### Action to be taken

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<th>RESTRICTED COUNCIL</th>
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### Strategy and framework applicable to knowledge transfer by CERN for the benefit of medical applications

The Council is invited to approve the strategy and framework set out in this document for medical applications-related activities, and to take note of the information contained in Annexes I and II.
Strategy and framework applicable to knowledge transfer  
by CERN for the benefit of medical applications

1. Introduction

This document sets out, for approval by the Council, a strategy and framework for medical applications-related activities at CERN, in line with the Organization’s mission of making available the results of its work to the widest possible public. Annex I provides an overview of ongoing and possible future projects in this domain, for the Council’s information, while Annex II sets out the organisation and decision-making flow chart for medical applications-related activities at CERN.

CERN’s involvement in medical applications-related activities and the resulting expectations placed on the Organization by all the relevant stakeholders (in particular Member States and the medical research community) have been growing over recent years to the point where knowledge transfer for the benefit of medical applications has become an established part of CERN’s programme of activities.

This document is submitted as a follow-up to the Status Report on CERN technologies for Medical Applications (CERN/3206), which was presented to the Council for information at its September 2015 Session and announced that a comprehensive strategy document would be submitted to the Council at a future date.

To further develop this aspect of its activities in accordance with its mission and in a cohesive and prudent manner, the Organization should ensure that its medical applications-related knowledge transfer activities are:

- given their proper place within the Laboratory’s mission;
- carried out in a manner that does not cause prejudice to CERN’s core mission of fundamental research in particle physics;
- relevant to the medical communities within CERN’s Member States and Associate Member States; and
- delivered within a sustainable funding model taking into account the fact that they are conducted primarily for the benefit of external parties.

This document therefore describes:

- how these activities fit within CERN’s mission (Chapter 2);
- the general pertinence of CERN’s particle physics technologies to medical applications (Chapter 3);
- the overall strategy, including funding principles (Chapter 4);
- the organisational framework, including the decision-taking process (Chapter 5);
- boundary conditions applicable to CERN’s activities in this domain (Chapter 6).
2. Medical applications as an activity within CERN’s mission

CERN’s core mission is basic research in particle physics. Yet, the “tools of the trade” of particle physics – accelerators, detectors, computing – find applications in a variety of fields and can have a societal impact going way beyond their initial scope and expectations. A well-known example is the World Wide Web, invented at CERN in 1989 to meet the demand for digital information-sharing between scientists in universities and institutes around the world.

Transferring CERN’s know-how and technology to other fields, and thus maximising the societal impact of the Laboratory’s research, is an integral part of CERN’s mission, as spelled out in Article II(1) of the CERN Convention:

“The Organization shall provide for collaboration among European States in nuclear research of a pure scientific and fundamental character, and in research essentially related thereto... the results of its experimental and theoretical work shall be published or otherwise made generally available.”

The Organization is thus committed, through its Convention, to identifying and making available opportunities for the dissemination and use of its results. The notion of “results” has, over time, come to include not only scientific results, but also the know-how and technologies developed by CERN in the construction of the accelerator, detector and computing infrastructure required for its research. It should be noted that medical applications-related work may require certain adjustments to the aforementioned infrastructure.

CERN’s knowledge transfer activities for the benefit of the medical community are in application of the above principles.

3. Pertinence of CERN technologies to the medical domain

Today, particle physics-related applications in the medical domain represent one of the most relevant knowledge transfer opportunities in terms of potential impact on society.

Innovative ideas and technologies from physics have contributed to great advances in the field of medicine over the last 100 years, since the advent of radiation-based medical diagnosis and treatment following the discovery of X-rays and radioactivity. Nowadays, state-of-the-art techniques derived from particle accelerators, detectors and computing are routinely used in clinical practice and medical research centres: from technology for PET scanners and dedicated accelerators for cancer therapy, to simulation and data analysis tools.

Over the past 60 years, CERN has developed widely recognised expertise and unique competencies in particle accelerators, detectors and computing in general. In addition, the Laboratory operates a one-of-a-kind accelerator complex and one of the largest
computing infrastructures in fundamental scientific research, and has significant experience in large-system integration.

Furthermore, the collaborative foundation of CERN’s experiments and public-private ventures such as the CERN openlab serve as proven models from which others take inspiration for their own collaborations.

It should also be noted that CERN has an excellent track-record as a training and education centre for particle physics and related technologies. The Knowledge Transfer (KT) Group is working to publicise CERN’s medical applications-related activities and to integrate them into its training programmes. CERN has further initiated numerous international and multidisciplinary collaborations and networks partially or entirely devoted to technologies with applications in the medical field, some of which have been funded by the European Commission (EC).

4. **Strategy underlying CERN’s medical applications-related activities**

The following constitute the principal elements of CERN’s strategy with respect to medical applications-related activities:

- CERN’s medical applications-related activities shall focus on R&D projects, using technologies and infrastructures that are uniquely available at CERN. This approach seeks to minimise any duplication of research efforts taking place in CERN’s Member States and to avoid overlap with the activities of external service providers, either in the market or otherwise.

- The most promising CERN technologies and infrastructure that are relevant to the medical domain shall be identified across the Laboratory’s three technology pillars – accelerators, detectors, and computing.

- The results of this identification exercise shall be matched with the requirements of the medical research communities, in particular in CERN’s Member States, which must always be the drivers of CERN’s engagement in this domain.

- Projects shall then be identified and established, taking into account, in particular:
  - the objective of maximising the impact of CERN’s engagement;
  - complementarities and synergies with the work in other laboratories in the Member States;
  - the existence of sufficient external funding to support each project;
  - the availability of resources, taking into account that CERN’s priority is its core mission of fundamental particle physics research.

Projects identified in this way shall be carried out with clear deliverables and milestones.
The external stakeholders must provide the funding needed to deliver their project. CERN can provide a limited amount of seed funding for medical applications projects and has done so since 2014, as is reflected in the MTP and the annual Budgets. As in the past, additional funding for CERN’s medical applications-related projects may be obtained through the EC Framework Programmes. The CERN & Society Foundation is another potential source of funding.

The selection of project participants shall take into account, in particular, the following:

- their location, with priority given to Member and Associate Member State participants;
- their proven competence in the field;
- their commitment to make available the results of the project for the purpose of medical applications; and
- their professional reputation and confirmation of the legal and regulatory compliance of their medical-related activities.

Access to CERN’s technologies and any other CERN resources shall be granted to project participants on a fair, transparent and equitable basis.

5. Organisational framework

Until recently, the transfer of knowledge and technology from physics to medicine at CERN has occurred serendipitously, essentially being driven by enthusiastic individuals on an ad hoc basis. This led to an increasing realisation, in-house, of CERN’s potential in this domain, which resulted in an elementary organisational structure being set up in 2014 and a small corresponding budget item being included in the MTP. As the activity has significantly evolved within CERN since then, a more robust organisational structure (see Annex II) was established in 2016, which operates under the delegated authority of the Director-General:

- The CERN Medical Applications Steering Committee (CMASC) selects, prioritises, approves and coordinates all proposed medical applications-related projects and their execution within their approved budget. It receives input from the Medical Applications Project Forum (MAPF), the CERN Medical Applications Advisory Committee (CMAAC) and various KT bodies, and acts in application of the strategy elements set out in Chapter 4.

The composition of the CMASC is as follows:

- Chair: Director for Accelerators and Technology or Director for Research and Computing;
- CERN Directorate;
- Heads of the relevant CERN Departments (currently BE, EN, TE, IT, EP, FAP, IPT);
External experts are invited by the Chair to attend the CMASC on an *ad hoc* basis when required.

The **CERN Medical Applications Advisory Committee (CMAAC)** provides input to the CMASC on the needs and priorities of the medical community and healthcare policy-makers. The members of the CMAAC are appointed by the CERN Director-General, and are medical doctors or experts from sectors that can potentially benefit from CERN’s medical applications-related work. The CMAAC Chair and members are appointed for a two-year mandate (renewable). The CMAAC Chair makes recommendations to the CERN DG concerning the appointment of the other members of the committee.

- **The CERN-Member States KT (knowledge-transfer) Thematic Forum** (KT Forum) brings together CERN and Member State representatives to
  - exchange information and ideas about KT activities, including those related to medical applications;
  - develop synergies and common approaches;
  - help CERN to liaise with industry and other stakeholders in the Member States, including through the network of Business Incubation Centres of CERN technologies;
  - help CERN to identify potential partners for participation in its knowledge transfer projects, including those related to medical applications.

The KT Forum comprises one or more representatives proposed by each Council delegation and is chaired by the KT Group Leader. Associate Member States are also welcome to participate.

Every year, at least one meeting of the KT Forum will be entirely devoted to the discussion of medical applications-related activities and will be co-chaired by the Chair of the CMASC and the KT Group Leader. The purpose of these meetings will be to:
- facilitate two-way communication between CERN and the Member and Associate Member States on the current and planned initiatives for the transfer of CERN technologies for the purpose of medical applications;
- avoid duplication of effort between CERN’s medical applications-related projects and initiatives of a similar nature in the Member and Associate Member States;
- provide input to the CMASC on the priorities and wishes of Member and Associate Member States.
Council delegates will be invited to appoint an additional representative, with appropriate knowledge of the medical applications-related activities taking place in their country, to attend these dedicated sessions of the KT Forum.

- The **CERN Medical Applications Project Forum** (MAPF) identifies the most promising CERN technologies and infrastructure that are relevant to the medical domain, and proposes related projects for consideration by the CMASC. It facilitates communication on medical applications-related work across CERN, as well as between the CERN experts and experts from external bodies. The composition of the MAPF is as follows:

  - the KT-MA Section Leader (Chair);
  - CERN scientists and engineers, proposed by their Department Heads, with expertise in technologies of potential interest for medical applications;
  - the CMASC Scientific Secretary (ex-officio).

The **CERN KT Medical Applications (KT-MA) Section** provides operational support for and coordinates CERN’s medical applications-related activities. It also negotiates and puts in place the necessary agreements with selected project partners and prepares medical applications-related input for KT’s annual progress report to the Council.

For projects that have an impact on CERN’s resources (personnel, infrastructure, accelerator schedule, etc.), approval of the **CERN Research Board** shall be sought, both for the initial proposal and for the yearly programme.

Council will be kept informed of medical applications-related projects through the annual approval process of the MTP. Projects of significant scope or having a substantial impact on CERN’s resources will be explicitly flagged by the Director-General.

6. **Boundary conditions applicable to medical applications-related activities**

CERN’s medical applications-related projects shall be implemented in accordance with the strategy and through the organisational structures set out above, and shall also observe the following boundary conditions:

- As an integral part of CERN’s KT activities, medical applications-related projects shall follow the overall CERN KT policies, including the policy on the “Management of Intellectual Property in Technology Transfer Activities at CERN” (CERN/FC/5434/RA).

- All medical applications-related projects taking place at CERN shall focus on R&D activities. No clinical trials, patient treatments or tests on animals shall be permitted on the CERN site.
• Medical applications-related projects shall comply with the specific legal framework in place at CERN. In particular, participants in a medical applications-related project are subject to CERN’s rules and regulations, including in matters of health, safety and the environment, when carrying out activities on the CERN site. More generally, project participants must also comply with the laws to which they and their activities are subject. This includes legislation in the domains of ethics in medical testing, as well as health, safety and the environment.

• Each project agreement shall, prior to that project’s commencement, address issues of ownership of materials and equipment contributed to or generated by a project, and related responsibilities and liabilities, including responsibility for disposal.

• Data handling in the context of medical applications-related activities must comply with CERN’s data privacy protection policies, developed and implemented through CERN’s Data Privacy Protection Office. In any event, personal medical-related data must be submitted to CERN in anonymised form and in a manner that prevents individuals from being identified.

• CERN policies on recognition and attribution, tuned for the specific context of medical applications-related projects, shall be applied to regulate the manner in which external participants in such projects may acknowledge CERN in their communications. Except as permitted under such policies, the use of CERN’s name, logo and acronym is subject to the express prior written permission of CERN.

• The agreements setting out the terms of any medical applications-related projects shall stipulate that CERN’s contribution is offered without warranty or representation and that liability with respect to the use of project results shall lie with project partners and not with CERN.

7. Conclusions
The transfer of know-how and technologies from CERN to the medical community represents one of the natural vehicles for CERN to disseminate the results of its work to society as widely as possible.

The Council is invited to approve the strategy and framework set out in this document for medical applications-related activities, and to take note of the information contained in Annexes I and II.
Glossary

BioLEIR  Ion beams for biomedical research
CCC  Crystal Clear Collaboration
CDR  Conceptual Design Report
CMAAC  CERN Medical Applications Advisory Committee
CMASC  CERN Medical Applications Steering Committee
CNAO  Centro Nazionale di Adroterapia Oncologica
EC  European Commission
EU  European Union
ENLIGHT  European Network for Light Ion Hadron Therapy
FLUKA  Fully integrated particle physics MonteCarlo simulation package
FuSuMaTech  Future Superconducting Magnet Technology
Geant4  Toolkit for the simulation of the passage of particles through matter
GEM  Gas Electron Multiplier
HEP  High-Energy Physics
HTS  High-Temperature Superconductors
ISOLDE  Isotope Separator On Line DEvice
KT  Knowledge Transfer
KT-MA  Knowledge Transfer – Medical Applications
LEIR  Low Energy Ion Ring
LHC  Large Hadron Collider
LTS  Low-Temperature Superconductors
MA  Medical Applications
MAPF  Medical Applications Project Forum
MEDICIS  Production of non-conventional radioisotopes for medical research
MoU  Memorandum of Understanding
MTP  Medium-Term Plan
PET  Positron Emission Tomography
PIMMS  Proton-Ion Medical Machine Study
TDR  Technical Design Report
TERA  TErapia con Radiazione Adronica
Annex I

Projects and activities

The CMASC, assisted by the MAPF, the CERN-MS KT Thematic Forum and the CMAAC, has identified a number of high-impact projects and activities for knowledge transfer by CERN for the benefit of medical applications. Some of these are long-established and will be monitored periodically. Others are at different stages of exploration, approval, or execution, as outlined below.

**CERN-MEDICIS**

Under the heading “R&D for medical applications”, CERN’s Medium-Term Plan for the period 2017-2021 (CERN/3246) includes an item entitled “Studies for the production of key radioactive isotopes for medical diagnostics”. In 2012, the Laboratory established the CERN-MEDICIS\(^1\) project, which will develop the necessary infrastructures in the ISOLDE Class A facility at CERN to handle radioactive sources suitable for the production of innovative medical isotopes. CERN-MEDICIS will exploit the non-interacting protons from the primary beam at ISOLDE, which will be directed onto a second target and then carried by an automated conveyor belt to the dedicated CERN-MEDICIS laboratory, where the isotopes will be collected and purified. The isotopes will be dispatched in small batches of up to 500MBq to the partner institutions of the CERN-MEDICIS collaboration for fundamental and pre-clinical medical research.

At present, the remote handling systems, the target front-end and the separator magnet have been completed and the other elements of the laboratory and beam line have been either procured or specified. CERN-MEDICIS will be ready to operate in 2017. Within the framework of this project, CERN is receiving support from external collaborating partners, according to the terms of the MoU that will be signed in the first half of 2017.

**BioLEIR**

Since the 2010 Physics for Health\(^2\) workshop, the international biomedical communities have been asking CERN to take the lead in the establishment of an open-access facility\(^3\) that would provide ion beams suitable for world-leading interdisciplinary studies, including radiobiology, nuclear physics models for medicine, advanced detectors and instrumentation for dosimetry, diagnostics, and imaging. In 2012, the idea of modifying the existing Low Energy Ion Ring (LEIR) accelerator was put forward to establish BioLEIR.

The total cost of BioLEIR cannot be sustained by CERN; an international collaboration should be formed to provide the necessary funding or in-kind contributions. As a necessary step

\(^1\) R.M. Dos Santos Augusto; L. Buehler; Z. Lawson; S. Marzari; M. Stachura; T. Stora; CERN-MEDICIS collaboration. CERN-MEDICIS (Medical Isotopes Collected from ISOLDE): A New Facility. *Appl. Sci.* **2014**, *4*, 265-281

\(^2\) [http://cern.ch/physics-for-health](http://cern.ch/physics-for-health), in particular see the Strategy Paper

\(^3\) This facility had been first envisaged at the 2005 meeting of ENLIGHT (European Network for Light Ion Hadron Therapy).
towards establishing such a collaboration, in spring 2017 CERN will produce a pre-CDR (Conceptual Design Report) setting out the technical feasibility and financial implications of modifying LEIR and of establishing a suitable area for biomedical experiments on the CERN site.

If the international collaboration for BioLEIR is established, CERN will finalise the design (CDR and TDR). Then BioLEIR facility will be submitted to the CERN Research Board and to the Council for approval.

If approved, BioLEIR would work in collaboration and synergy with existing facilities. Since its establishment in 2014, the CMAAC has been very supportive of BioLEIR.

**Accelerator design for future hadron therapy facilities**

The PIMMS (Proton-Ion Medical Machine Study)\(^4\) design that was initiated 20 years ago at CERN has made a fundamental contribution to the development of synchrotron-based accelerator systems for multi-ion cancer therapy. Since this pioneering study, great progress has been made in proton therapy accelerators: industry now provides turnkey solutions for new proton therapy facilities, including single-room units for hospitals. Custom design – often realised in partnership with research institutions – is still the norm for multi-ion facilities: two of Europe’s multi-ion centres are based on evolutions of PIMMS\(^5\); all are synchrotron-based. A collaborative design study coordinated by CERN would contribute to the development of a new generation of compact and cost-effective light-ion medical accelerators. A new initiative of this type would leverage existing and upcoming CERN technologies and the Laboratory’s expertise in the fields of radiofrequency systems, advanced magnet design, superconducting materials, and beam optics. The possible launch of such a study is currently being explored by CERN experts and a proposal will be put forward and evaluated by CERN’s medical applications decision-making structure.

**Computing and simulation for health applications**

Monte Carlo simulations are an essential tool for high-energy physics, and are constantly being improved. Simulation codes initially developed for HEP, such as Geant4 and FLUKA, have also become crucial to modelling the effects of radiation on biological tissues for a variety of applications in the medical field. These activities are carried out in a collaborative framework and constitute an established field of research for CERN.

CERN is exploring how to address the challenges related to the collection, storage and processing of increasingly larger data sets for medical research, clinical applications, and diagnostics\(^6\). Most of the research work carried out today to improve HEP computing infrastructures (including high-performance computing), data analysis and machine learning can have direct benefits also for medical research and other high-impact sustainable

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\(^4\) [https://cds.cern.ch/record/385378](https://cds.cern.ch/record/385378), [https://cds.cern.ch/record/449577](https://cds.cern.ch/record/449577)

\(^5\) The initial design was improved by the TERA Foundation, and finally evolved into the machine built for the CNAO treatment centre in Italy, with seminal contributions from INFN. Later on, MedAustron in Austria built its treatment centre starting from the CNAO design.


\(^6\) First exploratory projects were MammoGrid ([https://cds.cern.ch/record/46085](https://cds.cern.ch/record/46085)) and Health-e-Child ([http://cordis.europa.eu/project/rcn/105287_en.html](http://cordis.europa.eu/project/rcn/105287_en.html))
development goals. The same is true for services developed for HEP (e.g. for the open sharing of data).

Computing for medical applications is a strategic domain with a wealth of possible projects that will be assessed by CERN’s medical applications decision-making structure.

**Medical imaging**

Thanks to the activities performed by the Crystal Clear Collaboration (CCC) CERN has acquired internationally recognised expertise in the field of scintillating materials and their applications in HEP, medical imaging and other fields. In the framework of the general R&D carried out in the CCC and several EU-funded projects, CERN has made a significant contribution to the development of various high-performance positron emission tomography (PET) prototypes with variable geometry for a wide range of applications. Detectors with superior timing resolution have recently become a key development goal for both HEP and time-of-flight PET. CERN is involved in research efforts aimed at understanding the key challenges in this field.

Following the successful development of pixel detector readout chips for the LHC, the Medipix Collaborations developed successive generations of these chips for particle detection and imaging. The Medipix3 chip is being exploited for spectroscopic X-ray imaging in the pre-clinical environment. The Timepix chips have been evaluated for use as dose deposition monitors in hadron therapy. The recent Timepix3 should permit single semiconductor layer particle tracking during hadron therapy. Unlocking the full potential of these hybrid detectors for medical applications is a key challenge.

R&D activities in the field of scintillating crystals and hybrid silicon pixel detectors are well established and have mostly been conducted as part of collaborative efforts. These activities will be monitored and reviewed periodically.

**Dosimetry**

Particle detectors also have important applications in the field of dosimetry, where novel technologies can considerably improve the performance and reliability of dose monitoring procedures.

CERN is exploring the potential of GEMPix, a novel detector that couples two CERN technologies – the Gas Electron Multiplier (GEM) and Timepix. GEMPix is a promising technology for providing a 3D image of a particle beam and improved Quality Assurance procedures in radiation therapy. It can also act as a “tracking micro dosimeter” as it provides the possibility of measuring the track structure of ionising radiation down to the scale of tens of nanometres.

Due to the nature of the work done at CERN, the Laboratory has also deployed one of the most advanced personal dosimetry services in the world. The service will continue to evolve and

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7 Examples are already underway on a small scale: the GeneROOT project run by the IT and EP Departments aims at assessing the potential of the ROOT framework for large-scale genomic analysis; the BioDynaMo project is investigating how high-performance simulation techniques developed for Geant V can be applied to biological tissue growth simulation.

8 Approved in 1991 as CERN R&D research programme RD-18, “R&D on scintillation materials for novel ionizing radiation detectors for High Energy Physics, medical imaging and industrial applications”

9 [http://cern.ch/crystalclearweb](http://cern.ch/crystalclearweb)
many improvements and breakthrough innovations, such as a permanently traceable personal dosimeter, are of potential interest for the medical field. These activities are long-established and carried out often in collaboration across CERN Departments and Units, as well as with external collaborators. They will be monitored and reviewed periodically.

**Applications of high-field superconducting magnets**

CERN is developing novel accelerator magnet technologies in the range of 16 T (Low-Temperature Superconductors, LTS) to 20 T (High-Temperature Superconductors, HTS) which are directly relevant for developments in ultra-high field Magnetic Resonance Imaging and analytical Nuclear Magnetic Resonance. By fostering improvement of the superconductor performance, market availability of high-performance wires and tapes, and a reduction of the material cost, very-high-field medical instrumentation could become more compact and affordable. New magnet geometries are also being considered which, in combination with the improved superconducting materials, could provide innovative and efficient solutions for hadron therapy accelerators and gantries.

These applications are at an exploratory stage, triggered by the ad hoc Working Group on Future Superconducting Magnet Technology (FuSuMaTech) within the CERN-CEA collaboration agreement.
Annex II

CERN Medical Applications Steering Committee (CMASC)
Chair: Director for Accelerator and Technology

Medical Applications Section of CERN Knowledge Transfer Group (KT-MA)

CERN Medical Applications Advisory Committee (CMAAC)
Chair: P. Lambin (Maastricht)
Deputy Chair: M. Dosanjh (CERN)

Medical Applications Projects Forum (MAPF)
Chair: KT-MA Section Leader

CERN-MS Knowledge Transfer Thematic Forum (KTF)
Chair: KT Group Leader