
Draft Project plan for the CEN Workshop on "Processes for ink-based mono and multi- material fabrication of additive manufactured implants"

**Requests to participate in the Workshop
and/or comments on the project plan are
to be submitted by 2023-11-27 to
abenedicto@une.org¹**

Recipients of this project plan are kindly requested to name all patent rights known to them to be relevant to the Workshop and to make available all supporting documents.

2023-10-16 (Version 2)

¹ Applications for participating in the Workshop and comments on the project plan that are not received by the deadline do not need to be taken into consideration. Once constituted, the Workshop will decide whether or not to consider the comments received in good time.

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Summary

This CEN workshop is a proposal coming from the research H2020 project INKplant (full title: INK-BASED HYBRID MULTIMATERIAL FABRICATION OF NEXT GENERATION IMPLANTS), with the aim of transferring the developed technologies and processes to marketable solutions and of spreading the technological advances. Three documents are expected to be agreed, regarding a library of scaffolds and samples, regarding a workflow from medical images towards optimal personalized scaffolds and regarding methods for the process control of high-resolution mono- and multimaterial additive manufacturing, respectively.

1 Status of the project plan

Draft project plan for public commenting (Version 2.0)

This draft project plan is intended to inform the public of a new Workshop. Any interested party can take part in this Workshop and/or comment on this draft project plan. Please send any requests to participate or comments by e-mail to abenedicto@une.org.

All those who have applied for participation or have commented on the project plan by the deadline will be invited to the kick-off meeting of the Workshop on **2023-12-5**.

2 Workshop proposer and Workshop participants

2.1 Workshop proposer

<u>Person or organisation</u>	<u>Short description and interest in the subject</u>
<u>INKplant Project Consortium</u>	<p>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 953134.</p> <p>The vision of INKplant is the combination of different biomaterials, high-resolution additive manufacturing technologies, and advanced simulation and biological evaluation, to bring a new solution for the fabrication of biomimetic implants for tissue regeneration.</p>

2.2 Other potential participants

This CWA will be developed in a Workshop (temporary body) that is open to any interested party. The participation of other experts would be helpful and is desired. It is recommended that:

- Industry and commerce, companies on industrial printing systems, raw materials suppliers and manufacturers, companies in the field of medical devices and bioengineering.
- Government, regulatory bodies on medical devices
- Consumer, medical specialists and surgeons
- Academic and research, experts on the engineering and biomedical field, additive manufacturing and simulation and modelling

take part in the development of this CWAs.

2.3 Participants at the kick-off meeting

The following organisations already signed up to the kick-off meeting prior to the publication of the draft project plan.

BIOMED CENTER INNOVATION GGMBH – Daniel Seitz – WS Chairman and Leader CWA 3
BIOTECHNOLOGY INSTITUTE I MAS D

CHARITE - UNIVERSITAETSMEDIZIN BERLIN
ELKEM SILICONES FRANCE SAS
FLUIDINOVA SA
LITHOZ GMBH
LUDWIG BOLTZMANN GESELLSCHAFT OSTERREICHISCHE VEREINIGUNG ZUR FORDERUNG DER WISSENSCHAFTLICHEN FORSCHUNG
LUXINERGY GMBH
MEDIZINISCHE UNIVERSITAET WIEN – Francesco Moscato – Leader CWA 2
PROFACTOR GMBH
STRATASYS LTD
TIGER Coatings
TRANSTISSUE TECHNOLOGIES
UNIVERSIDAD POLITÉCNICA DE MADRID – Andrés Diaz-Lantada – Leader CWA 1
UNIVERSITAIR MEDISCH CENTRUM UTRECHT
UNIVERSITAT LINZ

3 Workshop objectives and scope

3.1 Background

- **Motivation for the creation of this Workshop**

This workshop is motivated by the currently ongoing Horizon 2020 INKplant project (INK-BASED HYBRID MULTIMATERIAL FABRICATION OF NEXT GENERATION IMPLANTS), whose general objective is the future incorporation of additive manufactured scaffolds into the daily routine of medical practice, so that the whole society benefits from personalized regenerative therapies. For this global aim INKplant sets the following overall objectives: to develop innovative manufacturing technologies for affordable patient-specific scaffolds; to create a workflow for the design optimization of 3D printed scaffolds; to demonstrate the INKplant approach in two different Use Cases (weight-bearing joints and dental implants & oral pathologies); to assure the future translation of the technology to clinical application, via European regulatory approval and commercialisation.

The creation of this CEN Workshop was identified by the project consortium as a very useful way for the translation of its results to marketable solutions. This initiative aligns the INKplant project with Commission Recommendation (EU) 2023/498 “Code of Practice on standardisation in the European Research Area” and Council Recommendation (EU) 2022/2415 “Guiding principles for knowledge valorisation”.

This workshop will be used for the dissemination of the project and its results reaching stakeholders on national, European and international level. INKplant will lead the development of 3 CWA closely connected to project objectives and the developed technologies and processes in order to bring these closer to the market and to spread technological advances.

- **Market environment**

INKplant’s ambition is to transform the status quo regarding tissue engineering of complex biological structures. At present, the manufacture of personalized implants usually relies on direct manufacturing from medical images employing powder-based laser processing of alloys. This leads to biomechanical mismatches, as the properties of alloys used importantly differ from human tissue features and as the designs obtained are not truly biomimetic. Currently, additive manufacturing within hospitals, more often than not, is limited to applying low-cost fused-deposition modelling (3D printers) to printing diagnostic models, surgical training systems and surgical guides, but the personalized creation of tissue repair constructs or implants is far from being commonplace. INKplant’s ambition is to convert personalised medicine in a daily clinical routine, to democratise high-quality tissue engineering, thanks to beyond state-of-the-art technologies delivering composite scaffolds and implants with improved biomechanical performance and biological response, achieved through new biomaterials and manufacturing strategies, knowledge-based design, modelling and to the combined use of multi-ceramic and multi-polymeric phases.

In the future paradigm, the medical diagnostic imaging departments are transformed into departments for personalised healthcare, with experts and technologies for performing medical imaging-related procedures, in

close collaboration with the suppliers and manufacturers of the personalised implants. Success relies on the development of long-lasting international collaborations, public-private partnerships, training activities and ambitious transformative technologies. This CEN workshop can strongly support these objectives by the standardization of technologies and processes, such as a library of scaffolds and samples, the workflow from medical images towards optimal personalized scaffolds, and the process control of high-resolution mono- and multimaterial additive manufacturing.

3.2 Scope

- CWA 1. Library of scaffolds and samples

The planned CEN Workshop Agreement defines a set of standardized geometries to be employed as tissue engineering scaffolds. These scaffolding geometries, whose aim is mimicking tissular extracellular matrices, are designed for mono- and multi-material additive manufacturing. They are conceived for comparative purposes, across all the applicable additive manufacturing technologies and biomaterials, usable for creating such biomimetic scaffolding structures. In consequence, the designed geometries include complex porous shapes, lattices and networks, multi-scale and fractal-like structures, and integrate a unique versatile library, with which manufacturability, repeatability, resolution and precision of additive manufacturing technologies and biomaterials can be evaluated and compared.

The planned CEN Workshop Agreement is intended to be used by researchers in the tissue engineering and biofabrication fields, as scaffolding geometries are fundamental in repair and regeneration studies, although comparing results between scientific publications is currently challenging due to the lack of standardized geometries. It is also intended to be used by developers of additive manufacturing technologies and biomaterials, as they should be able to systematically compare results across technologies and biomaterials and with the current gold standards, once a library of standardized geometries designed for additive manufacturing is available.

- CWA 2. Workflow from medical images towards optimal personalized scaffolds

The planned CEN Workshop Agreement defines a workflow to design scaffold implants from patient clinical imaging (such as CT-scans). In this workflow the different requirements for the involved steps in implant creation (such as image scan properties, software operations, systematic inclusion of clinicians input, considerations about manufacturability) to allow repeatability and designer-independent results.

The planned CEN Workshop Agreement is intended to be used by surgeons, implant designers and implant manufacturers. The considered implants are primarily intended to address pathologies of musculo-skeletal structures.

- CWA 3. Methods for the process control of high-resolution mono- and multimaterial additive manufacturing.

The planned CEN Workshop Agreement defines reference constructs and calculation methods for resolution, exactness and reproducibility controls for high-resolution printing systems including multimaterial prints. This approach specifies methods for the quantitative determination of resolution and exactness beyond simple measurement of lengths by employing reference patterns and test geometries. It treats the problem of resolution for ceramic printing, especially lithographic printing, which interacts both with printing resolution and sinter shrinkage, relevant for high accuracy and fine detail realizations. It also specifies methods to determine position accuracy, border effects, mixing, dimensional accuracy in z- versus x- and y-directions, time-related effects and material interaction during the entire printing process to quantitatively determine these important building parameters. Another aspect to be regarded is the mechanical stability of parts printed by small-scale combination of two or more materials, resulting from design-material interactions and the influence on crack propagation. The methods span the entire process from file creation and conversion to printing and post-processing. A subsection concerns the stability of inks or bed materials and their interaction.

The planned CEN Workshop Agreement is applicable to all exact printing methods but especially suited for inkjet, polyjet, lithographic and 2-photo-polymerization methods. It can also be applied to powder-bed based technologies, but with limited validity for dimensions in the range of the powder particles.

It is not suited for small-scale analysis of classical FDM, robocasting and extrusion printing but can be scaled for overall dimensional analysis of these fabrication methods. It will not cover the control of the integrity of these models or removal of support structures. It will also only cover density and porosity measurements in a very general way. It will not concern mechanical stability of single-material prints.

3.3 Related activities

The subjects of the planned CWAs are not at present the subject of a standard. However, there are committees, standards and/or other technical specifications that deal with related subjects and thus need to be taken into account - and involved, where necessary - during this Workshop:

CEN/TC 438 - Additive Manufacturing; ISO/TC 261 - Additive manufacturing

- EN ISO 17296-2:2016 Additive manufacturing - General principles - Part 2: Overview of process categories and feedstock
- EN ISO 17296-3:2016 Additive manufacturing - General principles - Part 3: Main characteristics and corresponding test methods
- EN ISO/ASTM 52900:2017 Additive manufacturing - General principles – Terminology
- EN ISO/ASTM 52902:2019 Additive manufacturing - Test artifacts - Geometric capability assessment of additive manufacturing systems
- EN ISO/ASTM 52910:2019 Additive manufacturing - Design - Requirements, guidelines and recommendations
- EN ISO/ASTM 52950:2021 Additive manufacturing - General principles - Overview of data processing
- CEN ISO/ASTM/TR 52916:2022 Additive manufacturing for medical - Data - Optimized medical image data
- CEN ISO/ASTM/TR 52917:2022 Additive manufacturing - Round robin testing - General guidelines

CEN/TC 285 - Non-active surgical implants ISO/TC 150 Implants for surgery ;

- EN ISO 14630:2012 Non-active surgical implants — General requirements
- ISO/AWI 5092 Additive manufacturing for medical — General principles — Additive manufacturing of non-active implants

4 Workshop programme

4.1 General

The kick-off meeting is planned to take place on 5TH December 2023, on-line.

A total of 4 virtual workshop meetings (kick-off meeting and Workshop meetings) will be held, during which the content of the CWAs will be presented, discussed and approved.

The CWA will be drawn up in English (language of meetings, minutes, etc.). The CWA will be written in English.

4.2 Workshop schedule

The timescale and work programme will be in principle the same for the development of the 3 work items stated in the project plan. The virtual meetings will be held jointly at the same date for the 3 work items, consecutively. The preliminary Workshop schedule will be the following:

Table 1: Workshop schedule (preliminary)

CEN Workshop	SEPT23	OCT23	NOV23	DEC23	JAN24	FEB24	MAR24	APR24	MAY24	JUN24	JUL24	
Initiation												
1. Proposal form submission and TC response												
2. Project plan development												
3. Open commenting period on draft project plan (mandatory)												
Operation												
4. Kick-off meeting												
5. CWA(s) development												
6. CWA(s) finalised and approved by Workshop participants												
Publication												
7. CWA(s) publication												
Dissemination (see 7)												
Milestones				K		V		V		V/A		P D

- K** Kick-off
- V** Virtual Workshop meeting
- A** Adoption of CWA
- P** Publication of CWA
- D** Online distribution of CWA

5 Resource planning

The administrative costs of the CEN Workshop will be financed by resources from the INKplant project. The final document will include the following paragraph: "Results incorporated in this CEN Workshop Agreement have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 953134".

Both registration and participation at the CEN Workshop described here are free of charge. The use of electronic meetings will be preferred. Nevertheless, in the case of physical meetings, they will be held in Europe and each participant has to bear his/her own costs for travel, accommodation, and subsistence.

6 Workshop structure and rules of cooperation

6.1 Participation in the Workshop

The Workshop will be constituted during the course of the kick-off meeting. By approving this project plan, the interested parties declare their willingness to participate in the Workshop and will be formally named as Workshop participants, with the associated rights and duties. Participants at the kick-off meeting who do not approve the project plan are not given the status of a Workshop participant and are thus excluded from further decisions made during the kick-off meeting and from any other decisions regarding the Workshop.

As a rule, the request to participate in the Workshop is closed once it is constituted. The current Workshop participants shall decide whether any additional members will be accepted or not.

Any new participant in the Workshop at a later date is decided on by the participants making up the Workshop at that time. It is particularly important to consider these aspects:

- a. expansion would be conducive to shortening the duration of the Workshop or to avoiding or averting an impending delay in the planned duration of the Workshop;
- b. the expansion would not result in the Workshop taking longer to complete;
- c. the new Workshop participant would not address any new or complementary issues beyond the scope defined and approved in the project plan;
- d. the new Workshop participant would bring complementary expertise into the Workshop in order to incorporate the latest scientific findings and state-of-the-art knowledge;
- e. the new Workshop participant would actively participate in the drafting of the manuscript by submitting concrete, not abstract, proposals and contributions;
- f. the new Workshop participant would ensure wider application of the CWA.

All Workshop participants who voted for the publication of the CWA or its draft will be named as authors in the European Foreword, including the organisations which they represent. All Workshop participants who voted against the publication of the CWA, or who have abstained, will not be named in the European Foreword.

6.2 Workshop responsibilities

The Workshop Chair is responsible for content management and any decision-making and voting procedures. The Workshop Chair is supported by the Workshop Vice-Chair and the responsible Workshop secretariat, whereby the Workshop secretariat will always remain neutral regarding the content of the CWA(s). Furthermore, the Workshop secretariat shall ensure that CEN-CENELEC's rules of procedure, rules of presentation, and the principles governing the publication of CWA(s) have been observed. Should a Workshop Chair no longer be able to carry out her/his duties, the Workshop secretariat shall initiate the election of a new Workshop Chair. The list below covers the main tasks of the Workshop Chair. It is not intended to be exhaustive.

- Content related contact point for the Workshop
- Presides at Workshop meetings
- Ensures that the development of the CWA respects the principles and content of the adopted project plan
- Manages the consensus building process, decides when the Workshop participants have reached agreement on the final CWA, on the basis of the comments received
- Ensures due information exchange with the Workshop secretariat
- Represents the Workshop and its results to exterior

The Workshop secretariat, provided by a CEN/CENELEC national member, is responsible for organising and leading the kick-off meeting, in consultation with the Workshop proposer. Further Workshop meetings and/or web

conferences shall be organised by the Workshop secretariat in consultation with the Workshop Chair. The list below covers the main tasks of the Workshop secretariat. It is not intended to be exhaustive.

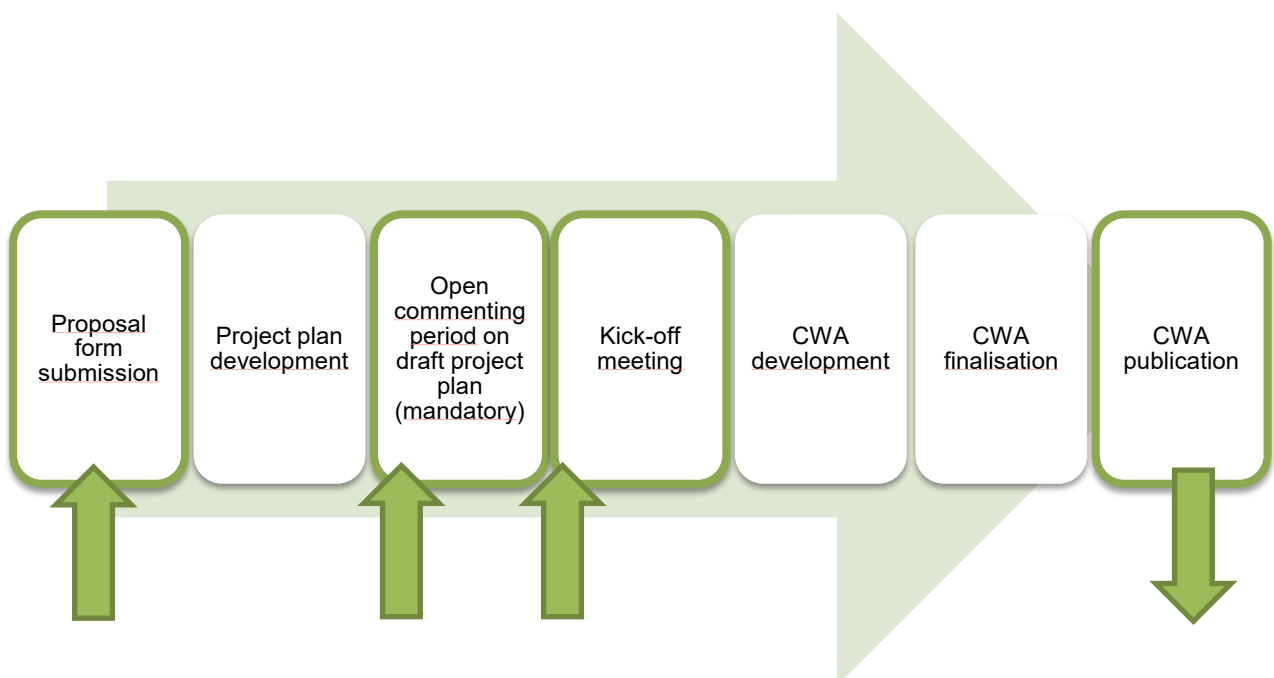
- Administrative and organisational contact point for the Workshop
- Ensures that the development of the CWA respects the principles and content of the adopted project plan and of the requirements of the CEN-CENELEC Guide 29
- Formally registers Workshop participants and maintains record of participating organisations and individuals
- Offers infrastructure and manage documents and their distribution through an electronic platform
- Prepares agenda and distribute information on meetings and meeting minutes as well as follow-up actions of the Workshop
- Initiates and manage CWA approval process upon decision by the Workshop Chair
- Interface with CEN-CENELEC Management Centre (CCMC) and Workshop Chair regarding strategic directions, problems arising, and external relationships
- Advises on CEN-CENELEC rules and bring any major problems encountered (if any) in the development of the CWA to the attention of CEN-CENELEC Management Centre (CCMC)
- Administrates the connection with relevant CEN or CENELEC/TCs

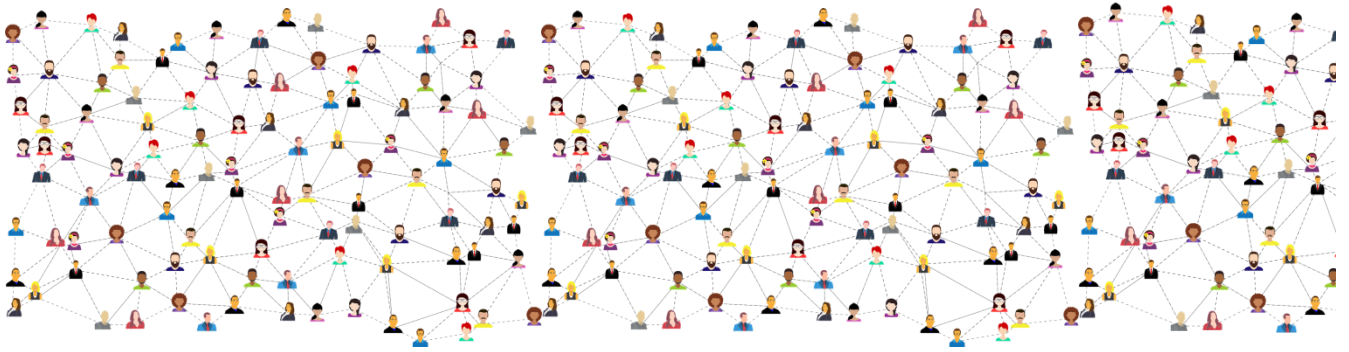
6.3 Decision making process

Each Workshop participant is entitled to vote and has one vote. If an organisation sends several experts to the Workshop, that organisation has only one vote, regardless of how many Workshop participants it sends. Transferring voting rights to other Workshop participants is not permitted. During voting procedures, decisions are passed by simple majority; abstentions do not count.

If Workshop participants cannot be present in the meetings when the CWA or its draft is adopted, an alternative means of including them in the voting procedure shall be used.

7 Dissemination and participation strategy





Proposal form submission

The Workshop proposal has been disseminated to the following relevant stakeholders and bodies for their information:

- CEN/TC 438 - Additive Manufacturing
- CEN/TC 285 - Non-active surgical implants

Open commenting period on draft project plan

The project plan will be disseminated to the following relevant stakeholders and bodies for commenting:

- CEN/TC 438 - Additive Manufacturing
- CEN/TC 285 - Non-active surgical implants

In addition to the CCMC website, the project plan and the date of the kick-off meeting will be advertised on the INKplant project webpage (<https://www.inkplant.eu/>) and its social networks to raise awareness. Interested parties are requested to contribute either through commenting of the project plan (short term) or through Workshop participation (long term).

CWA publication

The final CWAs will be disseminated to the following relevant stakeholders and bodies:

- CEN/TC 438 - Additive Manufacturing
- CEN/TC 285 - Non-active surgical implants

In addition to the CCMC website, the final CWA will be advertised on:

- INKplant project webpage (<https://www.inkplant.eu/>)
- INKplant social media:
 - Facebook
 - Instagram
 - LinkedIn
 - Twitter
- Research Gate

8 Contacts

- Workshop Chair:

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