Publishable Summary for 25HLT03 speCTraMet
Metrology for diagnostic imaging using spectral computed tomography

Overview

Computed Tomography (CT) is widely used across Europe for the imaging, diagnosis and clinical management of conditions such as cancer, cardiovascular disease, trauma and stroke. Spectral CT (sCT) imaging is an emerging technology that provides richer diagnostic information, enabling the extraction of imaging biomarkers, which are quantitative features in medical images that help characterise disease and assess treatment response, thereby supporting personalised medicine. However, variability between individual sCT scanners and a lack of standardised methods limit the clinical use of sCT for biomarker assessment. At the same time, patient safety must be ensured for any exposure to x-rays from sCT. This project will strengthen the reliability and safety of sCT imaging, by developing a methodology for the traceable characterisation of accurate sCT reference objects and providing a Good Practice Guide on how to use such objects to reduce variability of biomarker measurements at sCT scanners for future multicentre patient studies. It will also develop AI-based tools for personalised patient x-ray dose assessment tailored to sCT.

Need

CT is one of the most widely used clinical imaging methods in Europe, with over 60 million patient examinations annually. Spectral CT is an important new development which provides medical images as a function of x-ray energy (i.e. it delivers spectral information of the material properties). A typical clinical implementation of this technique uses specialised CT scanners that perform scans at two different energy levels. Based on this spectral information, imaging biomarkers can be developed that help doctors choose the best treatment and monitor how each patient responds. However, for these benefits to be realised across Europe, several critical gaps must be addressed.

First, hospitals currently lack reliable, standardised reference objects (“phantoms”) that allow them to check whether sCT scanners measure imaging biomarkers accurately. Existing phantoms are not characterised traceable to national measurement standards, meaning their material properties are not known at a metrological level and related uncertainties are unclear. Currently, metrology laboratories are unable to support the development of such phantoms because no methodology exists for their traceable characterisation.

Second, different manufacturers use different technologies to create sCT images. As a result, the same patient scanned on two separate systems can produce different numerical results. This variability makes it difficult to run multi-centre studies, compare results across hospitals, or set clinical thresholds. To address some of these challenges, the International Electrotechnical Commission (IEC) is currently developing a new standard specifically for sCT imaging: IEC 63483 (Performance Evaluation of Spectral CT). During their work, it has been found that the specification of meaningful measurement methods is strongly dependent on the phantoms used for these measurements. There is a clear need for harmonised calibration methods, uncertainty assessment, and guidance that allows scanners from different vendors to produce comparable quantitative outputs.

Third, while sCT has the potential to provide high quality quantitative data for personalised medicine, sCT uses x-rays which are a form of ionising radiation, and some sCT procedures require multiple scans resulting in increased radiation dose, thereby posing a risk to the patient. To protect patients, medical physicists must be able to measure and assess radiation dose accurately. Yet existing dosimeter calibration standards (e.g. IEC 61267) are designed for older CT technologies and do not reflect the radiation fields used in sCT. As a

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result, medical physicists and manufacturers rely on calibrations in reference radiation fields established for other purposes. To establish new reference radiation fields, spectrometry must be developed for sCT. Spectrometry has already been developed for other imaging modalities and for radiation protection purposes, but CT presents specific challenges, including relatively high radiation dose rates and imaging geometries that generate substantial photon scatter. Updated spectral characterisation methods and new reference radiation conditions are required to ensure safe, traceable dosimetry.

Finally, patient radiation dose management must comply with EU Council Directive 2013/59/Euratom, which requires that medical exposure be minimised while providing the necessary diagnostic information. Routinely used approaches for calculating patient radiation doses from dosimeter measurements are not scanner- and patient-specific, and proposed approaches for personalised dose estimation are currently too slow and labour-intensive for routine use. Artificial Intelligence (AI) offers a solution, but AI models must be trained on accurate data reflecting real sCT conditions, and their uncertainties must be well understood.

Objectives

The project's overarching objective is to build a reliable, standardised measurement infrastructure that will allow sCT imaging to be used confidently and safely in personalised medicine.

The specific objectives are:

1. **To develop a methodology for traceable characterisation of phantom inserts for phantoms used in spectral CT**. This will include: i) development of a method to measure energy binned linear attenuation coefficients of reference phantom inserts at specific x-ray photon energies with a target uncertainty of 1 %, established by at least 2 participating organisations, ii) characterisation of inserts for at least 1 reference standard phantom by the developed method and iii) development of a method to assess the uncertainties of the energy binned linear attenuation coefficients of the phantom inserts and derived quantities, using virtual phantoms.
2. **To assess the variability of the imaging biomarkers between multiple sCT scanners in a multisystem (multicentre and vendor) study** using the phantom inserts from objective 1. This will include the determination of a data set of sCT scan parameters that will be used to write a Good Practice Guide on the assessment and correction of the variability of biomarker measurements at sCT scanners and on harmonised protocols for multicentre studies.
3. **To develop metrological equipment and procedures for the spectral characterisation of sCT radiation fields**. This will include i) development of approaches for the improvement of sCT imaging and radiation dosimetry (e.g., measurement setups for spectrometry at clinical CTs) and ii) the application of the developed procedures on a representative set of sCT scanners for measurement of sCT in-beam x-ray fluence spectra.
4. **To develop a harmonised and validated software framework to facilitate personalised dosimetry in sCT and CT in clinical practice**. This will include developing i) algorithms for AI-assisted data-driven personalised dose assessment with an uncertainty of 20 %, ii) algorithms for AI-based organ segmentation and matching methods; iii) calculations of organ-dose volume histograms based on real patient anatomies, and iv) testing the applicability of the procedure in a multi-centre study.
5. **To facilitate the take up of the technology and measurement infrastructure developed in the project** by the measurement supply chain, standards-developing bodies (IEC TC 62), professional and scientific societies, international and regulatory organisations, industry and trade associations, and end users such as clinical stakeholders and manufacturers of medical and healthcare products.

Progress beyond the state of the art and results

Methodology for traceable characterisation of sCT phantoms

Today's reference phantoms used to test and calibrate CT scanners lack traceable, high-accuracy measurements of their physical properties. No accepted uncertainty budgets currently exist for the quantities relevant in sCT, such as iodine concentration. The project will overcome this gap by developing a new experimental methodology at multiple partners with a target uncertainty of 1%. As proof of principle, it will also

produce a fully characterised physical phantom. These advances will, for the first time, deliver traceable reference standards for sCT, enabling robust and reproducible quantitative imaging and encouraging the industrial uptake required for the widespread supply of such phantoms.

Good Practice Guide on the assessment and correction of the variability of biomarker measurements at sCT scanners and harmonised protocols for multicentre studies

Current sCT systems from different manufacturers use diverse technologies and processing algorithms, leading to variations in quantitative results. There is a variability in sCT data acquisition, image reconstruction and analysis/post-processing which leads to undesirable measurement inconsistencies between different sCT scanners. This variability restricts clinical adoption and complicates multi-centre research. The project will conduct a systematic multi-vendor, multi-centre comparison using the new reference phantoms developed in the project. It will identify sources of variability, quantify the associated uncertainties, and bring the results to literature. Based on this knowledge, a Good Practice Guide will be published that will allow clinicians to assess the variability at an individual scanner and determine related corrections. The results will help hospitals acquire consistent measurements, increase confidence in quantitative biomarkers, and support standardisation efforts.

Metrological equipment and procedures for spectral characterisation of sCT radiation fields

No standard exists for calibrating dosimeters under all the radiation fields used in new sCT scanners, leaving radiation dose measurements less accurate than desired. The project advances beyond current practice by developing new x-ray in-beam spectrometry methods and specialised measurement setups within at least two participating organisations, validated by an interlaboratory comparison. With these tools, it will generate a validated catalogue of sCT-specific x-ray spectra, data that manufacturers and metrologists currently lack but urgently need. These spectra are needed to define new reference radiation qualities for future IEC standards and support improved risk assessment and imaging detector development.

Personalised dosimetry framework for sCT

While AI has shown promise for medical image analysis and dose estimation, existing AI dose estimation models are proof-of-concept only: they are not adapted to sCT radiation fields, not in clinical use, and lack uncertainty budgets. This project will create the first AI-based, patient-specific dosimetry framework tailored to sCT. It will enable rapid automatic organ segmentation and fast dose calculations with a target uncertainty of 20 %. Crucially, it will include a full uncertainty evaluation aligned with international metrology guidance, supporting clinical trust and safety.

Outcomes and impact

Key dissemination and communication activities

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Outcomes for industrial and other user communities

The project will deliver several concrete outcomes that directly benefit industrial partners, healthcare providers, and other stakeholders involved in sCT imaging.

NMIs will be enabled to provide manufacturers of phantoms access to validated methodologies and traceable measurement procedures for quantifying material properties. This can enable manufacturers to increase their credibility for clinical use. The custom-designed phantoms developed within the project, and the demonstration of advanced 3D-printed models, will also stimulate innovation.

Manufacturers of sCT scanners will be supported to demonstrate compliance with standards. Access to a catalogue of well-characterised sCT x-ray spectra will help manufacturers refine detector designs, develop safer and more efficient imaging protocols, and improve dose-optimising algorithms.

Manufacturers of diagnostic dosimeters will be enabled to simulate and optimise their detector systems for sCT conditions using the spectrum catalogue that will be derived and validated within the project. If the IEC adopts these results as the basis for new radiation fields, and these are established at calibration laboratories, manufacturers will be able to calibrate and test their dosimeters under conditions that are demonstrably representative of sCT, thereby supporting compliance with existing standards and regulatory requirements.

Medical physicists and clinical imaging departments will gain tools that enhance clinical practice. If calibration laboratories implement the new methodologies as a service, medical physicists will be able to submit reference

phantoms for characterisation, obtaining well-defined uncertainties on material composition. This will enable more accurate quality assurance, while harmonised calibration recommendations and Good Practice Guides will reduce inter-scanner variability. AI-enabled dose assessment tools will allow clinics to quickly estimate patient-specific organ doses, improving risk assessment and supporting clinical justification of new sCT protocols. These innovations make quantitative imaging more reliable, supporting wider clinical adoption of personalised medicine.

Overall, these industrial and clinical outcomes support a standardised, and quality-assured sCT environment accelerating technology translation into routine healthcare.

Outcomes for the metrology and scientific communities

For the metrology community, the project will produce validated methods and optimised experimental setups for spectrometry of sCT radiation fields, new calibration capabilities, and reproducible procedures to determine energy-binned linear attenuation coefficients. These advancements will allow calibration laboratories to offer new calibration and characterisation services.

The scientific community will benefit from the possibility to create high-quality test objects and reference data, including phantoms with uncertainty-quantified material properties, validated virtual phantoms, and a catalogue of x-ray spectra. These datasets will significantly improve reproducibility in imaging research, a key challenge in quantitative imaging and biomarker development. Researchers will be able to benchmark reconstruction algorithms, test new detector technologies, validate Monte Carlo simulations, and conduct virtual imaging trials with traceable reference standards.

The personalised dosimetry framework will provide an openly accessible tool for advancing radiation risk estimation.

Collectively, these outcomes will strengthen the scientific foundations of sCT, enabling more rigorous biomarker studies, improved simulation tools, and robust cross-site comparability.

Outcomes for relevant standards

The project will have a direct impact on international standards through active engagement with IEC, IAEA, EURADOS, and ICRP working groups. Results from phantom characterisation, multisystem studies, and x-ray spectrometry measurements will feed into ongoing standardisation efforts, particularly: IEC 63483 – the emerging standard for sCT performance evaluation; IEC 61267 – standard reference radiation qualities for dosimeter calibration; IEC 61674 – performance testing of dosimetry instruments; IAEA TRS-457 – guidance on diagnostic radiology dosimetry.

Longer-term economic, social and environmental impacts

By providing the metrological foundations for reliable quantitative sCT, the project will strengthen the competitiveness of European manufacturers of scanners, phantoms, and dosimeters. Improved calibration standards will reduce development costs and accelerate regulatory approval. Hospitals will also benefit from greater diagnostic accuracy.

The improved reliability of quantitative biomarkers will support better monitoring of therapy response, and more effective personalised treatment plans for patients. Harmonised imaging protocols will allow patients to receive consistent results regardless of where they are scanned. AI-supported personalised dosimetry will help clinicians minimise unnecessary radiation, enhancing patient safety and strengthening public trust in medical imaging.

More efficient dose management can enable reductions in total population exposure to ionising radiation, aligning with EU safety directives and sustainability goals.

In summary, the project will result in better outcomes for patients, with more reliable treatment decisions and safer, more accurate treatment plans. It delivers major advances in measurement science, clinical practice, and supports industrial innovation. Its impacts extend well beyond the lifetime of the project, laying the groundwork for safer, more reliable sCT imaging across Europe.

List of publications

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Project start date and duration:		1 May 2026, 36 months
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Internal Beneficiaries: 1. PTB, Germany 2. CEA, France 3. CEM, Spain 4. CIEMAT, Spain 5. CMI, Czechia 6. ENEA, Italy 7. STUK, Finland 8. VSL, Netherlands	External Beneficiaries: 9. AOSP, Italy 10. CTU, Czechia 11. EFOMP, Netherlands 12. ERASMUS MC, Netherlands 13. HUS, Finland 14. KU Leuven, Belgium 15. MedUniWien, Austria 16. MIUN, Sweden 17. SKBS, Germany 18. VINS, Serbia	Unfunded Beneficiaries: 19. Comillas, Spain 20. SH, Germany