



PhD in DATA ANALYTICS AND DECISION SCIENCES - 39th cycle

PNRR 118 PA Research Field: DATA SCIENCE FOR REGULATORY PROCESSES IN MEDICAL DEVICES: TEXT ANALYTICS SOLUTIONS TO EXPLOIT AVAILABLE DATA, TO REDUCE UNCERTAINTY AND AUTOMATE DECISION MAKING

Monthly net income of PhDscholarship (max 36 months)

€ 1400.0

In case of a change of the welfare rates during the three-year period, the amount could be modified.

Context of the research activity

Motivation and objectives of the research in this field

'Regulatory science' for medical devices (MD) refers to the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of MD and that inform regulatory decision-making throughout the lifecycle of an MD. It encompasses basic and applied biomedical and social sciences and contributes to the development of regulatory standards and tools. With the large number of MD available worldwide, ruled by markets adopting different standards and procedures for their certification and post-market surveillance, it becomes important to generate a common knowledge that allows to properly monitor the situation and promptly react when safety concerns are raised due to a failing technology. To contribute to this goal, public available information in official web sources (national public regulatory agencies) could be accessed in an effort to generate links among data, mapping different taxonomies, solve uncertainties, perform data aggregation and create new knowledge useful to this worldwide market. Starting from these motivations and from end-users needs, the objectives of this research consist of the development and application of data science methods (text mining and analytics) to the field of MD regulatory science, in an attempt to digitalize and automate processes to exploit the power of already available data, thus improving both the work of the controlling authorities and that of the MD manufacturers.



<p>Methods and techniques that will be developed and used to carry out the research</p>	<p>Several methods and techniques will be developed and used to carry out the research:</p> <ol style="list-style-type: none"> 1. design data services able to extract the relevant attributes from several data sources; 2. identify and interpret selected attributes using text analytics and Natural Language Processing; 3. developing nomenclature mapping algorithms adopting pre-trained Language Models; 4. design and deploy a self-service client-server infrastructure and interactive dashboard in which final users can integrate and visualize the information needed; 5. define decision-making strategies based on interactive data exploration techniques exploiting Human-in-the-loop design concepts.
<p>Educational objectives</p>	<p>The proposal is highly innovative and multidisciplinary. Several competencies will be deepened or gained during this project: biomedical engineering concepts relevant to medical devices and healthcare organizations, knowledge of the regulatory processes involved in this field, computer science competencies in designing aggregator tools, software for text analytics, IT services, and user interfaces. Close collaboration with European and Italian institutions throughout the whole project will allow to be introduced to a network of stakeholders working in this field.</p>
<p>Job opportunities</p>	<p>The gained experience and competences will be pivotal for job opportunities in the field of regulatory science, both in industry and public sectors. Also, they could be translated to every domain in which text analytics and decision-making strategies could be derived from web information, opening several data science-related professional opportunities.</p>
<p>Composition of the research group</p>	<p>0 Full Professors 1 Associated Professors 2 Assistant Professors 5 PhD Students</p>



Name of the research directors	Prof. Enrico G Caiani
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Additional support - Financial aid per PhD student per year (gross amount)	
Housing - Foreign Students	--
Housing - Out-of-town residents (more than 80Km out of Milano)	--

Scholarship Increase for a period abroad	
Amount monthly	700.0 €
By number of months	6

National Operational Program for Research and Innovation	
Company where the candidate will attend the stage (name and brief description)	Regione Autonoma FVG - Azienda Regionale di Coordinamento per la Salute
By number of months at the company	6
Institution or company where the candidate will spend the period abroad (name and brief description)	Dutch National Institute for Public Health and the Environment (RIVM) - Ministry of Health, Welfare and Sport
By number of months abroad	6

Additional information: educational activity, teaching assistantship, computer availability, desk availability, any other information

Attinenza alla tematica prescelta del bando

La tematica trattata ha un'ottica multidisciplinare, orientata all'attività di ricerca applicata nelle pubbliche amministrazioni, ed in particolare nell'ambito dei dispositivi medici alla luce della attuazione della Regolamento EU 745/2017 (Medical Device Regulation). Le Mission del PNRR attinenti sono la M1 C1 (Digitalizzazione, innovazione e sicurezza nella PA), con focus sulla digitalizzazione della Pubblica Amministrazione e rafforzamento delle competenze digitali, la M4 C2 (Dalla ricerca all'impresa) e la M6 C2 (Innovazione, ricerca e digitalizzazione del Servizio Sanitario Nazionale) per le possibili ricadute a sostegno delle imprese nell'ambito delle attività di sviluppo di dispositivi medicali e nel relativo miglioramento del Servizio sanitario nazionale. SDG connessi:

- 3 (Good Health and Well-being), target 3.8 (Universal health coverage) and means of implementation 3.d (Emergency preparedness)
- 16 (Peace, justice and strong institutions), target 16.6 (Develop effective, accountable and



transparent institutions at all levels)

Impresa, centro di ricerca, pubblica amministrazione (per PA e PC) presso cui si svolgerà l'attività esterna

- Regione Autonoma Friuli Venezia Giulia - Azienda Regionale di Coordinamento per la Salute
Link alla pagina dell'azienda: - www.regione.fvg.it
- Descrizione sintetica attività: Le attività previste riguarderanno nel particolare la definizione di metodi di text analytics per ottenere una mappatura precisa delle nomenclature più utilizzate per i medical device (la European Medical Device Nomenclature, EMDN a livello EU, e la Global Medical Device Nomenclature, GMDN a livello USA/UK), nonché per l'aggiornamento delle relative tassonomie in relazione alla descrizione dei vari codici associate in relazione al loro utilizzo storico. L'ente prescelto, unitamente al Ministero della Salute, porta avanti da anni attività legate allo sviluppo ed aggiornamento della Classificazione Nazionale dei Dispositivi medici, che raggruppa i dispositivi medici in categorie omogenee di prodotti destinati ad effettuare un intervento diagnostico e/o terapeutico simile, ora alla base EMDN.

Ente, università, azienda, centro di ricerca presso cui si svolgerà il periodo di studio e ricerca all'estero.

- Dutch National Institute for Public Health and the Environment (RIVM) - Ministry of Health, Welfare and Sport
Link: <https://www.rivm.nl/>
- Descrizione sintetica attività: applicazione dei tool sviluppati al contesto Olandese, con verifica delle relative performance e usabilità in un contesto internazionale,, collegamenti con la European Medicine Agency (con sede ad Amsterdam) per possibili ulteriori applicazioni di quanto sviluppato.