group, Cardiovascular Systems, Inc., Celltrion, Centocor BV, Chiesi Farmaceutici, Clementia Pharmaceuticals Inc., Constellation, Corcept Therapeutics, Crescent Biopharma, Crinos, Daiichi Sankyo, Disc Dynamics, Dizal (Jiangsu), Dr. Falk, Eisai, Eli Lilly, European Association of Urology (EAU), European Cardiovascular Research Institute (ECRI), Ferring, General Electric Healthcare Inc. (GEH), FibroGen, Genmab, Glaxo Smith Kline, Hoechst, Hoffmann – La Roche, IBSA, IDI Farmaceutici, Immunogen, Integracts, Ipsen, IRCCS Istituto Clinico Humanitas Rozzano, Isotope Technology Munich (ITM), Italfarmaco, Italian Oncology Group of Clinical Research (GOIRC), Ivantis, IVRx, Janssen Cilag, Johnson & Johnson, Karyopharm, Klinik für Herz- und Gefäßchirurgie – Universitätsspital Zürich, Klinikum der Universität München, Lava Therapeutics, Malesci, Menarini, Merck, Merck Serono, Merz, Morphosys, National University of Galway Ireland, Nicox, Novartis, Novo Nordisk, Nurix Therapeutics Inc., Organon, Otsuka, Pfizer, Portola, ProQR Therapeutics, Q3 Medical, Recordati, ReGen Biologics, Roche, Sankyo, Sanofi – Aventis, Schering – Plough, Scirent, Serono, Shanghai MicroPort Medical Co. Inc., Topas Pharmaceuticals, WHO / Conrad, Upstream Bio Inc., Wyeth, Yamanouchi, Zambon, Zimmer.

The site visits have taken place in Italy, Germany, Switzerland and Austria (Italian and German speaking sites). Experience also in English speaking sites (United Kingdom and USA).

Deep knowledge of following systems:

Electronic Data Capture/electronic Case Report Form (EDC/eCRF)	Medidata Rave, Oracle, Medrio, Clindex, ClinTrak, Omnicomm, Fusion, IBM, Marvin, DataFax, Viedoc
Interactive Voice (Web) Response System (IVRS/IWRS)	ClinPhone, Almac, Suvoda, Rome, Rave RTSM, Cenduit, 4G, Endpoint, IQVIA
Clinical Trial Management System (CTMS)	Bioclinica, Cascade, Flex, Fusion, Veeva Vault, Medidata
Central laboratories	Covance, IQVIA, LabConnect, Cenetron, Parexel, PPD, Preclarus
Other systems	Electronic Trial Master Files (eTMFs), Clario (spirometers, proficiency tests, eCOA), ERT (ECGs), Investigator Space (SUSARs), Wingspan (eTMF)

PROFESSIONAL DEVELOPMENT / TRAININGS (MOST IMPORTANT)

- *May 2005 (Utrecht, The Netherlands):* ISO training
- *September 2005 (on-line training):* CRO's (name reserved) SOPs training with final test
- *January 24th – 26th, 2006 (Cambridge, United Kingdom):* database and clinical trial management system training
- *Throughout 2005 and 2006 (on-line training):* several online Novo Nordisk SOPs training
- *December 3rd, 2007 (Milano, Italy):* Quintiles' GCP training with audit simulation
- *February 12th - 13th, 2008 (Uxbridge, United Kingdom):* Electronic Data Capture (EDC) training
- *March 4th – 7th, 2008 (Zermatt, Switzerland):* communication strategy and quality control training
- *April 1st – 2nd, 2008 (Milano, Italy):* EDC training
- *January 16th, 2009 (on-line training):* GCP training successfully performed at PharmaSchool
- *March 19th – 22nd, 2009 (Zermatt, Switzerland):* communication strategy and quality control training
- *May 18th, 2009 (on-line training):* EDC training
- *February 9th – 14th, 2010 (Zermatt, Switzerland):* communication strategy and quality control training
- *April 16th, 2010 (on-line training):* EDC training
- *May 21st, 2010 (on-line training):* escalation of quality issue
- *July 19th, 2010 (on-line training):* escalation of quality issue
- *February 2nd – 6th, 2011 (Zermatt, Switzerland):* communication strategy and quality control training
- *From May to September 2011 (on-line training):* several on-line trainings regarding GCP, aseptic technique, fire safety, privacy, bribery, HIPAA and more
- *January 25th – 29th, 2012 (Zermatt, Switzerland):* communication strategy and quality control training

- March 23rd, 2012 (**on-line training**): IATA training (version 4.0)
- September 22nd, 2012 (**on-line training**): Barnett GCP training
- February 5th, 2013 (**on-line training**): Code of Conduct
- June 6th – 7th, 2013 (**Palermo, Italy**): real life monitoring training
- August 22nd, 2013 (**on-line training**): Roche Transcelerate GCP training
- September 15th, 2013 (**on-line training**): Policy Guidelines on Corporate Communications
- May 15th, 2014 (**on-line training**): anti-corruption training
- June 8th, 2014 (**on-line training**): Barnett GCP training
- November 30th – December 2nd, 2015 (**Barcelona, Spain**): Investigator Meeting with professional training/update
- February 21st – 23rd, 2016 (**Atlanta, USA**): Investigator Meeting with professional training/update
- October 8th, 2016 (**on-line training**): ClinTrak EDC system
- October 9th, 2016 (**on-line training**): The Global Health Network GCP training
- October 4th – 5th, 2017 (**London, United Kingdom**): Professional training/update
- October 25th – 26th, 2017 (**Vienna, Austria**): Investigator Meeting with professional training/update
- March 15th – 16th, 2018 (**Rotterdam, The Netherlands**): Cultural awareness, innovation in Coronary Heart Disease, innovation in structural heart treatment, congenital cardiology and case description, ISO 14155 versus GCP, General Data Protection Regulation, Medical Device Regulation
- September 24th, 2018 (**on-line training**): NIDA GCP training certificate
- September 26th - 27th, 2018 (**London, United Kingdom**): Sponsor's general training
- January 24th - 25th, 2019 (**Miami, USA**): Sponsor's general training
- March 26th - 27th, 2019 (**Köln, Germany**): Sponsor's general training
- May 16th, 2019 (**Amsterdam, The Netherlands**): Sponsor's general training
- June 14th- 15th, 2019 (**München, Germany**): Investigator/CRA Meeting with professional training/update
- February 3rd, 2020 (**on-line training**): Conducting a Site Evaluation Visit; Conducting a Site Initiation Visit; Conducting a Periodic Site Visit; Conducting a Site Termination Visit; Financial Disclosures by Clinical Investigators; Good Documentation Practice; Incident Management; On-site IMP Accountability; Preparation, Filing, Storage and Transfer of Essential Documents; Project Team Transition; Protocol Deviation Management; Regulatory Agency Site Inspection Preparation Visit; Regulatory Approval for Shipment of IMP to Clinical Sites; SAE Reporting; Serious or Persistent Non-compliance; Suspected Fraud in Bioreserarch
- June 4th, 2020 (**on-line training**): COVID-19 Emergency Business Practice; COVID-19 Remote Monitoring Business Practice
- August 24th, 2020 (**on-line training**): Good Clinical Laboratory Practice (GCLP) - Sample Management, Conduct of The Work, Data Recording and Data Reporting
- August 24th, 2020 (**on-line training**): Good Clinical Laboratory Practice (GCLP) – Quality Management
- October 7th, 2020 (**on-line training**): Research in Global Health Emergencies – Ethical Issues
- November 23rd, 2020: 21 CFR Part 11 Compliance Training for Operations
- November 24th, 2020: GCP_ICH E6 R2 Advanced Overview Clinical Operations
- November 25th, 2020: Global Data Privacy Regulation (GDPR)
- November 28th, 2020: Escalation of Significant Noncompliance
- December 4th, 2020: Remote SDV according to Communication AIFA dated 17Sep2020, EU commission Guidance and applicable Memos to File
- November 28th, 2020: HIPAA Training
- January 3rd, 2021 (**on-line training**): IQVIA GCP eLearning
- March 15th, 2021: Clinical studies CTAs and legal documents for EMEA
- March 15th, 2021: Clinical studies CTAs and legal documents for North and South America
- March 19th, 2021: Italian regulation overview (Part 2)
- April 13th, 2021: Worldwide anti-corruption policy, procedures and compliance certification
- April 14th, 2021: Centralised Monitoring & Surveillance Department Overview
- June 15th, 2021: GCP section 2 - ICH, harmonization and GCP principles - An introduction to ICH E6
- July 1st, 2021: Italian regulation overview (part 2)

- *August 9th, 2021:* Corporate-wide policies code of conduct
- *August 9th, 2021:* The reporting of safety information to regulatory authorities, ECs-IRBs
- *October 11th, 2021:* GMO studies - Submission process and timelines
- *October 18th, 2021:* Metabolism Pharmacocynetics
- *October 27th, 2021:* IMP essentials
- *November 19th, 2021:* Quality Risk Management Applied for Clinical Trial Projects, GCP relevant Processes and Systems
- *November 25th, 2021:* Process of obtaining Consent Form from routine to Clinical Trials
- *November 29th, 2021:* Update on ICH E8
- *November 29th, 2021:* Regulation (EU) #536/2014 – Safety reporting considerations
- *November 29th, 2021:* Audit Trial review – Practical aspects
- *February 2nd, 2022 (**on-line training**):* NIDA GCP training
- *February 14th, 2022:* Writing and reviewing Action Items
- *February 14th, 2022:* Notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
- *February 14th, 2022:* (EU) No. 536/2014 Labelling - New labelling requirements for IMP and AxMP
- *February 25th, 2022:* New CTS and readiness of Italy overview
- *April 4th, 2022:* Central Risk Management
- *May 20th, 2022:* Update about Italian regulation
- *June 30th, 2022:* Trip Report MVR writing
- *November 15th, 2022:* Quarterly Training of Italian Staff: Requirements for electronic source data and electronic patient files and Remote Source data verification
- *March 17th, 2023:* Round table about the recent decrees regarding the Ethic Committees in Italy
- *May 19th, 2023:* The development of the Clinical Research
- *June 7th, 2023:* Internal audit for compliance with MoH Decree - Findings and Actions
- *June 22nd, 2023:* Management of IMP on-site, Site Delegation Log-CV and staff documentation, Site management according to CTIS
- *June 23rd, 2023:* Digital therapies – Challenge and opportunity for the clinical research, the health and the National Sanitary System
- *June 23rd, 2023:* Stability and expiration dates of the clinical trials batches
- *June 24th, 2023:* Statistic calculation
- *September 9th, 2023:* GCP - Annual GxP refresher training
- *March 8th, 2024:* Handling of Safety Information Received By Non-Safety Associates Knowledge Assessment
- *May 17th, 2024:* Essential Documents Quality Review Assessment
- *July 9th, 2024:* Regulatory inspection management
- *July 9th, 2024:* Sponsor audit process
- *November 15th, 2024:* ISO 14155-2020 Good Clinical Practice for Medical Devices
- *November 20th, 2024:* GCP training
- *November 27th, 2024:* GCP refresher
- *February 5th, 2025:* IATA Dangerous Goods Regulations 66th Ed. v. 25
- *February 5th, 2025:* Understanding ISO 14155-2011 for Medical Devices (v. 1.0)
- *June 7th, 2025:* ICH GCP E6(R3) training
- *June 7th, 2025:* Monitoring Knowledge Check
- *July 26th, 2025:* ICH GCP E6(R3) training
- *September 12th and 19th, 2025:* ICH E6(R3) GCP- The new era of Good Clinical Practice has begun. Organised by Assomonitor
- *March 2nd, 2026:* ICH GCP E6 (R3) certification exam
- *March 6th, 2026:* Economics of cybercrime
- *July 3rd, 2026:* Secure browsing

Furthermore, for all Protocols an adequate training has been performed, as well as on all Sponsors'/CROs' SOPs.

I declare that I am certified as by Italian Ministry Decree about the CROs, dated November 15th, 2011.

COMPUTER EXPERIENCE

Internet, Mac-Apple, Windows-Microsoft, Office (Word, Excel, PowerPoint), Clinical Trial Management Systems (CTMS), Interactive Web/Voice Response Systems (IWRS/IVRS), Webinars, Social networks.

LANGUAGES

Italian: mother tongue (C2 level)

English: B2 level

German: B2 level

ADDITIONAL REMARKS

January 2008: co-founder member of **Assomonitor**, an Italian free-lance CRA association.

I have reviewed this document and confirm that the information is accurate and complete. I hereby give permission to distribute my CV to obtain projects on my behalf, either blinded or not. I understand that my rights under the European Data Protection laws (**#2016/679, dated April 27th, 2016, General Data Protection Regulation - GDPR**) or local country derivatives from this, or similar, legislation (**for Italy: Legislative Decree #196/2003, dated June 30th, 2003 and relevant update, i.e. Legislative Decree #101/2018, dated August 10th, 2018**) are not compromised by giving this permission and that I have the right to change, correct, update or remove my CV from database.

Signature:



Date: August 21st, 2026