

# A Pilot Project Proposal for the Implementation of a Geographic Information System for Immuno-Oncology in Italy

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**Keywords:** Spatial Data Science, Geographic Information System (GIS), Health GIS, Immuno-Oncology (I-O), Clinical Epidemiology, Clinical Governance.

**Abstract:** The purpose of this project is to exploit the potential given by the connection of two fields apparently distant in which research is recently making very rapid progress: Immuno-Oncology (I-O) and Spatial Data Science. The connection of these two fields has led the research group to propose the building of an I-O Geographic Information System. In section 1 of this paper, we explain the advantages of linking I-O and Spatial Data Science, in section 2, we explain the purposes and the objectives of the project, in section 3, we describe the phases of the Geographical Information System (GIS) implementation and in section 4, we indicate some main issues and future perspectives. In particular, in section 3.1 we describe some preliminary steps in the building of the project's database such as the collection of the Italian I-O Network Projects and the I-O excellence centres.

## 1 INTRODUCTION


The idea of building an Immuno-Oncology Geographical Information System was born from the connection of two fields apparently distant in which research is recently making very rapid progress: Immuno-Oncology (I-O) and Spatial Data Science.

The ingredient that launched the project was the intuition that the connection of these two fields could have a great role and potential in the dissemination of cancer-related information to doctors and patients, and in particular in the improvement of the Italian I-O Information System.

### 1.1 Immuno-Oncology

Immuno-Oncology is a science which is rapidly evolving worldwide, and is in charge of identifying innovative treatments in the fight against cancer.

Immunotherapy is currently indicated as the “fourth way” in therapeutic treatments against cancer after surgery, chemotherapy and radiotherapy. Some immuno-therapeutic drugs have been authorized in Italy and in the EU. For melanoma, lung cancer, and other types of cancer, there are Immuno-therapeutic drugs which are officially approved and already available in the Italian National Health System. There is also a lot of experimentation on Immuno-therapy for other types of cancers. Moreover, I-O is a fundamental topic in Translational Oncology which is also a rapidly developing approach in oncology research. This approach promotes the integration between preclinical and clinical practice, through the design and execution of multidisciplinary research projects among groups of researchers for the development of new therapeutic approaches, including personalized ones. In particular, translational oncology promotes basic, applied and

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industrial research in the field of cancer biology in order to broaden the knowledge on the molecular mechanisms of neoplastic transformation and its clinical evolution.

## 1.2 Spatial Data Science

Spatial Data Science concerns Spatial Data Representation, Visualization and Analysis, and can outline best practices and alternatives for visualizing spatial and geographic phenomena and for the analysis of spatial issues: different map options and data visualizations can provide different possibilities in the display of data and can show trends, patterns, critical points and spatial relations among data, and in particular, and can improve the detection of spatial networks among objects.

## 1.3 Reasons for Connecting *Immuno-Oncology and Spatial Data Science*

The main reason for connecting I-O and Spatial Data Science, was the “weak connection” detected among these two fields in Italy; As a proof of this “scientific gap” we can say that there is no wide literature available on the topic, even if some steps forward have been made in the 90’s: in Campbell’s publication on the foundation of clinical data representation, (Campbell, 1994). In the last years the National Institutes of Health (NIH), is promoting the Storing, managing, standardizing and publishing the vast amounts of data produced by biomedical research, and released its first “Strategic Plan for Data Science”, (NIH, 2018), that provides a roadmap for modernizing the NIH-funded biomedical data science ecosystem. Moreover, NIH is actively implementing its strategy and is continuing to seek the scientific community input. In Italy there is a central Observatory (Osservatorio Terapie Avanzate, OTA) on the collection of all the advanced bio-therapies available, also concerning Oncology, but it still to be improved on the side of data collection, management, interoperability and visualization. This research pilot project was born to promote and exploit the connection of I-O and Spatial Data Science, and to exploit data visualization and analysis in order to improve I-O information and communication especially in the Web (J. E. Brody, 2019).

To make the access to I-O information easier, fair and homogeneous, the research group proposed a pilot project that fully exploits the new Information and Communication Technology (ICT), through the implementation of Geographic Information System

(GIS) for Immuno-Oncology in Italy. The first step was to verify the status of the I-O information access, and to identify the difficulties encountered by patients, doctors and researchers in accessing information. The innovative contribution of this project is not only linked to the intention to reduce the I-O information gap, but also to put attention in how to improve the display of information itself promoting a visual approach:

- spatially representing all the data related to the immuno-therapies administered in the Italian authorized centres;
- using thematic maps and applications of smart data visualization to display, analyse and compare the data collected in the geo-database and identify trends, criticality, periodicity, relations and patterns.

In this way the project would provide to researchers, doctors and patients a graphic and visual support to I-O through the use of GIS software and digital cartographic displays. The expected results are, starting from the implementation of a WebGIS, also the implementation of a series of digital information tools useful for:

- Promoting the connection of I-O research centres;
- promoting the connection of I-O databases related;
- promoting the connection between the growing demand for innovative oncological treatments by the patients with the growing offer produced by research at national and international level.

## 2 PURPOSES OF THE PROJECT

The main purposes of the project are to promote, in Italy, the improvement of the I-O information system, concerning prevention, diagnosis, therapy and follow-up of patients with the introduction of the new indications available in clinical practice, through:

- The promotion of the building of a unique national systematic and updated database on I-O data with interoperable standards and statistics;
- A more systematic management (with interoperable standards) of the existing online database on experimental and non-experimental I-O clinical trials;

- The connection and implementation of the existing I-O fragmentary databases;
- The consolidation and the expansion of the networks of I-O hospitals and research centres.

These objectives can be achieved by the implementation of innovative techniques of visual representation and analysis of data, by the use of indicators of Immunotherapy information and statistics. Many improvements in I-O could be achieved through the sharing of data in the different phases of prevention, diagnostic, therapeutic and monitoring phases of cancers treated or treatable with immunotherapies and in particular through the optimization of:

- Therapeutic indications,
- experimental clinical trials,
- pharmacological research,
- economic resources for researchers and medical staff.

### 3 STRUCTURE AND PHASES OF THE PROJECT

The project is divided into three phases that are described in the following paragraphs.

#### 3.1 First Phase of the Project

The first phase of the project concerns the analysis of the Italian context and the evaluation of the existing landscape of Immuno-Oncology information in Italy, (Emens et. al., 2017). We analysed I-O structures, networks, online database and also I-O projects promoted by public institutions, foundations, associations, and companies. We started to build the project's database from the collection of data on:

1. **Italian structures, research centres and institutions** that deal with Immuno-Oncology;
2. **Real and virtual networks** that connect structures and research centres in Italy that deal with Immuno-Oncology;
3. **Online database and search-engines** available to access information about the Immunotherapies, clinical trials, treatments in Italy and abroad;
4. **Projects** involved in Immuno-Oncology that have been developed by structures and research centres in Italy.

In the following part each point is briefly illustrated:

1. **Structures and research centres** in Italy that deal with Immuno-Oncology. For the implementation of this point, we have started an independent survey, using different sources, such as AIOM publications (AIOM Libro Bianco, 2015, AIOM Libro Bianco, 2017), Fondazione Serono database, and other sources. We have built a database that we are using as a basic information layer for the mapping of the other information layers. For the moment, the Italian Regions with I-O hospital structures that we mapped in our project are ten.
2. **Real and virtual networks** that connect structures and research centres in Italy that deal with Immuno-Oncology. For the implementation of this point, we analysed the Italian Regions that have active oncological networks compared with the pilot Regions we started to map in our project. Some of the I-O institutions, promote I-O networks, as for example the Italian Network for Tumor Biotherapy (NIBIT) in Siena, Tuscany, and the Regional Network for Tumor Biotherapy "Rete del Lazio per la Medicina Traslazionale e Sviluppo delle Bioterapie dei Tumori" in the Latium Region. Besides the official networks there are many non-official networks that have been established independently. The objective of the project is to highlight all the networks and to promote a "network of networks" through the WebGIS.
3. **Online database and search-engines** available to access information about the Immunotherapies in Italy and abroad, that facilitate the diagnosis and therapies for patients and doctors.

In Figure 3.1 it is possible to see the preliminary UML model of the project's database.

#### 3.2 Second Phase of the Project

In the second part of this project, considering the important improvements in access to information given by the new digital information systems, and the indications to digitalisation of the entire public health sector, (medical records, diagnostic reports, etc.), we proposed the implementation of a Geographic Information System of Immuno-Oncology in Italy. This platform should be available on a website to all citizens, researchers and operators of the sector (by registration and passwords with dedicated access profiles according to the role), and it should also collect the information about the different phases of the project and in particular should display:

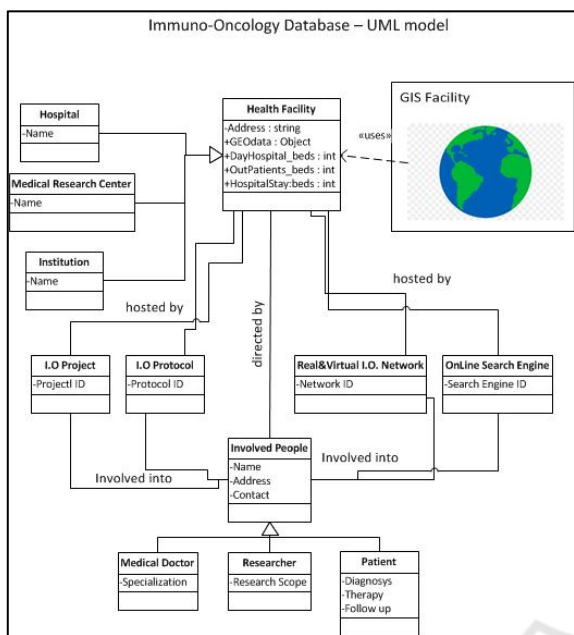


Figure 3.1: The UML model of the project’s database.

1. The existing literature on immune-therapies applied to oncology in Italy, for each immuno-therapy centre, easily visible on a map;
2. Database on medical and non-medical personnel involved in the research management and data managers, and administration of oncological immuno-therapies, for each hospital structure;
3. Database on treatments authorized by AIFA
4. Database on treatments mapped by Regions;
5. Clinical trials with immuno-therapy drugs, approved by ethic committees;
6. Dissemination and distribution in the territory of the results of the trials, with due caution;
7. The therapeutic offer in terms of immuno-oncology, for each hospital structure in Italy, divided into:
  - a. the number and type of protocols approved and available in clinical practice for each hospital facility;
  - b. the number and type of experimental clinical trials, protocols available for a single hospital structure;
8. Estimates of the volume of patients who prefer non-regional or foreign therapeutic centres;
9. Administration of a questionnaire by voluntary associations, to test doctors, patients and ordinary citizens on their knowledge about Immuno-oncology.

### 3.3 Third Phase of the Project

The third phase of the project concerns the implementation of a pilot study in a selected Italian area, that will be analysed through GIS, geo-statistics, and visual data analysis, in order to detect the relationships between geographical, economic, social and environmental factors and the therapies access, health inequalities and outcomes of the therapies. The testing process of the pilot Regions consists in the evaluation, through a set of indicators, of the improvement of the patients’ care and healing.

In the Italian Project Periplo, they analysed some indicators and discovered that where the networks are active, the patients’ healings grow, and also their life quality. In particular, they studied the diffusion of Diagnostic and therapeutic assistance paths (in Italian PDTA), that promote the personalized therapy. In our project we propose to use some of the Periplo’s set of indicators, but also other specific I-O indicators.

## 4 RESULTS, OPEN ISSUES AND PERSPECTIVES

The results we expect to present at the conclusion of the project pilot study are:

1. Representation of the network of pilot immuno-oncology centres;
2. development of an online platform for information sharing;
3. creation of interactive maps for easy access to information;
4. creation of statistical indicators for the network evaluation of clinical studies;
5. monitoring and assessment of the degree of satisfaction among the users of the online platform.

The specific issues that remain open for the implementation of the project are:

1. Identification of pilot hospital structures and their database;
2. difficulty in accessing and recovering data
3. patients’ privacy problem;
4. authorization to link the project’s database in the NIBIT website and with other national cancer networks websites;
5. caution in the communication and dissemination of experimental data under study;

6. approval of the project by the Italian expert centres (such as NIBIT, ISS, AIOM, AIRTUM, Ministry of Health, etc.

It is also important to say that an important topic to debate could be the implementation of a series of specific tools and network services (and the related digital information) useful to connect the research centres and the growing demand for innovative oncologic treatments with the growing offer of oncologic treatments produced by scientific research at National and International level.

## ACKNOWLEDGEMENTS

Prof. P. Ascierto, Director of the Complex Structure of Medical Oncology, Melanoma Immunotherapy Oncology and Innovative Therapies, Pascale Hospital, Naples, Italy.

Dr. Carlo Capalbo, oncology scientist, Sant'Andrea University Hospital, Rome, Italy.

Dr. Michele Maio, President of NIBIT Foundation, Director of the Division of Medical Oncology and Immunotherapy at the University Hospital of Siena - Department of Oncology, Adjunct Professor at the College of Science and Biotechnology at Temple University, Philadelphia, USA.

Prof. Andrea Laghi, Full Professor of Radiology, Department of Radiological Sciences, Oncology and Pathology, "Sapienza" - University of Rome

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Dr. Manlio Mencoboni, Director Unit of Medical Oncology, Hospital Villa Scassi, ASL 3 Genova, Italy.

Dr. Salvatore Vaccarella, Scientist at Infections and Cancer Epidemiology Group, IARC-WHO, Lyon, France.

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