TANGO

D7.3 Second data management plan

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A11-INITIATIVE FOR ECONOMIC AND SOCIAL RIGHTS	RS	A11
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LIST OF ACRONYMS

Acronym	Definition
DoA	Description of Action
EC	European Commission
HaDEA	European Health and Digital Executive Agency
WP	Work Package
DMP	Data Management Plan
DOI	Digital Object Identifier
EC	European Commission
EU	European Union
FAIR	Findable, Accessible, Interoperable and Reusable
GDPR	General Data Protection Regulation
ICT	Information and Communications Technology
ODbL	Open Database License
OpenAIRE	Open Access Infrastructure for Research in Europe
POPD	Protection of Personal Data
WP	Work Package
HDSS	Hybrid Decision Support Systems

Executive Summary

This document provides the first Data Management Plan (DMP) for the TANGO project. The deliverable provides an overview of how research data that is generated or collected during and after the project will be managed, while also describing which standards will be followed and how this data will be shared.

It is important to note that, at the moment of the writing of this new version of the DMP, the project as a whole is finishing its month number 18 and the tasks related to the organisation of the local case studies have started only for 9 months. While this has allowed us to expand the first version of the DMP to specify use case specific information (such as specific datasets, procedures and security measures), it is worth considering that the design and definition of all of the four use cases is still being actively evolved by the TANGO partners. Only one of the four case studies has, to this date, already submitted its research protocol to an ethics board for its approval.

As such, we expect the next revision of this DMP (at M36) will close the loop and address all outstanding areas like providing definitive datasets schemas for each case study, defining the local procedures for transparent data collection, its secure storage and generation of the final outputs while aligned with Open Science principles.

Please note that this document, after the introductory sections, follows the template for the Data Management Plan provided by the European Commission[1]. Furthermore, each of the sections will include a paragraph explaining what are the changes done within that section (if any) for the M18 revision of the DMP.

[1]https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

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1. Data Summary

The TANGO project objectives include the development of hybrid (AI and human) foundations, paradigms and decision support systems for real world applications. To achieve this hybrid approach the TANGO project necessarily requires the involvement of human participants and the management of their related data.

In a Work Package (WP) specific basis the following are the project's need for managing data:

- WP1: through the work in tasks T1.2 and T1.3, the TANGO work package 1 will execute experimental validation of hybrid human and ai theories. More than the standalone case studies organized by WP5, these experimental validations will take the form of small exercises and experiments with human participants. In the DoA, WP1 tasks mention that some of the datasets produced by these activities will be published in Open Data repositories so this will be further developed on this and future versions of this deliverable.
- WP5: in charge of coordinating (T5.1), organising and managing the main four TANGO case studies (T5.2, T5.3, T5.4 and T5.5). These case studies are used to evaluate and provide data for the developed TANGO AI systems. More information about these four use cases is discussed in the next sub section.
- WP2 and WP3: research-centric work packages that use original research and information coming from the case studies to propose and define AI algorithms. These include algorithms for synergistic human machine learning (WP2) and algorithms for hybrid decision-making (WP3).
- WP4: a technical and implementation focused work package. WP5 will specify and redesign (T4.1) the TANGO proposed AI systems, to then engineer and implement (T4.2) for their use in the project, which then would be able to be deployed and operated (T4.3) for their use in project demonstrators (T4.4). These activities imply the systematic management of user data and as such will be focused extensively on this and future versions of this document.
- The rest of the project: the rest of the project is organised to facilitate the organisation of the previous activities (WP7) and disseminating its key results for maximum impact (WP6). This last one point is of key importance and will be further discussed on this and future versions of this document.

Updates for M18 are mainly focused on 1.1.1. They show significant progress not only in defining the types of data to be produced across all case studies but also provide greater specificity regarding its nature, sources and alignment with FAIR principles. The design and organisation of data collection and management procedures for each of the case studies in the terms defined in the below subsection "1.1 Definition on research data", has revealed that in some cases (for additional data protection or for considerations related to its management) the two first layers identified in Figure 1 are carried out in-situ at the data provider's infrastructure. This means that sensitive data (e.g., medical records in T5.2/T5.3, financial data in T5.4, and government policy data in T5.5) will remain restricted to their respective institutions, while anonymized or aggregated datasets for internal project research will be either still be kept in their respective institutions or securely transferred to research environments depending on the case study.

Some aspects still need further refinement in future iterations of the DMP. For example, while the dataset structures have been outlined, details on final data formats for interoperability and archival still need to be determined. Additionally, annotation processes for AI model training (particularly in cases involving medical imaging in T5.3 and fairness audits in T5.4, T5.5) require further specification.

1.1 Definitions on research data

The TANGO project has committed to follow an Open Research Data approach to the management of research data. The project will collect and generate data mainly related to the case studies that will be designed, deployed, and piloted within the scope of WP5. The rest of the project will use this data internally for their research-centric objectives and, finally, a carefully chosen subset/summarization of that data will be published in open repositories.

These three stages and categories for the data managed in the TANGO project have been summarised, along with their key involved elements, in the following figure.

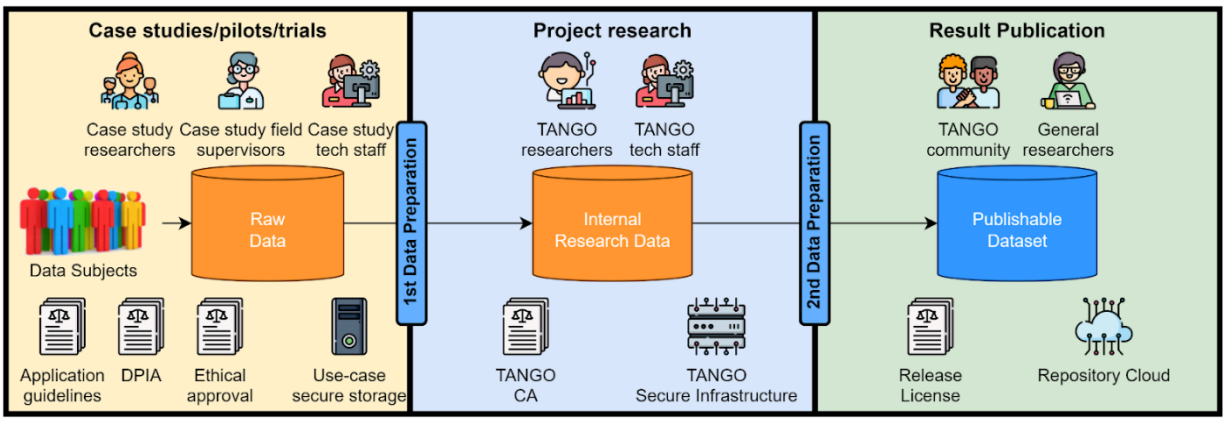

Figure 1: The TANGO project three data management categories and their involved persons, storage and regulating documentation.

1. Raw Data: data collected or generated during the TANGO project activities towards the achievements of its specified goals. This includes statistics, experiment results, measurements, and observations resulting from fieldwork, survey results, and interview recordings.
2. Internal Research Data: obtained from the previous level Raw collected/generated data by performing data preparation, anonymization and summarization operations. This category of data can be requested by TANGO partners for performing activities towards the project objectives.
3. Publishable Dataset: It is expected that the datasets produced during the TANGO project are of interest to researchers of a community wider than the TANGO project itself. Nevertheless, due to the sensitive nature of some data, only a limited subset, properly anonymised and aggregated, will be made publicly available for further research.

These categories and details for their management will be discussed throughout the rest of this document.

1.1.1. Datasets to be produced during the project

The TANGO project will need to produce and release numerous datasets of the three identified data management categories to achieve its objectives, and in this subsection the specifics related to the formats, dimensions and structure (fields and internal organisation) some of this information is already available in this version but the rest will be specified in future versions of this document.

Currently the TANGO project is before the end of its month 18 and none of the case studies have actually started their data collection/processing tasks, so this DMP document contains only partial information that will be finalized for the future D5.2 (the Design of case studies) and the next iterations of the DMP.

Generally speaking, at the current stage of the project, we can identify three main categories of data that will be generated through research activities in TANGO: personal data on the user (inc. data from personal health records in the perinatal wellbeing one), behavioural data and interactions data. To better give an idea of the context in which this will generated we present below a quick summary of the four TANGO use cases.

New to this version of the DMP are the "Dataset Overview", "Data Sources & Storage" and "Sensitive Data" considerations for each of the four case studies below:

- Perinatal health and wellbeing: this pilot will be focused on developing a personal assistant supporting women in making decisions during pregnancy and post-partum.
    - *Participants*: MLU, TUDA, AFL, UoS, UNIPI, UNITN.
    - *Activities*: design, implementation, and evaluation of a digital screening and interactive agent for decision support to help early detection of diseases and inferior peripartum outcomes.
    - *Location*: The study will be conducted at Depts for Halle and Tubingen in accordance with the Declaration of Helsinki, with participants recruited following defined inclusion criteria and data acquisition approved by the ethical board of Halle University.
    - *Evaluation*: The study will randomly assign participants to one of two groups: an intervention group, which will engage in interaction with the TANGO agent, and a control group, which will receive usual treatment. Evaluation will include (i) usefulness, (ii) user-satisfaction, (iii) user engagement, (iv) user behaviour. The study will provide feedback for cognitive studies.
    - *Dataset Overview*:
        - Self-reported outcomes (PROs): Data collected via the Mein Pia Health Mama Care app at five time points (T1-T5).
        - Medical history & pregnancy risk factors: BMI, nicotine consumption, exercise, and blood pressure.
        - Psychosocial burden data: Depression, anxiety, stress levels, and perinatal bonding.
        - Decision-making scenarios: AI-supported suggestions for social service referrals and vaginal birth after cesarean (VBAC).
        - Healthcare professional decisions: Records from medical staff on early interventions and patient counseling.
    - *Data Sources & Storage*:
        - Collected via mobile app and linked to hospital eCRF records.
        - Stored on secure hospital servers with encrypted pseudonymized IDs.

- *Sensitive data*: most of the data in this case study is highly sensitive, for this reason the current hospital infrastructure which already securely collects and uses this information will be used, avoiding duplicating or less safe research environments. More details about this are forthcoming.

- Supporting surgical teams in making intraoperative decisions: involves complex medical scenarios and teams of expert human decision makers. The objective is developing a tool for hybrid intraoperative decision making in the surgical operating room.
  - *Participants*: UNITN, APSS, SuS, AFL, UoS, UNIPI, UPC.
  - *Activities*: the trained agent will be integrated in the simulator running on the augmented operating room at DISI, and it will interactively engage with the team before and during the operation, to support them in making the most appropriate decisions.
  - *Location*: the task will be run in cooperation with the Centre for Medical Science of UNITN, APSS and the laboratory of Prof. Marco Zenati at the Harvard Medical School
  - *Evaluation*: the TANGO agent will be evaluated in simulated surgical operations where its effectiveness in contributing to the success of the endovascular surgery will be measured based on the reduction in the number of incorrect decisions made by a trainee surgical team when interacting with the agent, compared to the number of incorrect decisions made when operating without the support of the agent.
  - *Dataset Overview*:
    - Retrospective patient data: 1,200 EVAR cases over 10 years from Santa Chiara Hospital.
    - Medical imaging data: Pre- and post-operative CTA scans and intraoperative angiograms.
    - AI-extracted morphological and hemodynamic features: Vessel structure, blood flow, radiomics.
    - Surgical decision data: Stent-graft selection, procedural planning, and complication follow-up.
    - Simulation training data: Data from the ANGIO Mentor simulator for evaluating AI-guided intraoperative support.
  - *Data Sources & Storage*:
    - Raw patient data stored within APSS hospital servers (GDPR-compliant).
  - *Sensitive data*: while still medical the more specialized information in this case study makes it harder to retrace back to the individual and it also doesn't include social or medical history data. Regardless, a similar general approach will be used, where the data remains in the secure store of the institution that compiled and analysis is performed in-situ (without partial or total duplication). Furthermore researchers will only have access to an anonymized version of the dataset and further anonymization/generalizations will be considered for the research outputs.

- Supporting loan officers and loan applicants in credit lending: will develop a decision support system for credit lending, helping both bank officers to make fair and safe decisions on loan applications, and applicants to receive transparent explanations and recommendations.
    - *Participants*: FBK, ISP, UNITN, SNS, UNIPI, CNR, CEPS, BCAM.
    - *Activities*: design, implementation and evaluation of an interactive TANGO agent supporting bank officers and bank customers in the credit lending decision process. The Data Science and AI unit from the partner (ISP) will provide the domain expertise and data.
    - *Location*: Italy
    - *Evaluation*: The system will be evaluated with respect to answering the following questions: does the interaction orchestrated by TANGO: 1. increase the trust of the loan officer in AI systems? 2. help the loan officer assess applicants' creditworthiness? 3. help the loan applicant understand the outcome? 4. help the applicant reach the desired outcome?
    - *Dataset Overview*:
        - Loan application dataset: 235,000 personal loan applications (2016–2019) from Intesa San Paolo.
        - Socio-demographic attributes: Age, income levels, family size.
        - Financial history & risk assessment: Credit scoring, banking services used.
        - Loan decisions & AI explanations: Approval/rejection outcomes, counterfactual recourse pathways.
        - Bias detection outputs: AI fairness evaluations based on sensitive attributes.
    - *Data Sources & Storage*:
        - Historical banking data stored securely at Intesa San Paolo.
        - Loan officer decision records collected via AI system interactions.
        - A secure research environment is being put together for the research
    - *Sensitive data*: because of details of the study, sensitive socio-demographic and financial data are part of the Internal Research Data. Additionally to anonymization, this will be managed through secure local and project-wide infrastructures. The specifications for this are currently under development and will be shared in future documents.
- Supporting policy makers in shaping social welfare policies: the objective is developing a tool for hybrid social policy making, aimed at ensuring fairness and transparency in government incentive allocation in the domain of family welfare and demography.
    - *Participants*: IVI, FBK, MFWD, A11, SHARE, CEPS, BCAM
    - *Activities*: design, implementation and evaluation of a TANGO Hybrid Decision Support system supporting policymakers within Serbia's ministry of family care and demography (MFWD). Different stakeholders will interact with the TANGO framework through a web portal, connecting the AI agent, policy makers and citizens.
    - *Location*: Serbia
    - *Evaluation*: The system will be evaluated in terms of both policy maker and citizen satisfaction.
    - *Dataset Overview*:
        - Demographic & economic data: Income levels, regional disparities, welfare needs.

        - E-Science portal data: Researcher profiles, gender-based career gaps.
        - Survey data on female researchers: Work-life balance, mentorship access, discrimination experiences.
        - AI-generated policy insights: Welfare allocation recommendations, fairness audits.
        - Conversational AI interactions: Queries and responses for policy decision-making.
    - Data Sources & Storage:
        - Primary data collected from government databases (MFWD, E-Science Portal).
        - Survey responses stored on IVI and Ministry servers.
    - Sensitive data: similarly to the last use case, this case study contains sensitive socio-demographic and work experience data that will be anonymized before leaving its original storage. The specifications for the procedures and secure research infrastructure for the management of that data are currently being developed and will be part of future versions of this document.

1.1.2. Pre existing data

As stated in the TANGO DoA, the following datasets are available at the start of the project:

- UKHD/HALLE: has 3 years of anonymised data about perinatal outcomes and patient-reported-data.
- UNITN: anonymised data consisting of around 1,000 surgical procedures performed at the Santa Chiara Hospital in Trento in the last 10 years.
- ISP: 3+ years of anonymised data about credit lending procedures and their outcomes
- MFWD: long-term data concerning compensation for vulnerable groups such as parents with children with special needs, children without parental care, financially disadvantaged families, just to name a few. MFWD also has data about the demographic picture in the context of balancing the age structure, maintaining the spatial balance of the population and the revitalization of rural areas.

These datasets will be kept in their original institution and managed under their previous data management agreements and their current licences.

2. FAIR Data

The TANGO project has committed to following FAIR data principles as defined in H2020 Programme Guidelines on FAIR Data Management[2]. The M18 update includes a substantial expansion of metadata descriptions for each case study. This ensures that datasets can be easily identified, indexed, and retrieved in compliance with OpenAIRE and Open Science principles.

Nevertheless, as each case study is still designing their interventions there is still work to be done for defining how the research outputs are going to be shared. For example, the project still needs to establish a standardized metadata template that applies across all case studies to improve consistency and searchability. Additionally, the selection of repositories for dataset publication has not yet been finalized, and persistent

[2] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

identifiers (such as DOIs) have yet to be assigned to ensure long-term traceability. Future iterations of the DMP will clarify these issues, ensuring that datasets are both easily findable and compliant with Open Science best practices.

2.1. Making data findable

It is expected that the datasets produced during the TANGO project are of interest to researchers of a community wider than the TANGO project itself. As such, one of the main objectives of the data preparation operations for converting TANGO Internal Research Data to Publishable Data is to properly document it with machine-readable metadata to facilitate its discovery.

To facilitate finding and using of the resulting data, best practices for data stewardship (including data cleaning and curation, data preservation) will be adopted. All data will be supported by a rich set of metadata, expressing in a machine-readable format how the data was collected and processed. Finally, a rich set of keywords and a DOI will be provided for significant releases to further favour the indexing of the produced datasets.

2.2. Making data accessible

All TANGO partners are committed to making their results as open as possible, as early as possible, and as available as possible. The principles of openness and transparency will underlie all research activities, fostering sharing and collaboration as early as possible, and throughout the project´s life.

Data will be made accessible and findable also through Zenodo or similar open data repositories. The specific repository to store the TANGO project will be decided after a careful analysis. The considered factors for that analysis will encompass a number of qualitative issues that may completely override the numerical analysis (i.e. cost, capacity, expertise, investment, scalability, strategic importance).

With respect to data that is part of publications (e.g., articles, papers), they will be made available as open data. Open and transparent practices will be implemented in line with the open science policy in Horizon Europe, encouraging the use of the Open Research Europe (ORE) publishing platform, the European Open Science Cloud (EOSC) and the open repository for research objects, ensuring availability and findability.

Before data becomes of the Publishable Data category and is able to be published, and following what is stipulated in the TANGO GA and following the TANGO CA, an embargo period may be applied on the data.

2.3. Making data interoperable

The TANGO consortium in its effort to make the project's datasets as accessible and interoperable as possible will seek compliance with open standards. More specifically, data will be stored using open data formats and implementing open standards that will follow best practices and guidelines for working with open data.

Data stored will be accompanied by relevant metadata to ensure re-usability of the data by third parties. The project will adhere to W3C Data on the Web Best Practices.

2.4. Making data reusable

Datasets produced in the project will be annotated with documentation that contains, in a machine-readable way, global information about the dataset's origin (date and location of creation, details about the experiment that created it and the specific objectives for doing so) and its encoding format. Furthermore, each field/column will also be documented with information about its semantics, format, accuracy and other details. When considered necessary, a human-readable codebook will be generated for each dataset explaining details related to the execution of the activities that produced the dataset and possible issues and limitations for the dataset.

Continuing the project's commitment to Open Science, permissive and open licences will be used to maximise reusability of the produced datasets. More information will be provided in future releases of this document.

3. Other research outputs

Computer runnable code is one of the key 'other research output' identified at this stage of the project so more details are given in the subsection below. Other potential outputs (e.g., training materials, techniques, methodologies, modelling materials) along with their dissemination will be discussed in future versions of this document.

3.1. Computer Code

The TANGO project source code policy is in line with the open science philosophy. As stated in the DoA, the TANGO software library will be released as open source under an Apache v.2 licence. To maximise the impacts of the project activities, single components of the TANGO software ecosystem will be published (in the category `AI assets') in the AI-on-demand platform developed by AI4Europe.

This will ensure that the research community at large will be able to independently use the TANGO methods and algorithms, improve them and combine them to devise novel solutions to high-impact projects. At the same time, this will also allow innovators and entrepreneurs to build sustainable business propositions enabled by the TANGO results, leading to new ventures and job creation.

4. Allocation of resources

Most of the costs related to data management and GDPR/FAIR compliance have been already accounted for in the project proposal and then the TANGO DoA. The effort for these activities has already been distributed among the different data management centric work packages (mainly WP5 but also WP1, WP4, among others).

As compiled in D5.1, the trial handbook, the current responsible persons for each of the pilots is compiled in the following table.

Table 1: Trial Team roles, names and organisations.

Trial Name, Task	Trial Owner, Organization	Technical Coordinator, Organization	Practitioner coordinator, Organization	Evaluation coordinator, Organization
T5.2 (Improve/Increase) perinatal health	Prof. Dr. Markus Wallwiener (HALLE)	Tim Tobiasch (TUDa)	Prof. Dr. Stephanie Wallwiener (HALLE)	Prof. Dr. Eva Kantelhardt (HALLE)
T5.3 A surgical decision making	Andrea Passerini (UNITN)	Erich Robbi (UNITN)	Annalisa Trianni (APSS)	Stefano Bonvini (APSS)
T5.4 - Credit Lending	Bruno Lepri (FBK)	Simone Centellegher (FBK)	Daniele Regoli (ISP)	Andrea Cosentini (ISP)
T5.5 - Policy	Dubravko Culibrk (IVI)	Slobodan Ilic (IVI)	Ana Martinovic (SHARE)	Milica Marinkovic (A11)

At M18, there is a better definition of the types and volume or amount of data that will need to be stored and secured for achieving the project objectives. Nevertheless concrete details about the infrastructure that will be needed (or if any will be needed, as some case studies have decided to perform their research within the infrastructure of the hosting organizations for extra security) will be updated in future versions of this document with its details and management/security policies.

5. Data security

This section defines the general data security provisions for the two more restrictive TANGO data categories.

More concrete technical and operational details of how these requirements will be implemented have not been fixed yet, at the current state of the project when this document has been released. Nevertheless, this section will be updated with those details in future versions as the TANGO infrastructure is developed and the case studies and applications specified.

At M18 there has been good progress in defining the data that will be collected and how to keep it secure across different case studies. The following list is a quick summary of use case specific progress:

- Perinatal health and wellbeing:
  - Encrypted pseudonymized patient IDs.
  - At the end of the study, study keys and IDs will be deleted, and demographic data will be anonymized.
- Supporting surgical teams in making intraoperative decisions
  - Strict PACS storage controls for CTA and angiogram data.
  - Anonymization before AI feature extraction.
- Supporting loan officers and loan applicants in credit lending
  - Strict financial data security policies.
  - Loan application data is encrypted
- Supporting policy makers in shaping social welfare policies:

- Data from the E-Science portal is accessed securely by the research team

Taking these evolving specifications and requirements into consideration, the next DMP will formulate the appropriate general project-wide requirements and procedures for data security.

5.1 Provisions for Raw Data

The respective pilot, case study or application leaders (see Table 1) will serve as the data controller for the raw collected dated data and will be responsible to implementing the following security measures:

- Storage that is secure, encrypted and password protected by individual access credentials in the infrastructure from its institution.
- Transfers from and to this storage should be similarly encrypted and protected by individual access credentials.
- Participants will be identified by the use of pseudonymized study IDs
- The study's keys and access will be restricted only to the study/pilot staff and the developers of the applications.

5.2. Provisions for Internal Research Data

Research data is obtained from the previous level Raw collected/generated data by performing a data preparation operation. This data preparation operation will be carried out, under the responsibility of the original data controller of the raw collected data, within six months of the completion of the study that generated it and will involve:

1. The anonymization of the collected data by deleting the participant pseudonyms, other study keys and the sociodemographic/sensitive data.
2. The duly justification of any remaining personal and sensitive data to make sure that it is relevant and limited to the purposes of the project activities (in accordance with the 'data minimisation' principle).

The resulting data is called Research Data and has the following security requirements:

- Storage that is secure and password protected by individual access credentials in the infrastructure from its institution.
- Transfers from and to this storage should be similarly protected by individual access credentials.
- In accordance with GDPR's storage limitation principle this information will be kept for at most 5 years after the end of the pilot / case study that generated it. Though the door is open for certain categories and when duly justified (e.g. medical record keeping institutional policies), to extend this to 10 years.

The TANGO project consortium partners are the primary target audience for Research data. To access it, the TANGO partner will send a written request to the dataset controller in which the following information will be contained: i) name of the persons to be granted access, ii) duration of this access and iii)activities for

which the data will be used. The data controller will then decide to approve the request and share access information if the request is aligned with the TANGO project objectives.

The partner receiving access to Research Data, commits to:

- Follow the rules in the TANGO CA and TANGO GA related to data management and secrecy.
- To use the data during the timeframe and for the activities specified in the written access request and to delete it after these purposes have been achieved.
- To keep data secure and comply with the same security requirements as the data controller.

5.3. Case Study Data Governance Roles

The following are the identified Data Governance Roles for each of the Case Studies, those marked as "preliminary" are expected to be refined and finalized in the next iteration of this DMP.

- T5.2 – Perinatal Health and Wellbeing Data Controller:
  - University Hospital Halle (Saale), responsible for collecting and managing patient data via the "Mein Pia Health Mama Care" app and hospital records.
  - Data Processor: the app platform and any analytics tools used in the backend may act as processors under the hospital's oversight.
  - Accountability: ethical approval obtained, and consent forms clarify the data flow, including withdrawal rights. Data remains pseudonymized and stored locally.
- T5.3 – Surgical Decision-Making
  - Data Controller: APSS (Azienda Provinciale per i Servizi Sanitari), responsible for retrospective and prospective clinical data and imaging collected within the hospital systems.
  - Data Processor: University of Trento (UniTN) receives only anonymized AI-extracted features and does not process personal data directly.
  - Accountability: the protocol clearly defines that no identifiable data leaves the APSS infrastructure. Access to imaging and records is logged and restricted.
- T5.4 – Credit Lending (preliminary)
  - Data Controller: Intesa San Paolo (ISP), responsible for all historical and ongoing financial application data.
  - Data Processor: internal teams within ISP, as the data remains internal. Anonymized or aggregate outputs may be shared with other partners under specific agreements.
  - Accountability: Data remains within the bank; ethical risks are addressed through fairness audits and AI explainability research. No personal data is shared externally.
- T5.5 – Social Welfare Policy (preliminary)
  - Data Controller: Ministry for Family Welfare and Demography (MFWD), Republic of Serbia, managing data from the E-Science portal and government databases.
  - Data Processor: Institute for Artificial Intelligence Research and Development of Serbia (IVI), handling survey deployment and initial data collection.
  - Accountability: survey responses are anonymized upon collection. The Ministry oversees all personal data. AI-generated insights shared externally are fully anonymized.

With regards to processing the collected data, where precise methods are not yet fully defined, the projects commits to considering and employing additional technical anonymization standards such as:

- K-anonymity and L-diversity principles for structured data, to ensure no individual is uniquely identifiable in the dataset.
- Differential Privacy (e.g. Laplace mechanism) for statistical summaries and AI model training where applicable.
- Suppression and generalization (e.g. age ranges instead of birth dates, ZIP code truncation).
- Separation of quasi-identifiers and key files, with restricted access to re-identification keys and audit logging for all access.

Additionally, before sharing or Open Science publication, TANGO partners will follow the EDPB's 2021 guidelines on anonymization and conduct a re-identification risk assessment for datasets considered especially important or sensitive.

6. Applicable regulations

This section will detail the legislations, regulations and guidelines that the project will consider for its data management procedures and practices.

For M18 the reference to some of the regulations have been updated, furthermore, and in 6.1.5 a quick report on the progress on preventing bias related to gender issues has been added.

6.1. Ethics

6.1.1. General Data protection

When personal data is involved, the TANGO project will ensure compliance with the General Data Protection Regulation which regulates the processing of personal data in the EU and its aim is to ensure individual fundamental rights. This includes the following:

- DPIA, all TANGO case studies will act according to the article 35 of the GDPR performing the data protection impact assessment when needed. This includes providing detailed information
  - On what personal data is collected, stored and processed;
  - On the recruitment process, inclusion/exclusion criteria for participation;
  - On privacy/confidentiality and the procedures that are implemented for data collection, storage, access, sharing policies, protection, retention and destruction during and after the project;
  - On how informed consent is pursued;

        - if application/is needed to be filed with a local/institutional ethics review body (if personal data is being collected) and if yes, which bodies / where / when.
        - A dynamic and phased DPIA framework will be applied in order to maintain an ongoing risk assessment framework. DPIAs done at data collection time may be repeated before processing or sharing to account for the fast-changing landscape of data protection and emerging technological challenges.
    - All research and development activities conducted within the scope of the TANGO project will be mindful of the "Privacy by Design" principle of article 25 GDPR, as well as article 22 GDPR assuring compliance with automated individual decision-making including profiling.
    - Some of our case studies require sensitive data input (like for example pregnancy support and loan decisions) so the management of these in a responsible, ethical way is crucial for the project.

The TANGO project must process personal data under the Agreement in compliance with the applicable EU, international and national law on data protection (in particular, Regulation 2016/67916). The project must ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subjects
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the data.

The TANGO project may grant its consortium members access to personal data only if it is strictly necessary for implementing, managing, and monitoring the project. The TANGO project must ensure that its members having this access are under a confidentiality obligation.

6.1.2. Raw Data management

The previously defined TANGO Raw Data category is specifically relevant as it is the one containing the most sensitive information in the project and as such should be the most protected.

The data management of this category of data will be guided and regulated by the following documents (as seen in Figure 1):

- Application Guidelines: document with guidelines for the implementation and coordination of the applications. It will provide common guidance, best practice and support for the TANGO applications and case studies. This will be released as deliverable D5.1 in M6.
- DPIA: each data processing operation where personal data is involved (like project applications or case studies) requires the creation of a Data Protection Impact Assessment (DPIA). The objective of

this document is to help assess, identify, and minimise risks that may result from data processing. DPIAs are further used to interact, get feedback and ultimately the approval of privacy protecting officers and ethical committees.

- Ethics Approval: each data processing operation where personal data is involved is required to be approved by a local ethics commission. The existence of this document ensures that the project activities and their particular implementation in the target location, have been deemed ethically appropriate. The partner in charge of the application or case study must submit the request for review of their institution's ethics committee and get its approval. In the absence of the ethics committee figure, the partner must work with the coordinator to identify the alternative suitable figures to perform this task. As part of the Ethics approval, two further documents must be also created:
    - Privacy Statement: document used to inform the potential participants on the technical and organisational measures to safeguard the rights of the research participants. The main objective of this document is to promote transparency and to give individuals more control over the way their data is collected and used.
    - Informed Consent: to be processed, personal data requires free and fully informed consent from the involved persons. Obtaining in advance and clearly documenting the data subject informed consent ensures that all participation in these project activities are voluntary and the subjects are aware of their rights.

6.1.3. Consent management and data subject rights

Across the TANGO case studies, informed consent is recognized as a cornerstone of ethical data processing. The mechanisms for obtaining, recording, and managing consent vary by case study, reflecting the diversity of data types and regulatory environments. For example, in the T5.2 Perinatal Health case study, informed consent is obtained directly through participating clinics at University Hospital Halle. Participants are provided with detailed written information explaining the purpose of the study, data handling procedures, and their rights. Consent is documented using hospital-standard forms and stored with encrypted identifiers. Additionally, in T5.3 Surgical Decision-Making, APSS collects written consent during patient onboarding, and a clear distinction is made between clinical care and participation in research. The protocol includes a GDPR-compliant template (that can be found in the appendix) that details how patient data will be used, anonymized, and, where applicable, used.

In studies involving direct participant contact, data subjects can withdraw their consent at any time. The withdrawal process is described in the consent forms and includes contact information and a no-retaliation clause. Upon withdrawal, all personal data associated with the participant is deleted unless no longer possible. Data subjects have the right to access, rectify, or erase their personal data in accordance with GDPR Articles 15–17. These rights are communicated in consent forms and managed by the institutional data controllers, with requests processed within the regulatory timeframe (usually 30 days).

6.1.4. Proof of due diligence documentation

In order to keep an auditable document trail of the project data management activities and agreements, the following signed documents need to be accessible digitally in a project shared storage space:

- DPIAs: final version of the DPIA document, with the written approval (through email or document) by the institution data protection authority.
- Ethical Approvals: final version of the document and all associated material submitted to the Ethical Committee for their approval. The letter or email where the committee expresses their feedback and approval should also be preserved.
- Privacy Statements: the final text of the Privacy Statement given/displayed to study participants.
- Proof of informed consent: either a signed document (in the case of a paper/in person-based study) or a table summarizing the names/pseudonyms (in the case of a digital based study) of the persons that have voluntarily accepted participating in the study.

This documentation will be shared with the project's Ethical Advisor for feedback and identification of potential issues. Furthermore, it will be preserved for at most 5 years after the conclusion of the studies they refer to.

6.1.5. Non-personal data

In terms of the governance of non-personal data, the Non-Personal Data Regulation and Open Data Directive both will be complied with while designing and running AI applications between project partners while exchanging datasets or re-using public datasets for project purposes. Furthermore, case studies will adopt state of the art ethical standards for datasets and model reporting such as Model Cards or Datasheets frameworks. Project will also comply with national data protection legislation and relevant technology norms and standards.

6.1.6. AI, Marketplaces and Gender considerations

Beyond the Data Protection aspects and the requirements of approval by local Ethics Committees that were previously mentioned and, because of the type of objectives and subjects that the TANGO project is focused on, significant regulatory progress is expected throughout the duration of the project with regards to the topics of Digital Markets and Artificial Intelligence.

To take into the account this combination of both mature and evolving regulation and make sure that the TANGO project complies with its commitment to ethical research practices, it will follow the following four-point strategy:

1. Compliance with regulations will be achieved by considering a broad legal framework at every relevant step of the project. The machine learning development process and the case studies specifically will be continuously assessed for compliance with existing and forthcoming EU Directives and Regulations. Such existing legal texts include in particular Directive 2000/31/EC on electronic commerce, Directive 2002/58/EC on the processing of personal data and the protection of privacy in the electronic communications sector (E-Privacy Directive), Regulation (EU) 2016/679 best known as General Data Protection Regulation (GDPR), Regulation (EU) 2018/1807 on the free flow of non-personal data, and the Directive (EU) 2019/1024 on open data and the reuse of public sector information.
2. The Ethics Guidelines for Trustworthy AI will be considered at every step of the project and provide an additional AI governance framework to ensure responsible use and creation of AI. We will ensure

that the project's methodology complies with the 'do no significant harm' principle as per Article 17 of Regulation (EU) No 2020/852 on the establishment of a framework to facilitate sustainable investment, also known as the EU Taxonomy Regulation. This means that the project is designed in a way it is not significantly harming any of the six environmental objectives.

3. At the heart of the compliance assessments will be a data justice approach [Solano, et al. 2022], which centres on equity, recognition and representation of plural interests, and the creation and preservation of public goods. Beyond compliance with existing EU regulations, the TANGO coordinator will continuously monitor if a pilot or the TANGO technology requires consideration of a broader normative context. Soft law approaches like the digital rights theory, and industry standards will be consulted where law lacks sufficient effectiveness to mitigate risks related to the cutting-edge technology employed in the case studies. The project's outcomes will be future proofed through a focus on compliance with forthcoming regulations like the so-called AI Act, the AI Liability Directive, the Data Act, and the Data Governance Act.
4. Where appropriate, cross-disciplinary recommendations for future regulation will be put forward with the aim of enhancing effectiveness and efficiency of the governance of cutting-edge AI technology

Since the main legislative act tasked with fundamental rights protection in the AI domain is still a work in progress, the project will turn to soft normative frameworks for AI governance. Furthermore, the project is set to run in the interval of substantial legal volatility regarding digital economy regulation. The next years might see the normative landscape of the AI governance transformed under not only horizontal regulations such as the AI Act but also specific sectoral regulation making compliance an even more hectic endeavour than it regularly is. TANGO partners are aware of this specificity and will adjust the compliance strategy accordingly to the legal reality.

In particular, to prevent gender bias in machine learning models, the TANGO project will develop methods for mitigating unexpected, at times, catastrophic failure in learning caused by subgroup imbalance within the training data. In the context of algorithmic fairness, subgroups refer to demographic attributes including overlapping dimensions of race, sex, gender, age, and disability (intersectional fairness). Methods for auditing inappropriate bias against those protected subgroups will also be developed.

At M18 General methodological progress has been made in avoiding biases (including gender related ones) in deliverables that will be implemented as part of the project work. Additionally, use cases are also working on case-study-specific AI governance measures. Ensuring that AI systems used in medical decision-making, financial lending, and social policy are explainable, bias-aware, and compliant with ethical guidelines.

Finally, it is worth noting that the TANGO project has an ethical advisor that will closely follow and produce written assessments and feedback that will be taken into account for the evolution of the data management strategies in the project.

6.2. Legislation

All partners will adhere to relevant national and international laws, guidelines and policies, including:

1. Legislation and recommendation on human rights, dignity and integrity of the user
    a. Universal Declaration of Human Rights (United Nations)
    b. Charter of Fundamental Rights of the European Union (2010/C83/02)
    c. Convention for the Protection of Human Rights and Fundamental Freedoms (Council of Europe)
2. Legislation and recommendations on personal data
    a. EU General Data Protection Regulation (GDPR) on the protection of individuals with regard to the processing of personal data and on the free movement of such data and was designed to harmonise data privacy laws across Europe, to protect and empower all EU citizens data privacy and to reshape the way organisations across the region approach data privacy. The General Data Protection Regulation No 2016/679 applies from 25 May 2018.
    b. Article 29 Working Group 05/2014 Opinion on Anonymization Techniques.
    c. Handbook on European data protection law by the European Union Agency for Fundamental Rights and the Council of Europe (2013)
    d. (within the territory of Serbia) Serbia Data Protection Law (Official Gazette of RS 87/2018) from 9 November 2018, with its applicability starting from 21 August 2019.

7. Other Issues

No major updates of this section for M18, the progress in each of the case studies has just confirmed that no confirms that no direct transfers of raw personal data outside the EU are needed.

7.1. Non-EU Countries

In the case personal data is transferred from the EU to a non-EU country or international organisation, it must be in accordance with Chapter V of the General Data Protection Regulation 2016/679. In case personal data is transferred from a non-EU country to the EU (or another third state), it must comply with the laws of the country in which the data was collected. Furthermore, the project provides that non-EU members will be compliant with European regulations as legally binding in the signed Grant agreement. Therefore, the enforcement on these countries will be based on the procedure and documents produced in the context of European legislation, with measures that safeguard local law.

As previously stated, the TANGO project will comply not only with the General Data Protection Regulation (GDPR) from the European Union, but also will adhere to high ethical standards for data management. Even Non-EU project members, who signed the Grant Agreement, will be legally bound to the GDPR Regulations and have committed to follow the project's ethical standards.

The challenge of transferring data from the European Union to project members in non-EU countries and vice versa will be addressed by establishing adequate technical and organisational measures protecting the personal data from our data subjects across continents and considering intercultural information ethics as the basis for data protection activities. This involves the use of the following legal mechanisms where appropriate:

- Standard Contractual Clauses (SCCs) for transfers to countries without an adequacy decision.
- Adequacy Decisions where the recipient country is recognized as providing an adequate level of protection
- Data Transfer Agreements (DTAs) will be signed between partners to outline safeguards, responsibilities, and redress mechanisms.
- Technical measures such as encryption, minimization, and pseudonymization will be applied prior to transfer to mitigate re-identification risk.

8. Conclusions

This document represents the first TANGO Data Management Plan (DMP) that was delivered at the end of the eighteenth month of the project. It is important to note that no activities related to data collection or generation have yet officially started. And as such the policies and procedures contained in this document should guide the creation of the more operative documents to be used for those activities.

Three levels of category of data within the TANGO project have been defined in this document: i) raw collected/generated data; ii) research data; and iii) publishable data. Data processing pipelines and methodologies have been established for each. It is also defined that to the extent consented by privacy directives all data that is generated will be openly available as FAIR data, using interoperable data formats and published under licences facilitating reuse. Furthermore, these datasets will be uploaded for long term preservation to the Zenodo or similar open repositories.

As the project keeps evolving and different types of activities are planned and executed, each subsequent version of the DMP will contain further development and specification of its different sections.

The M18 DMP update represents a step forward when defining case study specific data structures, security, accessibility, and AI governance measures. However, as these are only the initial months of the case studies and none of them has actually started data collection/analysis, further refinements will be needed in upcoming versions. As the project advances toward full-scale data collection, analysis, and publication, these areas will be progressively addressed.

Two further official releases for the DMP document are expected: a) at the project's month 36, were the focus will be on unifying the details emerging from each of case studies into a general TANGO project-wide set of rules, procedures and operative details; b) at the project's month 48, at the project's end, the focus will be on how to licence and distribute the different results produced in the project.

A1: Annex I – Surgical decision-making privacy terms

Modulo "Informativa e Consenso al trattamento dei dati personali", Versione n. 3 del 23.05.2024, Comitato Etico Territoriale della Provincia Autonoma di Trento per le Sperimentazioni Cliniche

Azienda Provinciale per i Servizi Sanitari
Provincia Autonoma di Trento

INFORMATIVA SUL TRATTAMENTO DEI DATI PERSONALI
(Artt. 13 e 14 del Regolamento UE 2016/679)

Codice Protocollo	
Titolo Protocollo	Supporting surgical teams in pre-, intra-, and post-operative decision making
Promotore	Dipartimento di Ingegneria e Scienza dell'Informazione (DISI), Università degli Studi di Trento
Centro di sperimentazione (U.O./Servizio/ Ospedale)	U.O.M Chirurgia Vascolare
Sperimentatore principale	Stefano Bonvini
Contatto dello Sperimentatore principale	

1. Titolare del trattamento

Il Titolare del trattamento è Azienda Provinciale per i Servizi Sanitari della Provincia Autonoma di Trento (A.P.S.S.), sede legale in via Alcide Degasperi, 79 - 38123 Trento C.F. e P.I. 01429410226; e-mail/pec: urp@apss.tn.it; apss@pec.apss.tn.it

Il Titolare in accordo alle responsabilità previste dalle norme della buona pratica clinica (D.Lgs. 211/2003), tratterà i Suoi dati personali nel rispetto della normativa sulla protezione dei dati personali e in particolare dei principi di liceità, correttezza e trasparenza, pertinenza, non eccedenza, minimizzazione, e limitazione della conservazione e della finalità, e sicurezza, in conformità al Regolamento dell'Unione europea 2016/679 (o "GDPR") e al Decreto Legislativo n. 196/2003, "Codice in materia di protezione dei dati personali".

2. Contatti del Responsabile della protezione dei dati

Funded by the European Union

Il Titolare ha designato, ai sensi dell'art. 37 del GDPR, il Responsabile della Protezione dei dati personali ("DPO"), contattabile nelle seguenti modalità:

- Azienda Provinciale per i Servizi Sanitari della Provincia Autonoma di Trento (A.P.S.S.), e-mail: urp@apss.tn.it; responsabileprotezionedati@apss.tn.it; PEC: apss@pec.apss.tn.it

3. Finalità del trattamento e base giuridica

Il trattamento dei dati personali è effettuato per le finalità di ricerca relativa allo studio "Supporting surgical teams in pre-, intra-, and post-operative decision making", avente l'obiettivo di sviluppare un modello di intelligenza artificiale (AI) per supportare il chirurgo nel processo decisionale durante le procedure di riparazione dell'aneurisma aortico addominale tramite approccio endovascolare (EVAR), con il fine di ridurre l'incidenza di eventi avversi.

A conclusione dello studio, i dati personali anonimizzati verranno aggregati per consentire la divulgazione e pubblicazione scientifica dei risultati e per eventuali e ulteriori finalità di ricerca in ambito sanitario.

Il trattamento è effettuato a fronte del consenso esplicito dell'interessato o, in caso di impossibilità di ottenere il consenso, come nel caso di pazienti defunti, legittimato dalla Valutazione di Impatto del Trattamento dei Dati (Data Protection Impact Assessment - DPIA).

4. Categorie di dati personali trattati

La realizzazione delle finalità necessita il trattamento delle seguenti categorie di dati:

- Dati personali comuni;
- Categorie particolari di dati (Dati sensibili):
  - Dati relativi alla salute

5. Natura del conferimento dei dati

Il trattamento dei dati personali è indispensabile allo svolgimento dello studio: il mancato consenso al trattamento dei Suoi dati, non Le consentirà di partecipare allo studio stesso

6. Modalità del trattamento dei dati

Il trattamento dei dati personali è effettuato in modalità informatizzata e automatizzata da parte di soggetti autorizzati al trattamento e nel rispetto dei principi del trattamento dei dati. I dati saranno trattati in modo da garantirne la riservatezza e sicurezza da parte di personale autorizzato e istruito e da eventuali responsabili del trattamento ai sensi dell'art. 28 del GDPR.

Qualsiasi dato personale (immagini di tomografia assiale (TC) acquisite prima e dopo l'intervento chirurgico, immagini fluoroscopiche acquisite durante l'intervento chirurgico, referto della visita cardiologica pre-intervento e delle visite di follow-up eseguite a seguito dell'intervento) specificati in dettaglio nel protocollo dello studio, saranno raccolti dal personale del Centro di sperimentazione, organizzati, pre-elaborati, e trasmessi in forma completamente anonima ai Dipartimenti di Ingegneria e Scienza dell'Informazione (DISI) e di Matematica dell'Università degli Studi di Trento.

Il trattamento non comporta profilazioni dell'interessato o decisioni automatizzate che producono effetti giuridici o incidono in modo analogo significativamente sulla sua persona.
La documentazione sarà conservata in un archivio elettronico per il tempo prescritto dalla normativa vigente.
I dati, trattati mediante strumenti anche elettronici, saranno diffusi solo in forma rigorosamente anonima e/o aggregata per pubblicazioni scientifiche, statistiche e convegni scientifici.

7. Destinatari dei dati personali

Per le finalità sopra indicate i dati personali verranno comunicati unicamente a APSS e ad altri soggetti terzi in adempimento di un obbligo di legge o di un provvedimento dell'autorità giudiziaria.

La Sua partecipazione allo studio implica che, in conformità alla normativa sulle sperimentazioni cliniche dei medicinali, il personale del titolare o delle società esterne che eseguono per conto del primo il monitoraggio e la verifica dello studio, il Comitato etico e le autorità sanitarie italiane e straniere potranno conoscere i dati che La riguardano, contenuti anche nella Sua documentazione clinica originale, con modalità tali da garantire la riservatezza della Sua identità.

8. Trasferimento dei dati a un paese terzo e a organizzazioni internazionali

I dati personali non verranno trasferiti al di fuori dello Spazio Economico Europeo

9. Periodo di conservazione dei dati

I dati personali sono trattati per il tempo necessario alla realizzazione delle finalità sopra indicate e in particolare i dati personali saranno conservati per la durata dello studio. La durata di tale periodo potrà eventualmente essere maggiore per l'adempimento della normativa vigente.

Al termine del periodo di conservazione i dati personali saranno sottoposti ad una procedura di anonimizzazione, ovvero verranno rimossi tutti gli elementi identificativi che possono far risalire alla sua identità.

10. Esercizio dei diritti

In qualità di interessato potrà esercitare i diritti di cui agli artt. 15 e ss. del GDPR:

- diritto di accedere ai dati personali;
- diritto di rettifica dei dati qualora siano inesatti, o sia necessario integrarli aggiornarli;
- diritto di opporsi al trattamento;
- diritto di cancellazione dei dati, tranne il caso in cui si debba conservarli ai sensi dell'art. 17, par. 3 GDPR;
- diritto di limitazione del trattamento e di opposizione;
- diritto di revocare il consenso prestato. Tuttavia, la revoca non pregiudica la liceità del trattamento basata sul consenso precedentemente prestato.

Potrà interrompere in ogni momento e senza fornire alcuna giustificazione la Sua partecipazione allo studio: in tal caso, non saranno raccolti ulteriori dati che La riguardano, ferma restando l'utilizzazione di quelli eventualmente già raccolti per determinare, senza alterarli, i risultati della ricerca.

Per l'esercizio dei diritti è possibile contattare i Responsabili della Protezione dei dati personali agli indirizzi nel paragrafo 2 sopra, oppure l'Azienda Provinciale per i Servizi Sanitari della Provincia Autonoma di Trento PEC: apss@pec.apss.tn.it.

Ha altresì diritto di presentare reclamo all'Autorità Garante per la protezione dei dati personali in caso di illecito trattamento o di ritardo nella risposta del titolare a una richiesta che rientri nei diritti dell'interessato.

MANIFESTAZIONE DEL CONSENSO AL TRATTAMENTO DEI DATI PERSONALI

Codice Protocollo	
Titolo Protocollo	Supporting surgical teams in pre-, intra-, and post-operative decision making
Centro di sperimentazione (U.O. /Servizio/ Ospedale)	U.O.M Chirurgia Vascolare - Presidio Ospedaliero S.Chiara APSS
Sperimentatore principale	Stefano Bonvini
Contatto dello Sperimentatore principale	segreteriachirurgiavascolare@apss.tn.it

Il/la sottoscritto/a _____nato/a a _____
(____) il ____/____/____, per sé,
oppure
Il/la sottoscritto/a, _____ in qualità di _____
(*specificare se rappresentante legale quale tutore, curatore, amministratore di sostegno*) di _____
_____ nato/a a
_____(__) il __/__/__,

letta e compresa l'informativa di cui agli artt. 13 e 14 del Regolamento (UE) 2016/679 fornitami congiuntamente al presente documento e di cui è parte integrante, nonché ricevute tutte le informazioni comprensibili ed esaurienti sugli scopi e i limiti dello studio per il quale viene rilasciata la presente dichiarazione,

□ Acconsento □ Non acconsento
al trattamento dei miei dati personali per gli scopi inerenti allo studio nei limiti e con le modalità indicate nella predetta informativa,

alla consultazione della mia cartella clinica (cartella medica, cartella infermieristica, referti specialistici e diagnostici, relazioni sanitarie, altri documenti sanitari in essa contenuti) da parte del personale del titolare/dei titolari/dei contitolari e delle società esterne che eseguono per conto della prima il monitoraggio e la verifica dello studio, del Comitato etico e delle autorità sanitarie italiane e straniere, ai soli fini del presente studio. Il personale che avrà accesso alla mia documentazione medica sarà comunque tenuto al segreto professionale sui dati conosciuti.
□ Acconsento □ Non acconsento

alla anonimizzazione e aggregazione dei dati personali, ovvero rimozione di tutti gli elementi identificativi che possono far risalire alla mia identità, dopo la conclusione dello studio per consentire la divulgazione e pubblicazione scientifica dei risultati e per eventuali e ulteriori finalità di ricerca in ambito sanitario.

□ Acconsento □ Non acconsento

Trento,
Firma dell'interessato

Firma di *(specificare se esercente la responsabilità genitoriale, rappresentante legale)*

Firma dello sperimentatore/della sperimentatrice

Dichiarazione in merito all'impossibilità di raccogliere il consenso informato degli interessati o informarli del trattamento dei dati personali

Il sottoscritto Dott. Stefano Bonvini sperimentatore principale dello studio dal titolo: Supporting surgical teams in pre-, intra-, and post-operative decision making

DICHIARA

sotto la propria integrale responsabilità, in conformità alle previsioni del Regolamento UE 679/2016, del D.Lgs. 196/2003, come modificato dal D.Lgs. 101/2018 e dal Provvedimento del Garante per la protezione dei dati personali n. 146 del 05/06/2019, che non risulta possibile l'acquisizione di uno specifico consenso da parte degli interessati inclusi nello studio a causa della sussistenza di una delle seguenti ragioni documentate nel progetto di studio:

□ **Motivi di impossibilità organizzativa:** trattandosi di studio retrospettivo su un elevato numero di pazienti con una patologia grave e di norma anziani, è probabile che al momento dell'arruolamento allo studio siano deceduti.

Resta fermo l'obbligo di raccogliere il consenso al trattamento dei dati degli interessati inclusi nello studio in tutti i casi in cui, nel corso dello studio stesso, sia possibile rendere loro un'adeguata informativa e raccogliere la manifestazione di consenso.

_____, _____
(Luogo e data)

Firma dello sperimentatore/della sperimentatrice

Dichiarazione sostitutiva di consenso informato

Codice Protocollo	
Titolo Protocollo	Supporting surgical teams in pre-, intra-, and post-operative decision making
Promotore	Dipartimento di Ingegneria e Scienza dell'Informazione (DISI), Università degli Studi di Trento
Centro di sperimentazione (U.O./Servizio/ Ospedale)	U.O.M Chirurgia Vascolare - Presidio Ospedaliero S.Chiara APSS
Sperimentatore principale	Stefano Bonvini
Contatto dello Sperimentatore principale	segreteriachirurgiavascolare@apss.tn.it
N. Identificativo paziente o Nome e Cognome del paziente	

Il sottoscritto Dott. Stefano Bonvini, sperimentatore dello studio dal titolo: **Supporting surgical teams in pre-, intra-, and post-operative decision making**

dichiara

sotto la propria responsabilità, che secondo quanto previsto dal protocollo dello studio in oggetto, con riferimento al paziente indicato nel presente documento si procederà alla raccolta dei suoi dati personali senza la previa acquisizione del relativo consenso in quanto all'esito dei tentativi svolti di mettersi in contatto con lo stesso rappresentati in particolare da verifica dello stato in vita, consultazione dei dati riportati nella documentazione clinica, impiego dei recapiti telefonici in possesso del centro, nonché acquisizione dei dati di contatto presso l'anagrafe degli assistiti o della popolazione residente è risultato:

deceduto ☐ non rintracciabile ☐

a seguito di n. contatti totali effettuati tramite telefono ☐ mail ☐ altro _____

A2: Annex II – Surgical decision-making consent document

Informativa e Consenso al trattamento dei dati personali, versione 1 del 14/4/2021

Azienda Provinciale per i Servizi Sanitari
Provincia Autonoma di Trento

Comitato Etico per le Sperimentazioni Cliniche

INFORMAZIONI PER I PARTECIPANTI ALLO STUDIO

Codice Protocollo	
Promotori	Dipartimento di Ingegneria e Scienza dell'Informazione (DISI) dell'Università di Trento (UniTn)
Titolo Protocollo	**Supporting surgical teams in pre-, intra-, and post-operative decision making**
Centro di sperimentazione (U.O. /Servizio/ Ospedale)	U.O.M Chirurgia Vascolare
Sperimentatore principale	Stefano Bonvini
Nome e cognome del paziente	

Informazioni generali

Gent.mo paziente,
Lei è invitata/o a partecipare ad uno studio di ricerca che viene effettuato presso questo ospedale cui Lei si è rivolto per motivi di diagnosi o cura.

La ricerca richiederà di poter utilizzare dei dati che la riguardano, ed in particolare le immagini diagnostiche acquisite durante il suo percorso diagnostico-terapeutico.
La partecipazione allo studio è libera; la decisione di non partecipare, così come la decisione di ritirarsi in qualsiasi momento, non pregiudica le cure attuali e future alle quali lei ha diritto né il conseguente risultato terapeutico.
La preghiamo di leggere attentamente queste informazioni prima di prendere una decisione in merito ad una Sua eventuale partecipazione. Lei ha diritto di prendersi il tempo necessario per decidere se partecipare o meno; qualora lo ritenga utile è opportuno che discuta con i suoi familiari ed amici e con il suo medico di famiglia ed eventualmente con altri medici che l'hanno in cura.
Il protocollo per analizzare i dati che la riguardano ha ricevuto il parere favorevole da parte del Comitato etico territoriale della Provincia autonoma di Trento per le sperimentazioni cliniche. I medici responsabili dello studio sono a disposizione del paziente per fornire ulteriori informazioni sullo studio.

Informazioni sullo studio

Titolo: "**Supporting surgical teams in pre-, intra-, and post-operative decision making**".
Lo studio, che non ha finalità di lucro, è promosso dal Dipartimento di Ingegneria e Scienza dell'Informazione (DISI) dell'Università di Trento (UniTn) in collaborazione con l'U.O. di Chirurgia Vascolare e l'U.O. di Fisica Sanitaria dell'APSS.
L'obiettivo primario di questo studio di ricerca è lo sviluppo di un modello di intelligenza artificiale che supporti il chirurgo nel processo decisionale nell'ambito per le procedure EVAR con lo scopo di ridurre l'occorrenza di eventi avversi.
Lei è invitato a partecipare allo studio perché era affetto da aneurisma aortico intra-addominale ed è stato sottoposto ad intervento chirurgico di tipo endovascolare.
Il trattamento che ha ricevuto e i controlli che sono seguiti e seguiranno al trattamento stesso rispettano gli standard attuali di cura per il suo tipo di patologia.
Durante lo studio verranno valutate le immagini tomografiche assiali dell'aorta addominale ottenute prima e dopo la Sua operazione e quelle fluoroscopiche acquisite durante l'intervento. Inoltre verranno utilizzati i dati presenti nei referti della visita cardiologica effettuata prima dell'intervento e delle visite di follow-up eseguite dai chirurghi vascolari a seguito dell'intervento. Lo studio non prevede dunque nessuna analisi o esame aggiuntivo rispetto al Suo normale percorso clinico.
Il suo percorso diagnostico terapeutico non sarà modificato rispetto alla normale pratica clinica in conseguenza di questo studio.
È possibile ritirarsi dallo studio:

- per sua decisione, in qualunque momento e senza conseguenze sull'assistenza che riceverà. In questo caso è importante avvertire il medico responsabile dell'intenzione di ritirarsi
- per decisione del medico, perché lo studio è stato interrotto.

Benefici attesi per i partecipanti e per la comunità

Accettando di partecipare allo studio, Lei non riceverà alcun beneficio immediato e diretto rispetto al trattamento in essere.

Ci attendiamo un aumento delle conoscenze che in futuro permettano un miglioramento dell'approccio terapeutico. In particolare le informazioni raccolte da questo studio serviranno a sviluppare un modello predittivo per gli eventi avversi in seguito a procedura EVAR basato sull'imaging pre-, intra- e post- operatorio. L'implementazione di modelli predittivi potrebbe in futuro agevolare il lavoro del chirurgo, migliorare il flusso di lavoro e ridurre il rischio di effetti avversi per il paziente.

La Sua partecipazione allo studio non comporta alcun rischio per la Sua salute.

Per ottenere eventuali maggiori informazioni o chiarimenti può rivolgersi all'U.O. di Chirurgia Vascolare (e-mail: chirurgiavascolare@apss.tn.it; telefono: 0461903359).

Alternative alla partecipazione

Nel caso lei decidesse di non partecipare allo studio questo non pregiudicherà le cure attuali e future alle quali lei ha diritto né il conseguente risultato terapeutico: lei verrà seguito e riceverà le procedure di controllo ad oggi previste per la sua patologia.

Assistenza del soggetto al termine della partecipazione allo studio

Al termine della sua partecipazione allo studio, qualora siano necessarie delle cure aggiuntive, riceverà comunque i trattamenti che sarebbero previsti per le sue condizioni cliniche.

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MANIFESTAZIONE DEL CONSENSO ALLA PARTECIPAZIONE ALLO STUDIO

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Nome e cognome del paziente	

Ho letto le informazioni per il paziente allegate, ho avuto il tempo necessario per prendere la mia decisione ed ho avuto l'opportunità di fare delle domande sullo studio, che sono state soddisfatte in maniera esauriente.

Accetto liberamente e volontariamente di partecipare allo studio, consapevole del fatto che:

- la mia decisione sulla partecipazione è libera ed è stata presa sulla base delle informazioni contenute nel modulo di informazioni per il paziente e delle altre informazioni fornitemi dal personale medico
- anche dopo aver dato il mio consenso, sono libero di decidere in qualsiasi momento di ritirarmi dallo studio senza che ciò modifichi in alcun modo l'assistenza che riceverò.

Il Dott. _____ mi ha consegnato una copia del foglio informativo ed una copia, datata e firmata, del presente modulo.

_____ Firma del Paziente		_____ Data (il paziente deve datare personalmente)
_____ Timbro e firma del Medico che ha ottenuto il consenso		_____ Data (Colui che ottiene il consenso deve datare personalmente)