



TANGO

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SCUOLA NORMALE SUPERIORE	IT	SNS
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U-HOPPER SRL	IT	UH
INTESA SANPAOLO SPA	IT	ISP
EIT DIGITAL	BE	EITD
SHARE FONDACIJA	RS	SHARE
A11-INITIATIVE FOR ECONOMIC AND SOCIAL RIGHTS	RS	A11
MINISTARSTVO ZA BRIGU O PORODICI I DEMOGRAFIJU	RS	MFWD
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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
GDPR	General Data Protection Regulation

EXECUTIVE SUMMARY

The Application Guidelines of TANGO project are meant to provide general, high-level guidance to case study leaders on how to address the development of each case-study guaranteeing systematic and compelling collection of data and information related to each.

After a short introduction about the purpose of this document, two main sections illustrate the approach adopted to structure the so-called Trial Handbook and a preliminary table of contents for the Trial Handbook, subject to updates as soon as more data on the case study will become available in the months to come.

Application guidelines are delivered at M6 of the project duration while case study related activities will officially start at M9. For this reason, modifications and updates to the Trial Handbook might be released at a later stage.

The Trial Handbook is a methodology and tool already successfully deployed in other European funded collaborative projects where case studies and trials were at the core of the project validation methodology.

The Trial Handbook is meant to collect relevant (including sensitive) information about the developments of each case study and for this reason it will not be disclosed, in its complete and compiled version, outside of the TANGO consortium. This document contains a template for usage in the different case studies based on field testing, where sensitive data will be collected and not disclosed.

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1 Introduction

1.1 Purpose of the document

This deliverable includes guidelines for the implementation and coordination of the applications of the TANGO methodology and tools to be developed in WP5 which is focusing on TANGO case studies. The purpose of D5.1 Application guidelines, in alignment with the project's Description of Action (DoA), is to cover the suggested guidelines to develop, coordinate and implement the four case studies foreseen as practical validation of TANGO methodology and tools for hybrid decision making. Within the project's roadmap this deliverable produces the so-called Trial Handbook, which will serve as a means to store relevant methodological and factual information related to each of the case studies, facilitating the work of Task Managers for each of the trials and ease their collection of information in a coherent and consistent fashion across disciplines.

D5.1 is a public deliverable so it is also intended to be made available to the general public interested in the TANGO project as well as to other EU funded projects involving validation of methodologies and tools through the use of case studies, in need to collect data in a systematic way.

1.2 Relation to other project work

Due to the scope of D5.1 Application guidelines and the objective of providing a unified methodology for storing case studies factual information, the work in this deliverable is related to all tasks and deliverables developed within WP5 TANGO case studies but also connects to other WPs in the project, in particular WP2 Algorithms for Synergistic Human Machine Learning, WP3 Algorithms for Hybrid Decision Making and WP4 The TANGO software ecosystem on the technical side, and WP6 on the Communication, Dissemination and Exploitation side.

D5.1 is a direct output of T5.1 Coordination and orchestration of applications which lasts until M48 of the project and supports the coordination among case studies throughout project duration. D5.1 impacts directly on T5.1, T5.2, T5.3 and T5.4 as it will guide the methodology for collecting and storing the set-up, development and result information related to each of the case studies being carried out in each of the tasks of WP5. D5.1 will provide valuable input for D5.2, D5.3 and D5.4 which will be focusing, respectively, on the design of the case studies, intermediate and final report of the case studies.

D5.1 also indirectly impacts WP6 as some of the information stored through the Trial Handbook might be disclosed – when not including sensitive or GDPR related data – through targeted Communication and Dissemination actions in T6.1 and T6.2, as well as be evaluated for specific exploitation activities in T6.3.

1.3 Structure of the document

This document is presented in two major sections:

- Section 2 is focusing on the approach to set-up a working group within WP5 to work towards establishment of the Trial Handbook strategy.
- Section 3 includes a preliminary release of the Trial Handbook table of contents, subject to further modification and updates.

1.4 Glossary adopted in this document and external references

- Trial Handbook: in the context of European Project the Trial Handbook is now established as a tool to provide guidance in systematically setting-up, developing and monitoring trials independently from the industry or scientific sector in which they are developed

The Trial Handbook was successfully deployed as a tool for activity tracking in a number of projects funded by the European Commission in several scientific and technical sectors, such as:

- Driver
- Re4dy
- Boost 4.0
- XMANAI
- Qu4lity

2 Approach

2.1 Onboarding of case studies and establishment of a working group

EITD first presented the option to be managing the case studies of the TANGO project during the kick-off physical meeting held in Trento, Italy at the beginning of October 2023.

WP5 partners have raised some questions and received clarifications already during that occurrence, and further discussion took place in the following weeks to clarify pending questions.

A working group consisting of one representative per case study started meeting on a bi-weekly basis since October 2023 to further contribute to the definition of the Trial Handbook. These meetings will be recurring throughout T5.1 duration, basically until project completion, to continuously foster alignment on progress of each case study towards the overarching objective of validating TANGO methodologies and tools.

The case studies involved in the activity are listed below.

- T5.2 HALLE, title: Supporting women in perinatal health and wellbeing (M9-M48)
- T5.3 UNITN, title: Supporting surgical teams in making intraoperative decisions (M9-M48)
- T5.4 FBK, title: Supporting loan officers and loan applicants in credit lending DM (M9-M48)
- T5.5 IVI, title: Supporting policy makers in shaping social welfare policies (M9-M48)

The list above also reports the title and duration of each case study, to ease reading of the report.

The working group on T5.1 also welcomed the contribution of CEPS as project beneficiary specialising in ethics and policy making, to foster alignment of those critical topics from the very early stage of project development.

2.2 Agreement on an organizational strategy for trial management

EITD proposed to each case study leader to structure dedicated trial teams, following an already validated approach inspired by another EU funded project, called Driver+ project <https://www.driver-project.eu>. Despite being focused on a different sector, crisis management, the project Trial Guidance methodology provides very interesting insights made available to the public and with a strong track record in successfully supporting trial set-up, execution and monitoring in different settings <https://www.driver-project.eu/wp-content/uploads/2020/02/TGM-handbook-FINAL.pdf>.

Case study leaders agreed to be nominating the following roles for their trials:

- Trial owner – responsible for the trial (most likely the case study task leader) and specifically for ensuring planning, execution and evaluation take place in a timely manner and the expected level of detail and quality;
- Technical Coordinator – responsible for the technical set-up of the trial, focusing on definition of the test-bed, solution provision and eventually training of trial participants;
- Practitioner Coordinator – responsible for ensuring effective and efficient engagement of all stakeholders related to the specific case study, both referring to trial participants and potential trial observers (if any);
- Evaluation coordinator – responsible for ensuring neutral approach to evaluation of trial output and ethics compliance and/or validation with the project ethics' advisor (recommended to be not directly involved in the above roles);

Once the roles for each trial have been assigned, the case study leaders communicated the list of contacts per each role to the Work Package leader. Contacts pertaining to each role are summarized in 2.3.1 Trial Team Introduction

Case study leaders launched trial specific recurring meetings since M9 and the Work Package leader is participating in these meetings to maintain cross case study alignment.

2.3 Creation of trial teams to engage in the Trial Handbook

Each case study named a trial team according to the role distribution presented and agreed in Section 2.2 of this deliverable, distributing responsibilities across the organizations involved in the trial execution, as follows:

- T5.2 HALLE, TUDa

- T5.3 UNITN, APSS
- T5.4 FBK, ISP
- T5.5 IVI, SHARE, A11

2.3.1 Trial team introduction

A total of four members per team are defined, to cover for all the proposed roles.

Designated team members are summarized in the table below.

Table 1: Trial Team roles, names and organizations

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)

2.4 Interviews with case study leaders to collect specific requirements

EITD organized bilateral interviews with each case study leader to discuss requirements specific to the case studies that might differ from one case to the others.

Interviews highlighted the importance of appropriate data management strategies for each of the case studies. More details about TANGO project data management are available in the Data Management Plan (D7.2, D7.3, D7.4, D7.5) which will have several releases during the course of the project.

Case study leaders have also raised a point about creating specific agreements for particularly sensitive data, to be discussed when the need arises.

Further details on the specific needs of case studies will be available as soon as the specific activities will be kicking-off, at M9 of project duration so about 3 months after the submission of this report.

2.5 Versioning and update of the Trial Handbook

Provided that the Trial Handbook has been developed prior to the official kick-off of the case study activities, EITD and all case study task leaders will keep the document updated and use it as a living document, to accommodate for any changes needed throughout the project duration, both at the general or vertical/single-case level.

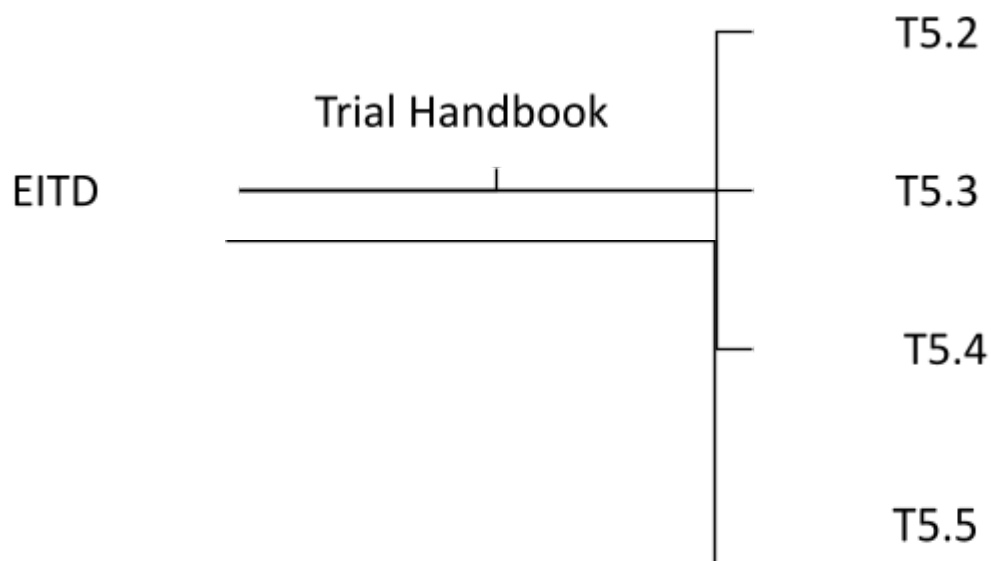


Figure 1: Relationship between EITD as WP5 leader and WP5 Tasks for Trial Handbook continuous update

3 Trial Handbook description

This section describes the general set-up of the TANGO Trial Handbook sections that case study leaders will be required to use to set-up, execute and collect information on the trials developed within the TANGO project.

In the following, the words “Trial” and “Case-study” are to be intended as synonyms, to ease reading.

3.1 Responsibility to provide and manage the information in the Trial Handbook

Each Trial Leader is required to fill the information for the Trial according to the sections proposed in the Trial Handbook structure first release.

Trial Leaders ensure that information made available in the Trial Handbook is constantly updated.

Sensitivity issues regarding each specific Trial are to be managed according to provisions included in the TANGO Data Management Plan and also accounting for any needed additional provisions and constraints not included in the Data Management Plan.

Each Trial will produce a separate Trial Handbook. Documents will be stored in the project shared drive but can be password protected, stored in restricted folders or stored outside of the shared drive when deemed necessary to ensure appropriate data handling.

Each Trial leader should communicate to WP5 leader, EIT Digital, the decision about where and how to store the Trial Handbook.

Whenever possible, Trial leaders are encouraged to exchange information and best practices on methodologies adopted for data collection, data analysis, results interpretation and alignment of the single trial to the specific project objective.

3.2 Trial Handbook proposed table of contents

This section illustrates a preliminary table of contents for the Trial Handbook. Chapters and sections mentioned below will be available at different points in time, according to each trial's status of development and will be subject to continuous updates based on most recent progress.

The table of contents proposed for each Trial Handbook follows the structure below:

1. Trial overview
 - a. Expected benefits
 - b. General description
 - c. Participants
 - d. State of the art and gap identification
2. Trial detailed description
 - a. Trial specific objective identification
 - b. Research question
 - c. Trial present scenario
 - d. Trial high-level methodology and execution plan
 - e. Ethical, Gender, Legal, and Social Aspects integration
 - f. Trial risk analysis and mitigation measures
 - g. Weaknesses and bottlenecks
3. Trial detailed methodology and action plan
 - a. Data collection methods
 - b. Data sources
 - c. Data management (add-on to TANGO Data Management Plan)
 - d. Design-of-experiment
 - e. Data analysis method
 - f. Timeline of the trial
4. Trial impact
 - a. Trial evaluation approach and metrics
 - b. Trial future scenario
 - c. Ethical, Gender, Legal, and Social Impacts
 - d. Expected results
 - e. Actual results and final evaluation of the trial
 - f. Alignment of trial results to TANGO objectives

- g. Lesson learned and relevant input for TANGO project
 - h. Contribution of the trial to TANGO project KPIs
 - i. Input for dissemination, communication and exploitation
 - j. Final evaluation of the trial and envisaged next steps
5. Annexes
- a. Tools, toolkits, methods
 - b. Data tables
 - c. GDPR documentation
 - d. Ethics documentation
 - e. Other, e.g. code

3.2.1 Comments on Trial Handbook sections: expected timeline and connections to specific WPs

This section illustrates specific details on each section of the Trial Handbook.

Chapter 1 will include the detailed description of the case study. Case study leaders will be able to start working on this section from the beginning of tasks where case studies will be developed, so T5.2, T5.3, T5.4 and T5.5. The chapter will provide insights on the scope of the case studies, participants involved in it and the knowledge gap being the rationale for the specific trial. This chapter is expected to be delivered in its complete and final version shortly after task initiation, but it will be constantly kept up to date, especially in case modifications to the trial setting need to be operated during the course of trial development.

Chapter 2 will include the technical definition of the trial. This chapter will be built including contents from the technical Work Packages, provided that case studies undertake a validation effort to prove validity of methodology and tools developed in the project. There is a link between T4.3 and T4.4 and the way the trials will be designed and executed to ensure reliable validation.

Chapter 3 will include a detailed overview of the trial methodology, including details on data collection, analysis, management according to GDPR principles as an add-on to topics already included in the project's Data Management Plan. It will also describe the design of the experiment for the specific trial, including the data analysis methodology and an accurate timeline for trial activities.

Chapter 4 will include the systematic collection of trial impact. This chapter will be populated based on results of the case study validation activities and will undergo subsequent updates and releases as long as the case study activity will be under development. This chapter can only be considered as final when the trial is over and all results are collected, correctly stored and interpreted to the benefit of TANGO project development.

Chapter 5 will include any additional material in support of the trial, such as detailed description of methodology and tools, data sets, GDPR and ethics support documents and any other means deemed necessary to provide a compelling view of the case study development.

3.3 Impact of trials: measuring impacts and comparing impacts across case studies

TANGO is a complex project whose impact can be guaranteed based on continuous alignment among scientific and technical developments pursued in Technical Work Packages (WP1, 2, 3 and 4) with the case study validation work carried out in WP5.

Given the project's early stage, particularly the work on the case studies (which began in M9), some suggestions on how to ensure the best impact and measure effectiveness of the case studies in contributing to the overall project objectives are summarized below.

The first deliverable on the impact generation strategy (D6.2) was submitted in M6.

The identification of key exploitable results is expected by M18 and will include detailed actions related to the trials, as most of the project exploitable results are linked to case studies development.

Here below, the document summarizes the expected contribution of each trial to the specific destination objective of the project, following the structure of the GA and section 1.3 Impact of the Project Technical Report. Based on this structure and recommendations, each trial leader will report the contribution to the overall project impact within the trial handbook.

The first destination impact of TANGO project is I1 - Increased inclusiveness, by supporting a human-centered approach to technology development aligned with European social and ethical values & sustainability:

- **Increased fairness of decisions taken by the hybrid decision support system (30%). Our ongoing research on algorithmic fairness and, more generally, performative prediction (a computational framework to study a feedback effect of predictions) has the potential to substantially increase the fairness aspect of hybrid decision support systems, especially in the setting where predictions interact with high-stakes decision-making processes such as loan approval and social policy making.**
 - Contribution of trial applications to the impact: trials will demonstrate an improvement of fairness in the quality of decisions taken by the hybrid decision making support system. Each trial will demonstrate improvements for their own application, and will commit to share learnings with the other case studies in terms of methodologies used to fine-tune the decision making mechanisms.
- **increased engagement of pregnant women in AI-assisted health and wellbeing improvement (30%). Low-threshold recruitment (app installation and consent), clear structured informational material within the app, individualization of content based on questionnaires, interactive app tools, regular app usage are relevant factors that we plan to focus on for increasing the engagement of pregnant women, thereby promoting long-term health prevention and enhancing awareness and utilization of local offerings.**
 - Contribution of trial applications to the impact: trial leaders for the case study trial developed in T5.2 will record progress of engagement of pregnant women in AI-assisted health. Engagement will be measured numerically using analytics of usage of the app. This activity will be carried out within the trial activities and can be further supported benefitting from community building and focus groups in WP6.
- **increased engagement of bank customers in taking actions to improve their risk profile (25%). To increase the engagement of bank customers in taking actions to improve**

their risk profile, the project plans to involve some of the Intesa bank customers on providing feedback on the algorithmic recourse strategies suggested by the Tango agent.

- Contribution of trial applications to the impact: trial leaders for the case study developed in T5.3 will record the improvements in the engagement of bank customers based on interactions and feedback provided by the clients on the strategies suggested by the algorithmic recourse.
- **increased engagement of citizens in the design and validation phases of the policy making process (50%):** To ensure greater citizen engagement, A11 and SHARE plans to involve affected citizens in all phases of designing and validating the TANGO framework. This will help shape policies and thus directly address citizen needs. Citizens will actively participate, providing feedback that will result in more effective and relevant policy outcomes. This feedback will be continuously gathered, ensuring that policies are widely supported and aligned with the needs of those they impact.
- Contribution of trial applications to the impact: trial leaders for the case study developed in T5.4 will monitor the involvement of citizens categories affected by policy making decisions and collect their feedback, to ensure the final version of policy support decision is aligned to their needs.

The second destination impact of TANGO project is I2 - Sustainable, high-quality jobs by targeting skills mismatches, the need to empower workers, and ethical considerations relating to technological progress

- Increase of effectiveness of workers' DM processes (healthcare professionals: 20%-30%; bank officers: 10%-20%; policy makers: 20%-30%). Our ongoing research on hybrid human-machine decision-making has the potential to significantly enhance decision-making across diverse work environments. In the medical field, we expect physicians to catch potential oversights, identify missed symptoms, or reconsider treatment options by engaging in multi-step dialogues with properly fine-tuned LLMs/VLMs. In the financial sector, we aim to improve bank officers' decision-making by providing an initial automated evaluation of a customer's risk profile.
- Contribution of trial applications to the impact: trial leaders of all case studies will track how decision making processes are improved in the specific case study and communicate the quality and analytic results of the improvements to other case studies. Benchmark will be defined at the beginning of case study design, to ensure this impact is duly monitored during project development.

4 Conclusions

TANGO project grounds the validation of methodology and tools developed within the project on four different case studies, namely

- T5.2 led by HALLE, title: Supporting women in perinatal health and wellbeing (M9-M48)
- T5.3 led by UNITN, title: Supporting surgical teams in making intraoperative decisions (M9-M48)
- T5.4 led by FBK, title: Supporting loan officers and loan applicants in credit lending (M9-M48)
- T5.5 led by IVI, title: Supporting policy makers in shaping social welfare policies (M9-M48)

Provided the four case studies are spanning across different scientific and technical sectors, the “Trial Handbook” is proposed as a methodological tool to allow for compelling and comparable collection of data and information related to the four case studies.

In the first months of the project duration, EIT Digital has been working together with project partners to finalize the first release of an agreed Table of Contents for the Trial Handbook, to be deployed separately for each case study.

The Trial Handbook in its final and complete version for each case study is to be considered as a sensitive information report, and as such will not be disclosed outside of the TANGO consortium. It will also be managed individually by each case study leader, to ensure appropriate data handling in alignment with the project Data Management Plan



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