



TANGO

D5.1 Application guidelines

Submission date: 31/03/2024

Due date: 31/03/2024

DOCUMENT SUMMARY INFORMATION

Grant Agreement No	101120763	Acronym	TANGO
Full Title	It takes two to tango: a synergistic approach to human-machine decision-making		
Start Date	01/10/2023	Duration	48 months
Project type	Research and Innovation Action (RIA)	Funding programme	Horizon Europe
Deliverable	D5.1: Application guidelines		
Work Package	WP5 – TANGO case studies		
Type	R	Dissemination Level	PU
Lead Beneficiary	EITD		
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DOCUMENT HISTORY

Version	Date	Changes	Contributor(s)
V0.1	24/01/2024	First release	Annalisa Andaloro
V0.3	31/03/2024	Final release	Annalisa Andaloro

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UNIVERSITE PARIS CITE	FR	UPC
FONDAZIONE BRUNO KESSLER	IT	FBK
CARR COMMUNICATIONS LIMITED	IE	CARR
ISTRAZIVACKO-RAZVOJNI INSTITUT ZA VESTACKU INTELIGENCIJU SRBIJE	RS	IVI
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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);

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.

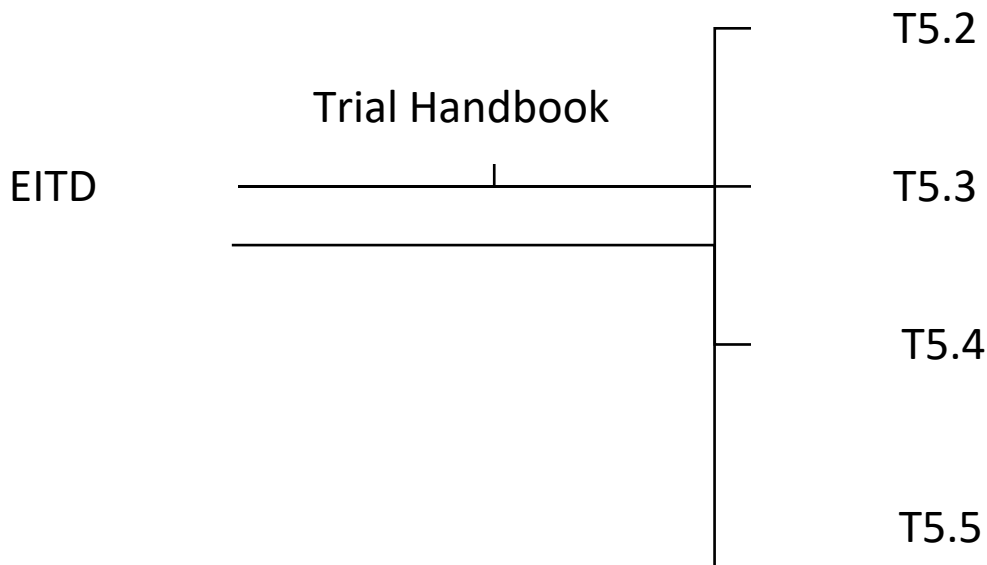


Figure 1: Relationship between EITD as WP5 leader and WP5 Tasks for Trial Handbook continuous update

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.

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 risk analysis and mitigation measures
 - e. Weaknesses and bottlenecks
 - f. Trial execution plan
3. Trial impact
 - a. Trial evaluation approach and metrics
 - b. Trial future scenario
 - c. Ethical, Legal, and Social Impacts
 - d. Expected results
 - e. Actual results and final evaluation of the trial
 - f. Lesson learned and relevant input for TANGO project
 - g. Input for dissemination, communication and exploitation
4. Annexes
 - a. Tools, toolkits, methods
 - b. Data tables
 - c. 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 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 4 will include any additional material in support of the trial, such as detailed description of methodology and tools, data sets and any other means deemed necessary to provide a compelling view of the case study 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 DM (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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