## **Curriculum Vitae**

## Personal information

First name/Surname

Vincenzo Giurlanda

Address

Telephone Mobile

E-mail

Nationality

Italian

Date of birth

Gender Male

## Work experience

Dates

March 2023 - onward

**Autonomous University** 

Occupation or position held

UniSR Operations Directorate

Main activities and current responsibilities

Point of contact between the clinical research activities carried out at the IRCCS Ospedale San Raffaele and the offices involved in the process of authorising and conducting clinical trials: Pl's, Legal Office, Clinical Trial Centre, Scientific Direction, Technical-Scientific Secretariats CE

Name and address of employer

Università Vita-Salute San Raffaele

Type of business or sector

November 2021 – June 2022 and June 2023 – onward

Occupation or position held

Head of the Technical Scientific Secretariat of CE IRCCS San Raffale Hospital (Comitato Etico Territoriale Lombardia 1) according to regulations.

Main activities and current responsibilities

Coordination and supervision of secretarial staff dedicated to the validation of studies/amendments/adverse events subimitted to the attention of the Ethics Committee. Managing communications with the Ministry of Health and AIFA about clinical trial activities including updating the Ministry of Health Observatory and communications about therapeutic uses of medicines.

Managing referral entities to the secretariat and verifying that activities undertaken comply with current regulations.

Actively participate in the meetings of the Ethics Committee.

Name and address of employer

ss or sector Private Research Hospital

Type of business or sector

Dates November 2020 - March 2023

Ospedale San Raffaele Milano

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Occupation or position held

Administrative Associate - Legal Office

Main activities and current responsibilities

Opinions on research activities relating financial and regulatory aspects. Loan agreements, intra-group and extra-group scientific collaborations.

Name and address of employer

Università Vita-Salute San Raffaele

Type of business or sector

**Autonomous University** 

Dates

November 2015 - October 2020

Occupation or position held

Contract Specialist - Clinical Research Office -'Ospedale San Raffaele di Milano

Main activities and current responsibilities

- Draw up, negotiation and finalization of agreements for both interventional and non interventional trials: site agreements, loan of equipment, contracts with different entities like pharmacy or hospital departments. Responsible for contracts between the Hospital and the Sponsors for any trial and between Hospital and other Italian sites for non profit studies.
- Adaptation of Sponsor's budget to Hospital requirements for profit studies, budget negotiation and finalization
- Liaising between Hospital, Pls (principal investigator) and Sponsors throughout study, including pre and post study phases, identifying and resolving potential legal and economic problems, verifying availability and need of equipment for the study as mentioned in agreement;
- Deep knowledge of Italian requirements and law applicable to clinical trials (loan, insurance, payments).

Name and address of employer

Ospedale San Raffaele Milano

Type of business or sector

Private Research Hospital

Dates

July 2009 - October 2015

Occupation or position held Hospital's contract specialist and member of Ethic Committee Secretariat

Main activities and current responsibilities

- Pre-selection of potential studies for presentation to Ethics Committees
- Set-up requests of submission for clinical trials, evaluation of compliance with legislative decrees, regional references and ministerial decrees, identification of appropriate legal framework to particular requests.
- Check, approval and validation of correct folder to submit EC; deep experience in regulatory submission and a good knowledge of applicable regional requirements.
- Clear understanding of timelines and phases of the whole start up process, under both ethical and contractual aspects
- Consultant for developing and maintaining contracting policies and procedures to comply with changes in laws, regulations and ordinances;
- Involved in the development of the Hospital contract template, on the basis of the Regional template
- Collaborator in various projects such as:
  - "The sources of research funding: support the request for access to funds, administrative management and reporting"
  - "Program management and monitoring of clinical trials: the role of the secretariat of the Ethics Committees"

Name and address of employer

Fondazione IRCCS Policlinico San Matteo – Pavia

Type of business or sector

covered

Pubblic Research Hospital

Education and training

Dates 08/06/2021

Principal subjects/occupational skills

Speaker: La costruzione del Budget negli Studi Clinici

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Name and type of organisation Formafutura providing education and training Dates 21/06/2019 Principal subjects/occupational skills GDPR e Studi Clinici: novità, pratiche. covered Name and type of organisation Formafutura providing education and training 17/11/2017 Principal subjects/occupational skills Speaker: Topics nella gestione di uno studio clinico - Assicurazione e contratti Name and type of organisation Gruppo Italiano Data Manager providing education and training 14/10/2016 Dates Principal subjects/occupational skills Clinical Trials in Oncology: Italian and Lombardy Region as an example for the world Name and type of organisation Regione Lombardia providing education and training 09/06/2016 Principal subjects/occupational skills English contract law covered Name and type of organisation Bird & Bird, Milano providing education and training 19/04/2016 Dates High specialization course / studies profit: all agreements Principal subjects/occupational skills Name and type of organisation Forma Futura providing education and training Dates 24/03/2016 Principal subjects/occupational skills GCP: how to ensure ethics and quality in clinical trials Name and type of organisation Ospedale San Raffaele providing education and training 14-15.05.2015 Dates Principal subjects/occupational skills High specialization course / studies no-profit: all agreements Name and type of organisation FormaFutura providing education and training Dates 14.04.2015

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Principal subjects/occupational skills Study day "from Region to Europe from Europe to Region: the European regulation on clinical covered Name and type of organisation Palazzo Lombardia, Milan (Italy) providing education and training **Dates** 08.04.2014 Principal subjects/occupational skills Study day "clinical trial as a tool to speed up patient access to innovative treatments and an opportunity for the economy" Name and type of organisation Palazzo Lombardia, Milan (Italy) providing education and training Dates 15.04.2013 Principal subjects/occupational skills Course "publication of administrative acts: the need for transparency and the protection of confidentiality" Name and type of organisation Ospedale di Circolo and Fondazione Macchi, Varese (Italy) providing education and training

15.10.2012

Dates

Principal subjects/occupational skills Conference "Improving Scientific Research. From the bibliometric indicators to the publicprivate evaluation criteria " covered

Name and type of organisation Fondazione IRCCS Policlinico San Matteo, Pavia (Italy) providing education and training

> 27.09.2012 Dates

Principal subjects/occupational skills Educational event "validity and applicability of informed consent in critical situations. The new regulatory issues and future challenges ".

Name and type of organisation Hospital Niguarda Ca' Granda Hospital in Milan (Italy) providing education and training

> 19.09.2012 Dates

Principal subjects/occupational skills Seminar "Principles of PK / PD applied in phase I studies" covered

Name and type of organisation Fondazione IRCCS Policlinico San Matteo, Pavia (Italy) providing education and training

> 25.06.2012; 14.12.2011; 16.06.2011; 15.12.10; 16.12.2009; 21.06.2009 Dates

Principal subjects/occupational skills Collaborator on technical committee for the definition of the development of the National Clinical Trials of Medicines (OsSC) "Project E-Submission" covered

Name and type of organisation Headquarters of AIFA, Rome (Italy) providing education and training

> 2010 - 2015 Dates

Title of qualification awarded

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Principal subjects/occupational skills Tutor on the project "Components Ethics Committee Meetings" covered Name and type of organisation Fondazione IRCCS Policlinico San Matteo, Pavia (Italy) providing education and training **Dates** 06.07.2009 Principal subjects/occupational skills Conference "Biomedical sciences and law: a dialogue between disciplines, cultures and languages" Name and type of organisation Collegio Ghislieri, Pavia. (Italy) providing education and training 08.- 09.05.2009 Dates Principal subjects/occupational skills Conference "Informed Consent in Clinical Trials" Name and type of organisation Collegio Ghislieri, Pavia. (Italy) providing education and training Dates 2007 - 2009 Principal subjects/occupational skills Scholarship on "scientific documentation over the network in the organization of clinical trials" Fondazione IRCCS Policlinico San Matteo, Pavia (Italy) Name and type of organisation providing education and training Dates 25.06. 2007 - 03.08.2007 Title of qualification awarded ESL course Name and type of organisation St. Charles Adult Education Centres, Hamilton, Ontario (USA) providing education and training 19.04.2007 Dates Title of qualification awarded Degree in law Principal subjects/occupational skills Italian law covered Name and type of organisation Università degli Studi di Pavia (Italy) providing education and training Personal skills and competences Mother tongue(s) Italian Other language(s) **English** Self-assessment **Understanding** Speaking Writing European level (\* Listening Reading Spoken interaction Spoken production Page 5/6- Curriculum vitae of Vincenzo

Giurlanda

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(\*) Common European Framework of Reference for Languages

Skills

During my experience at the Scientific Secretariat of the Ethics Committee of the Fondazione San Matteo in Pavia, I have implemented and developed my social skills and team work with my colleagues, with the components of the Ethics Committee, with the investigators and the directors.

In San Raffaele Hospital, preparing and finalizing the contracts has developed my organizational skills, my ability to work independently and to successfully manage priorities. Budgetary work brought me to a clear understanding of financial terms including cash flow and revenue recognition.

Computer skills and competences

Proficiency in all aspects of Microsoft Office, including Word, Excel, PowerPoint Good experience with implementation and development of databases: Certificate of Completion Microsoft Access 2016

Driving licence A and B

I authorize the treatment of my personal data in compliance with Art. 13 of the Legislative Decree 196/2003 and GDPR 679/16

Signature: Wiene Janah

Date: 02/11/2023