

## **PERSONAL INFORMATION**

Name	Donato Bonifazi
WORK EXPERIENCE	
Period	2007-at present
Company name and address	Consorzio per Valutazioni Biologiche e Farmacologiche – Via Putignani 178, 70122 Bari, Italy
Position	Chief Executive Officer from 10/01/2012
• Corporate sector	Academic CRO - Not for profit research organisation
• Main duties and responsibilities	Clinical Trial Management, Network and Infrastructure Capacity Building. Project management and human resources management, administration, financial and control management.
	<b>Project Coordinator</b> - From July 2024 (ongoing), with reference to the EU-funded Project entitled <b>OrphaDev4kids</b> – <b>Orphan Device for paediatric patients: a unique</b>

**OrphaDev4kids** – **Orphan Device for paediatric patients: a unique platform providing innovative services** (HADEA/A/01 - EU4Health Programme – EU4H-2023-PJ-11-G.A.101161377).

### **Project Coordinator**

- From January 2018 to April 2022, with reference to the EU-funded Project entitled **ID-EPTRI – European Paediatric Translational Research Infrastructure** (H2020 – INFRADEV-1-2017-single-stage-G.A.777554). Currently established as EPTRI AISBL, based in Leuven, Belgium.

# **Project Coordinator and Trial Leader**

- From January 2011 to August 2016, with reference to the EU-funded Project entitled **DEferiprone Evaluation in Paediatrics - DEEP** (FP7 - SP1 - Cooperation HEALTH-F4-2010-single-stage-G.A.261483).

### Expert of Project Management and Monitoring, Networking, Translational Research, Clinical Research Methodology and Clinical Trial Management

- From January 2024 (ongoing), with reference to the EU-funded Project entitled **ERAMET – Ecosystem for Rapid Adoption of modelling and simulation METhods to address regulatory needs in the development of orphan and paediatric medicines** (HADEA/A/03 - HORIZON Research and Innovation Actions – HORIZON-HLTH-2023-IND-06-04-G.A.101137141). - From January 2019 to August 2024, with reference to the EU-funded Project entitled **EJP RD European Joint Programme on Rare Diseases** (H2020-SC1-2018-Single-Stage-RTD-G.A.825575) within WP1 'Coordination and management' WP2 'Integrative research and innovation strategy' and WP19 'Facilitating partnerships and accelerating translation for higher patient impact' activities. - From May 2018 (ongoing), with reference to the EU-funded Project entitled **conect4children (c4c) - COllaborative Network for European Clinical Trials For Children (**G.A. 777389 - H2020-JTI-IMI2-2016-10), within WP6 'Network Research Personnel Education and Training', WP7 'Planning and Execution of Clinical Trials' and WP8 'Communication, Dissemination, Exploitation and Impact Assessment'.

- From January 2017 to June 2021, as WP3 Leader in the EU-funded Project entitled "**Paediatric Clinical Research Infrastructure Network** – **PedCRIN**" (H2020-INFRADEV-03-2016-2017 – G.A. 731046), aimed to create and update existing tools for paediatric clinical trials.

- From February 2014 to April 2020, with reference to the EU-funded Project entitled "**Treatment of late onset bacterial sepsis caused by vancomycin susceptible bacteria in neonates and infants aged under three months** – NeoVanc" (FP7-HEALTH-2013-INNOVATION-1- G.A. 242146).

- From July 2013 to June 2019, with reference to the EU-funded Project entitled "**GAbapentin for Paediatric Pain – GAPP**" (FP7-HEALTH-2013-INNOVATION-1- G.A. 602962).

- From January 2011 to June 2017, with reference to the EU-funded Project entitled "**Global Research in Paediatrics** – **GRiP**" (FP7-HEALTH-F5-2010-G.A. 261060).

- From January 2010 to June 2015, with reference to the EU-funded Project entitled "European multicenter network to evaluate pharmacokinetics, safety and efficacy of Meropenem in neonatal sepsis and meningitis – NeoMero" (FP7-HEALTH-2009-4.2-1- G.A. 242146).

• Period 2017-at present

<ul> <li>Company name and address</li> </ul>	<b>TEDDY European Network of Excellence for Paediatric Research</b>
	Via L. Porta 14, 27100 Pavia, Italy
Position	member of the Board

- Corporate sector European Research Network
- Main duties and Network development and coordination. Project and financial management.

Expert in Patient Engagement and Innovative Research Methodologies

- From September 2024 (ongoing), with reference to the EU-funded Project entitled **ERDERA – EUROPEAN RARE DISEASES RESEARCH ALLIANCE** (HADEA/A/03 - HORIZON Programme Cofund Actions – HORIZON-HLTH-2023-DISEASE-07-01-G.A. 101156595).

- From January 2024 (ongoing), with reference to the EU-funded Project entitled **INVENTS** – **Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs** (HADEA/A/03 - HORIZON Research and Innovation Actions – HORIZON-HLTH-2023-IND-06-04-G.A.101136365).

• Period 2007-2016
 • Company name and address Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus – via Abate Eusterie 30, 70010 Velenzene (Peri)

Position

- Eustasio 30, 70010 Valenzano (Bari) Founder and Secretary of the Board of Directors
- Corporate sector Not for profit research organisation

• Main duties and responsibilities	Administration, project management and reporting human resources management and control management.
	<ul> <li><i>Expert in Networking and Communication activities</i></li> <li>From December 2013 to November 2016, with reference to the EU-funded Project entitled d "Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit– CloSed" (FP7-HEALTH-2013-INNOVATION-1- 602453).</li> <li>From April 2013 to September 2015, with reference to the EU-funded Project entitled "Inherited NeuroMetabolic Diseases Information Network – InNerMeD-I-Network" (Second Health Programme 2008-2013, 2012 12 12).</li> </ul>
• Dates	2002-2006
• Name and address of employer	Lavoro e Servizi per l'Impiego Soc. Coop. a r.l. – Bari - Società di mediazione di lavoro (aut. Min. Lav. n. 2263 del 4-7-02), Via Quintino Sella 118 – 70122 Bari
• Type of business or sector	Employment Services
Position	Chairman of the Board
<ul> <li>Main tasks and responsibilities</li> </ul>	Consulting for business organization, with reference to the human resources management, setting and managing of business processes for identification of professional and training needs, search and selection of the personnel and orientation and training.
• Dates	1995-at present
• Name and address of employer	Mediterranea Associazione per lo Sviluppo Locale – Bari Via Putignani 178 – 70122 Bari
• Type of business or sector	Educational institution and social promotion
• Main tasks and responsibilities	Member (President of the Governing Council and Legal Representative up to 11/06/2004, Regional Director up to 20/11/2005), responsible of agreements with the Apulia Region for the realization of training projects for Measures 3.3, 3.4, 3.8, 3.14 of P.O.R. Puglia 2000-2006, with the Municipality of Bari for the management of Services to the public of the "Informagiovani" and Office of the Public Relations and for the management of the service of family mediation ex 1. 285/97, with the Ministry of Education, University and
	Research for management of the Master in Management of Cultural Assets and of the High Level Training Course "Experts in technical and economic evaluation of clinical research projects", with the Ministry of Labour for the management of the project Orientalavoro (prov. di Lecce)
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<ul> <li>Main tasks and</li> </ul>	Project for a new exhibition dedicated to innovative environmental services
responsibilities	and technologies "TE.R.R.A Tecnologie e Ricerche per il Riequilibrio
	Ambientale"; executive plan for the first edition (11-15 November 1992); sale
	of exhibition spaces; management of partnership with institutions and
	associations (Province of Bari, Cispel, Federambiente, Assoambiente, Anci);
	coordination of the event and conferences. Management of the organization of
	the second edition of TERRA (27-30 October 1994); internationalization of
	the initiative (thanks to the participation of Swiss, French, German and English
	exhibitors, and more than one hundred qualified operators from 18 countries
	of East Europe and Mediterranean countries); collaboration with the EU DG
	XI for the presentation at TERRA '94 national preview of the Community
	program Thermie on innovative energy technologies.
	Market analysis and planning of new initiatives; support to working groups
	dedicated to the organization of other exhibitions at the Fiera del Levante
	(Expolevante, Exposhow, Expocomics, Festa d'Estate).

### EDUCATION AND TRAINING

• Dates • Name and type of organization proving education • Qualification awarded	1985 – 1989 LUISS, Roma Degree in Management – Marketing specialisation
• Level in national classification	110/110 with honor
• Dates	2001
• Name and type of organization proving education	SDA BOCCONI, Milano
• Qualification awarded	Master in 'Competences and technique for personnel selection'
• Dates	2011
• Name and type of organization proving education	Europa Media, Budapest
• Qualification awarded	FP7 - Financial and Project Management Advanced Course
PERSONAL SKILLS AND COMPETENCES	
FIRST LANGUAGE	Italian
OTHER LANGUAGES	English
Reading skill	Excellent
• Writing skill	Excellent
•Verbal skill	Very Good

MANAGERIAL SKILLS AND COMPETENCES	Certification for Project Manager released on 08.03.2016 by CEPAS srl - Certification Body of Professionalism and Training, registered at No. 0001455702 at the Ministry of Economic Development
COMPUTER SKILLS AND COMPETENCES	Excellent knowledge of operating system Office for Windows, internet, and email.
APPOINTMENTS	<ul> <li>From January 2024 member of the Board at AICRO – Italian Association of Contract Research Organizations</li> <li>From December 2023 member of the Accelerating Clinical Trial EU Platform Advisory Group</li> <li>From 2022 Member of the iCAN international Children Advocacy Network Advisory Board</li> <li>From 2019 Member of Coordinating Group of Enpr-EMA at EMA (European Network for Paediatric Research at the European Medicines Agency)</li> <li>2018 – 2020 President of AICRO – Italian Association of Contract Research Organizations</li> <li>Member of the Paediatric Working Group of the EUCROF (European CRO Federation) and of the EFGCP (European Forum for Good Clinical Practice)</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Founder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Pounder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Pounder of INCiPiT, the Italian Network for paediatric clinical trials</li> <li>Pounder of INCiPiT, the Italian Second of Directors of the TEDDY KIDS</li> <li>Network</li> <li>2002 - 2006 Member of the Board of Directors of the Service Center Volunteering San Nicola Bari, Treasurer from 14.04.04 to 22.06.06 (2002 - 2005 Member of the Selection Commission for the public competition of the Province of Bari</li> <li>2001 Interreg Coop Puglia Training Coordinator 1999 - 2000 Member of the Selection Commission for the public competition of the</li></ul>
	r autorize the processing of my personal data.

Bari, December 12<sup>th</sup>, 2024

Jonein Beile