

Multi Partner Project: STRATUM, co-creation protocol and advanced smart GUI for a 3D neurosurgery supporting tool

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Abstract — STRATUM is a Horizon Europe multi-partner project developing a clinically validated, real-time 3D decision support tool for brain tumour surgery. The system integrates Hyperspectral Imaging (HSI), AI-based multimodal data fusion, and heterogeneous High-Performance Computing (HPC) architectures combining Graphics Processing Units (GPUs), Field-Programmable Gate Arrays (FPGAs), and Processing-In-Memory (PIM) technologies. A touchless augmented reality interface facilitates safe and intuitive intraoperative interaction. The distinguishing characteristic of STRATUM is its end-to-end co-designed approach, which integrates advanced computing, state-of-the-art imaging and clinical expertise into a unified Point-of-Care (PoC) platform. Utilising a structured co-creation methodology involving surgeons, engineers, and social scientists, the project ensures usability, safety and regulatory compliance from its early design stages to its clinical validation. The usability of STRATUM will be tested in three hospitals located in different European regions with diverse conditions and regulations. This will allow to collect advice and remarks from surgical staff in a continuous co-creation and co-tuning protocol. Beyond its clinical objectives, STRATUM contributes to the advancement of heterogeneous computing for real-time diagnostics, AI acceleration in critical medical environments and energy-efficient system integration. Furthermore, it delivers open datasets, validated AI pipelines, and performance benchmarks with a view to fostering future research and industrial innovation in digital surgery. The STRATUM project establishes a replicable model for intelligent, human-centred computing integrating microelectronics, AI and medicine.

The paper presents an overview of the project in terms of aims, concepts and technologies and the description of the state of the work when approaching the end of the second of the five

years planned. Specifically, the outcomes of the steps related to the collaboration with surgeons and medical staff (co-creation process) and the intelligent Graphical User Interface (GUI) development will be described. The latter allows for contactless interaction of the surgeon with several functions that have already been developed in the system.

Keywords—brain tumour detection, multimodal imaging, PoC computing, neurosurgery, HPC

I. INTRODUCTION

Brain and central nervous system tumours represent one of the most critical forms of cancer, both for their risk of mortality and for their localization. Evaluating global statistics from 1990 to 2021, a 106% increase in incidence has been observed, together with a 63.67% rise in the number of deaths [1]. The most common malignant primary brain tumour in adults is glioblastoma, which has a median overall survival time of only 14.6 - 16.7 months [2], [3]. Precisely due to their position, brain tumour surgery, (the standard procedure for the treatment), still presents a series of issues and an intrinsic complexity [4]: neurosurgeons face challenges to identify cancerous mass and to distinguish brain tumour margins, especially in high grade gliomas (e.g., glioblastoma). There is a lack of appropriate tools to enhance surgeons' vision, since the tumour is quite similar to healthy tissue for the human eye, and to provide real-time personalized diagnostics as well as real-time representation, interpretation and analysis methodologies for big data acquired by diverse and independent systems before and during the surgery. In particular, still no adequate visualization and analysis

approaches are available to evaluate and compensate for the brain shift phenomenon (produced after performing the craniotomy and starting the resection) [5]. In addition, waiting times for intraoperative pathology consultation remain very long and can provide only a preliminary diagnosis. Such factors are still not adequately addressed by current intraoperative diagnostic tools, thus showing limitations in their real world application [4]. In the broad field of neuronavigation, multiple research approaches focus on diverse aspects such as electrosurgery, radiosurgery and electrophysiological monitoring, as well as precise biopsies and brain morbidities other than tumours [6], [7], [8]. Thus, these approaches tackle different or only partially pertinent issues with regard to the aim of the presented project. In addition, neuronavigation solutions traditionally supply information about anatomical structures in real time based only on preoperative images used to construct a 3D model of the cranium, the tumour and relevant anatomical structures. Moreover, intraoperative brain shift is usually addressed by calculating an estimation which can be employed to update preoperative brain images, but it is still very difficult to model accurately [9], [10]. The innovation brought by the presented approach lies in the integration of intrasurgical hyperspectral imaging, as well as additional data, compared with traditional and commercial solutions [11], [12], paving the way for a more precise tumour identification and an improved brain shift compensation.

To overcome these issues, the STRATUM (3D Decision Support Tool for Brain Tumor Surgery - 101137416) European project will develop a neurosurgical decision support tool able to provide quick, accurate and highly personalized diagnostics for optimal decision-making in neurosurgical practice, ensuring a reduction of errors and delays during surgeries [13]. A decrease, moreover, will be earned in associated medical costs, also related to the use of photosensitive drugs or contrast agents employing fluorescent guidance tools (overcoming related side effects for patients). This project represents a significant opportunity to integrate, in a unified tool, relevant features coming from different fields [14]:

- **Hyperspectral Imaging:** to be used as an image guidance and diagnostic methodology together with High-Definition (HD) video imaging and depth data, providing high spatial resolution and depth information to generate 3D brain surface reconstructions;
- **Intraoperative Augmented Reality (AR) Neuronavigation** based on pre-operative data, namely Magnetic Resonance Imaging (MRI) or Computed Tomography (CT), combined with HSI. Brain shifts and deformations will be addressed in the loop to provide accurate intraoperative information through an interactive, easy-to-use and non-contact 3D GUI, as a 3D model of the patient's brain combined with the diagnostic results of the algorithms;
- **Intraoperative Neurophysiological Monitoring (IONM)** and life support systems, to provide valuable feedback about the status of the surgery and the patient during the procedure;
- **HPC** platforms to integrate, combine and interpret all data sources through innovative and robust AI algorithms, providing quick, detailed, accurate and highly personalised diagnostics.

HSI is a well-known methodology in the field of remote sensing [15], but it represents an approach being increasingly used also for medical diagnosis, especially for the detection and classification of tumoral tissue [16], [17], [18], [19], [20]. More specifically, STRATUM stems from previous projects devoted to the exploitation of HSI for the detection of brain tumour tissue during neurosurgery, with the aim of improving intrasurgical accuracy and of introducing a new touchless and unobtrusive methodology [21], [22], [23], [24]. Compared to other imaging approaches, HSI is low cost and easy to use; however, it produces up to hundreds of colour bands for each pixel in a single image, a much higher data size compared to RGB images. Hence, AI approaches and computing architectures that can suitably handle such data are required. For this purpose, appropriate architectures have been and will be evaluated with the aim of finding the best approach in terms of energy consumption and accuracy of the algorithms implemented [25].

[13] Such energy-efficient computing tool will integrate also diagnostic features based on multimodal data processing through AI algorithms. Technology Readiness Level 7 (TRL7) is expected to be reached by the end of the 5-year project. To accomplish this, the following objectives need to be achieved:

1. Achieve advance personalized medicine by leveraging multimodal data through the creation of a large public database;
2. enhance intraoperative diagnostic accuracy for brain tumours, by increasing the rate of gross total resection while minimizing the removal of healthy tissue compared to current procedures;
3. reduce neurosurgery duration by limiting intraoperative pathological assessment, thanks to multimodal approaches and HPC platforms for real-time data processing;
4. improve cost- and energy-efficiency of neurosurgical workflows by integrating different data sources into an interactive 3D GUI, to improve visualization and minimize expenses related to the use of contrast agents and intraoperative pathology;
5. conduct a two-year clinical study to validate the prototype across three clinical sites in Spain and Sweden, including early Health Technology Assessment (HTA);
6. develop an initial business plan and a strategic roadmap to achieve TRL9 after the project's completion, with the aim of commercialising it by 2030. Such strategy will be based on the results obtained from the two-year clinical study and the co-creation process, that will be updated throughout the project to include new outcomes and adapt actions [13].

STRATUM represents a reference model of transdisciplinary collaboration for AI-powered intraoperative decision-making tools. For this purpose, the paper shows the organization and the first stages of the project, officially started in December 2023 until December 2028: in Section II the consortium composition and the co-creation protocol are introduced, while Section III presents the overall architecture of the DST. Section IV describes the envisioned validation strategy, both from the technical and clinical perspectives, followed by the Conclusions in Section V.

II. CONSORTIUM AND CO-CREATION METHODOLOGY

2.1 STRATUM Consortium Structure

The STRATUM Consortium is composed of 12 partners located across 6 countries: universities, hospitals, research centres, industry, SMEs (Small and Medium Enterprises) and Non-Governmental Organizations (NGOs). Fields involved span across computer science, biomedical engineering, clinical neurosurgery, pathology, radiology, medical device manufacturing, electronics, health economics and social sciences.

2.2 Co-Creation Process

The STRATUM co-creation process establishes a structured plan for the design, development, and validation of the STRATUM DST for brain surgery. Its main goal is to ensure that the needs, expectations, and preferences of end-users (primarily neurosurgeons) and stakeholders are considered throughout the entire development process. The co-creation process is organized into three main phases. The *co-design phase* focuses on identifying key stakeholders (e.g., neurosurgeons, radiologists, neurophysiologists, pathologists, nurses, patients, and caregivers). Initial focus groups and individual interviews are conducted to explore needs, limitations of current systems, and requirements for accessibility, usability, and clinical integration. The *co-production phase* includes regular meetings between researchers and users to prioritize functionalities, evaluate developed modules and algorithms, and make adjustments based on feedback. The aim is continuous and iterative improvement through regular “check-ins” with involved actors. Finally, the *co-delivery phase* brings the findings from the whole process, i.e., the fully working prototype of the STRATUM DST. In this phase, the prototype is shown and evaluated by different stakeholders, end-users, the research team and even external people. Focus groups with patients and relatives are planned to understand their perceptions, acceptance, and concerns regarding the use of AI in neurosurgery.

The co-creation methodology follows a user-centred design approach. Data are collected through focus groups and individual interviews, guided by semi-structured instruments (Questioning Route Documents). The resulting data are analysed using a descriptive deductive content analysis [26]. Key aspects include usability, user experience and interoperability (secure and effective integration of clinical data according to the European Interoperability Framework [27]). Importantly, the participation of the European Citizen Science Association (ECSA) ensures that the co-creation process aligns with broader ethical and social dimensions. ECSA’s involvement promotes transparency, inclusivity, and societal relevance in the development of the STRATUM Tool, ensuring that the project respects citizen perspectives and public values while addressing clinical needs. The process is open and continuous, encouraging adaptation to new findings and iterative improvement of the prototype.

III. STRATUM DST ARCHITECTURE

3.1 Multimodal Imaging Acquisition Subsystem

The first crucial outcome of the project is the design and development of a Multimodal Intraoperative Acquisition System (MIAS), which is aimed at the clinical capture of HSI, High-Definition RGB video and depth sensing for 3D reconstruction during brain tumour surgery. This tool is a non-

contact, label-free, and real-time imaging solution for tumour margin identification using HSI. Such system has been under development since the very beginning of the project and is now progressively incorporating multiple imaging modalities.

HSI is a new potential tool to be used in the medical domain due to its non-invasive, non-contact, non-ionizing, and label-free imaging features [28]. HSI combines traditional imaging and spectroscopy to conform hyperspectral images, which contain both spatial and spectral information (within and beyond the visual spectral range) of the captured scene. This technology has already been used as a proof-of-concept to provide neurosurgical guidance maps with tumour areas identified at pixel level (red area in Figure 1).

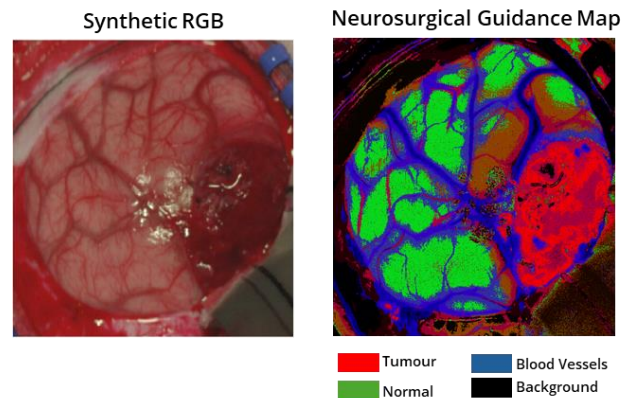


Figure 1: Example of a synthetic RGB image (generated from a HS image) of an exposed brain surface and the corresponding neurosurgical guidance map generated through AI-based processing [29], where the tumour area is represented in red.

The MIAS integration, that represents the first resulting version of the acquisition prototype, is shown in Figure 2. The optical system is divided into the microscope head, based on the surgical microscope OPTOMIC OP-C16 (OPTOMIC España S.A., Spain), and an independent illumination module, denoted STRATUM HS illumination system, which are connected through a two-meter fibre optic light guide. Narrowband illumination is generated with Liquid Crystal Tunable Filters (LCTFs), that transmits light in a single spectral band while rejecting the rest of the spectrum. Two LCTFs are integrated: i) a Kurios VB1 (Thorlabs, Inc., NJ, USA) driven by a high-CRI (Color Rendering Index) white LED (Light-Emitting Diode) and covering the range from 450 to 730 nm, and ii) a Kurios XE2 (Thorlabs, Inc., NJ, USA), illuminated by a halogen lamp and covering from 650 to 1100 nm. The outputs of the different filters are selectively connected to the output light guide by using a motorized mirror.

The HS data is acquired by a LP126MU (Thorlabs, Inc., NJ, USA) panchromatic camera, which has high spatial resolution (4096×3000 pixels) and 12-bit resolution. A secondary RGB camera LP126CU (Thorlabs, Inc., NJ, USA) with identical resolution is present in the microscope head for RGB real-time visualization. The combination of both cameras exploits the stereoscopic vision from the surgical microscope allowing the generation of depth maps. These depth maps are further refined by using AI to model the surface shapes and details of the exposed brain surface. The MIAS captures intraoperatively HS cubes with 130 bands with 5 nm spectral resolution between 450 to 1000 nm in 50 s. This time could be noticeably shortened by reducing the number of

captured bands thanks to the configurability of the HS illumination system. The pixel size for the cameras is $22\ \mu\text{m}$ with a $\times 1$ magnification, providing adequate resolution for fine brain structures.

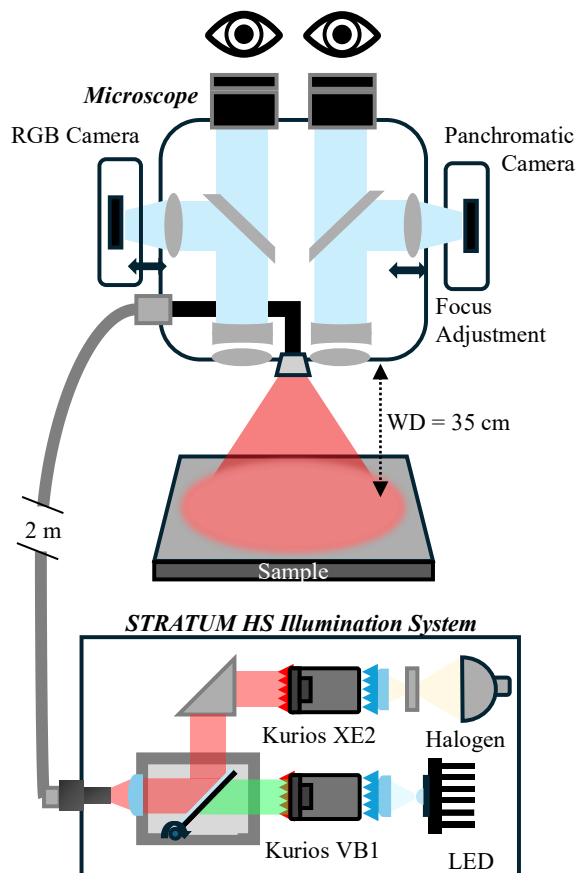


Figure 2: Schematic diagram of the MIAS composed by microscope head and the STRATUM hyperspectral illumination system.

Based on the spectral characteristics of the proposed MIAS, a methodology to generate a simulated HS dataset (using data captured in previous projects [29]) has been proposed in STRATUM [14]. These simulated data will be employed as starting point for the algorithms developed within the project in order to pre-train the AI-based algorithms, increasing in this way the number of subjects and HS images employed for such purpose (in addition to those recruited within the STRATUM Observational Study).

3.2 High-Performance Computing Platform

The HPC Platform is the computational foundation of the STRATUM DST, responsible for executing real-time data processing, multimodal fusion, and AI-based tissue classification during neurosurgical procedures. The platform has been developed on the basis of the architecture outlined in the STRATUM project design and described in previous works [4], [14]. It is conceived as a heterogeneous computing environment capable of handling the large data volumes and low-latency constraints typical of intraoperative use. The objective of the system is to facilitate the integration of IONM, HSI, MRI, CT, RGB and depth cameras into a unified decision-support workflow. The system design is organised into three layers, which reflect the logical structure of the STRATUM processing chain. All layers are currently under development by the different work packages of the project and a definitive outcome cannot yet be shown, since it will be

represented by the integration of the results of the three layers, which are all strictly intertwined.

3.2.1 Data Acquisition and Management Layer

It is responsible for the ingestion, synchronisation, and preliminary preprocessing of multimodal data streams. The system receives inputs from the intraoperative acquisition devices and clinical imaging systems through standardised interfaces (e.g., GigE Vision for HSI, DICOM - Digital Imaging and Communications in Medicine - for MRI/CT, and HL7 for hospital data). The integrity of the data is ensured prior to computational processing by dedicated preprocessing modules that perform calibration, denoising, and temporal alignment.

3.2.2 AI Processing and Integration Layer

This Layer represents a fundamental component of the platform's architecture. Situated at the core of the system, this layer is responsible for executing AI-driven diagnostic algorithms. These algorithms are designed to facilitate the classification, segmentation and data fusion of tissue samples. The system operates on a heterogeneous architecture, combining GPUs for massively parallel operations, FPGAs for deterministic low-latency tasks, and PIM devices to reduce data transfer overhead and energy consumption. Each computational kernel, whether it is concerned with feature extraction, tumour probability estimation, or spectral unmixing, is mapped to the most suitable hardware resource using CUDA, OpenCL, or High-Level Synthesis design tools, depending on its computational profile.

3.2.3 Visualization and Communication Layer

The last layer is responsible for the real-time communication between the HPC platform and the 3D interactive GUI. The transmission of AI results is facilitated by a lightweight publisher-subscriber protocol, thereby ensuring continuous data updates with minimal latency. The output data are structured in a standardised 3D format (meshes, overlays, and tissue probability maps) which is optimised for GPU-based rendering in the AR visualisation module. It is imperative to acknowledge the paramount importance of intraoperative utilisation in this context. Consequently, the platform has been meticulously engineered to facilitate real-time deterministic operations, as opposed to prioritising maximum throughput. In order to guarantee consistent performance under conditions of variable load, STRATUM employs a set of technologies:

- the concept of parallel pipelining involves the concurrent execution of acquisition, AI processing, and visualisation tasks. This approach is designed to minimise end-to-end latency;
- the scheduling process should be predictable, with critical kernels (e.g., tumour detection) being prioritised and executed within fixed time constraints;
- the presence of hardware redundancy and watchdog mechanisms is crucial, as they ensure continuity of operation even in the event of partial hardware degradation;
- error propagation control is a process that is designed to prevent corrupted data or incomplete computations from reaching the visualization layer.

This design philosophy reflects the project's objective to produce a computing backbone that is clinically robust,

capable of sustained, predictable performance in real-world surgical environments.

3.3 3D Interactive Graphical User Interface

The GUI of the STRATUM DST represents the surgeon's primary access point to all multimodal and AI-processed information generated during brain tumour surgery. The design of the GUI is based on a human-centred, safety-critical philosophy, wherein the principles of usability, ergonomics and asepsis are prioritised in conjunction with computational efficiency. The GUI works as a real-time visualisation and interaction hub, thereby enabling neurosurgeons to explore 3D anatomical and functional information derived from HSI, MRI, CT and IONM within a single, coherent AR environment. A touchless AR-based neuronavigation system is implemented, whereby 3D reconstructions of the patient's brain, tumour margins, and surrounding tissues are visualised interactively. The AR visualisation technique integrates the patient's pre-operative data (obtained from MRI and CT scans) with real-time intraoperative acquisitions (HSI, RGB, and depth maps) to provide an accurate and up-to-date spatial reference of the surgical field. This hybrid spatial mapping facilitates precise localisation of tumour boundaries and critical structures, thereby supporting safer resections with improved tissue preservation.

The STRATUM GUI is a novel innovation in the field of neuronavigation systems. It is a paradigm shift from traditional systems that require manual input or dedicated controllers. Such interface is a hands-free system that allows manipulation of the visualization using gesture and voice commands. This includes rotation, zoom, clipping planes and transparency adjustments. This capability ensures that the surgeon remains fully sterile and focused, thereby eliminating unnecessary interruptions and enhancing workflow continuity. The AR environment has the capacity to display dynamic annotations and heatmaps representing tumour probability and AI-inferred tissue composition, which can be selectively enabled through natural interactions.

A pivotal innovation of the GUI lies in its integrated visualisation framework, where multimodal datasets and AI-based diagnostic outputs are processed, fused, and displayed in real time. AI-generated maps derived from HSI and other intraoperative sensors are overlaid on pre-operative MRI and CT images, allowing the user to correlate functional and spectral information with structural anatomy. This innovative approach involves merging data from MRI scans and potentially other images taken before surgery, depending on their usefulness, with data acquired during the operation. This produces a composite image with much higher informational content.

Furthermore, IONM data are continuously streamed and synchronised within the interface to provide immediate feedback on neural activity and patient safety. This integration transforms the GUI into a decision-centric workspace, enabling surgeons to visually assess correlations between tumour delineation, anatomical constraints, and physiological responses during resection. From an engineering perspective, the GUI administers heterogeneous data sources through a modular visualization pipeline, thereby ensuring efficient rendering even under high computational load. Latency is minimised by leveraging real-time communication with the HPC platform, which delivers processed AI outputs to the GUI in a format optimised for immediate display. This

architecture ensures low-latency visual updates (<200 ms), which are key factors for intraoperative use, and facilitates parallel rendering threads for concurrent 2D/3D visualisation. In order to accommodate a variety of operating room scenarios, the STRATUM GUI supports three complementary interaction modes. These modes have been designed to ensure redundancy and robustness. The implementation of gesture recognition utilising Google MediaPipe [30] facilitates real-time detection and interpretation of hand and finger movements captured by depth cameras integrated within the operative environment. MediaPipe's lightweight architecture facilitates low-latency inference directly on the workstation's GPU, thereby ensuring smooth control even under variable lighting or occlusion conditions. It is evident that a number of common gestures have been identified, which include the rotation of 3D models, zooming, the slicing of planes, the toggling of layers, and the selection of AI results.

The utilisation of voice commands, integrated through the STRATUM speech recognition module, facilitates context-dependent control, for instance, switching between visualisation modes, enabling AR overlays, or requesting specific patient data. The module has been optimised for use in noisy clinical environments through the implementation of adaptive noise suppression and limited-domain grammars. A keyboard and touchpad interface serve as a fallback mechanism outside the sterile area, ensuring uninterrupted system operability during calibration, emergencies, or non-sterile sessions. The GUI has been entirely developed using Qt and VTK (Visualization Toolkit) [31], [32]. Qt is the cross-platform foundation for event management, user interface layout, and integration with clinical data management systems. VTK, meanwhile, powers the 3D rendering engine, volumetric reconstruction, and AR visualisation. The rendering capabilities of VTK, accelerated by GPU, in conjunction with its extensive medical imaging support (e.g., DICOM compatibility and multi-volume blending) are particularly suitable for real-time intraoperative applications. In order to ensure regulatory compliance and clinical readiness, the GUI development adheres to two major international standards: IEC 62304:2006 and the ISO 13485:2016 [33], [34]. IEC 62304:2006, entitled "Medical Device Software – Software Life Cycle Processes" is a standard that defines structured workflows for software development, validation, and maintenance. STRATUM implements its guidelines through continuous integration pipelines, traceability matrices, and systematic risk management across all software modules. The ISO 13485:2016 standard, entitled "Quality Management Systems for Medical Devices", is a comprehensive framework that aims to ensure the quality assurance, documentation control, and safety management of medical devices throughout their development process. The standard guides verification, validation, usability testing, and post-deployment monitoring, which are all essential for obtaining medical device certification. Adherence to these standards is pivotal in ensuring that the GUI attains clinical-grade reliability, traceability, and regulatory alignment, which are indispensable prerequisites for attaining certification at TRL7 and, consequently, progressing towards TRL9.

IV. TECHNICAL AND CLINICAL VALIDATION STRATEGY

The STRATUM DST will be technically and clinically validated in international and multicentre clinical studies to measure the diagnostic performance and usability of the tool

in neurosurgical workflows. Starting from a clinical study involving one hospital, the process will progressively engage additional structures. During this process, it is expected to generate a large public multimodal database with more than 500 patients affected by intra-axial brain tumours, including more than 200 associated variables as metadata.

4.1 Clinical Settings

The recruitment of patients and the validation of the proposed tool will be carried out at 3 clinical sites: 1) Hospital Universitario de Gran Canaria Doctor Negrín (Las Palmas de Gran Canaria, Spain), 2) Karolinska University Hospital (Solna, Sweden) and 3) Hospital Universitario 12 de Octubre (Madrid, Spain). The participation of these clinical sites will ensure the validation of the tool into diverse neurosurgical environments that may have diverse infrastructure. The results are expected to have greater external validity than if it had been conducted in a single centre, as it will be evaluated simultaneously in three hospitals in two different countries.

4.2 Validation Protocol

The first clinical study is an observational study (STRATUM-OS) with the main goal of collecting a large set of multimodal data and variables from patients affected by intra-axial brain tumours (both primary and secondary) [35]. These data are collected pre-, intra- and post-operatively from the Electronic Case Reporting (ECR) of the patient and self-reported questionnaires, information collected from the different professionals involved in the neurosurgical workflows and data collected intraoperatively using the STRATUM intraoperative acquisition system. By using the data collected in STRATUM-OS, the AI-driven algorithms will be developed and implemented onto hardware accelerators for achieving real-time performance. Additionally, these data will serve to technically validate the STRATUM fully working prototype, measuring the diagnostic performance of the tool for discrimination between tumour and non-tumour tissue samples, using definitive histopathological analysis as the reference standard; and Contrast-Enhancing Tumour (CET) or non-Contrast-Enhancing Tumour (nCET/FLAIR-positive) regions in MRI, using histopathological and radiological reports as the reference.

All patients recruited in STRATUM-OS will serve as historical control group for the second clinical study that will be carried out the last two years of the project by integrating the fully working STRATUM tool into the neurosurgical workflows in each clinical site, in addition to the standard procedures and tools employed during surgery. This clinical study will be a non-randomized, historically controlled, clinical trial (STRATUM-NRCCT) with the goal of measuring the performance, usability and usefulness of STRATUM in a real environment. In addition, the tool will undergo an early process of HTA, including cost-effectiveness and economic impact assessment for the Swedish and Spanish contexts, together with an examination of the potential organizational impact.

4.3 Ethics

The clinical studies will adhere to the ethical principles for medical research involving human subjects established in the Declaration of Helsinki and the Good Clinical Practice Guidelines. The Ethics Committee of Hospital Universitario de Gran Canaria Dr. Negrin (Spain), Hospital Universitario 12

de Octubre (Spain) and Karolinska University Hospital (Sweden) have approved the STRATUM-OS study (No. 2024-395-1 and 25/088), and the study protocol has been registered in ClinicalTrials.gov (NCT07036783). An insurance policy has been issued for STRATUM-OS under the number 08057767-30092.

V. CONCLUSION

The STRATUM project demonstrates how the integration of AI, multimodal data, and HPC can enhance neurosurgery by providing surgeons with real-time, data-driven decision-making support. The development of a 3D interactive platform that merges multimodal imaging, AI-based diagnostics, and AR visualisation represents a significant contribution to a new paradigm of intelligent, human-centred digital surgery.

The project's strength lies in its transdisciplinary collaboration among universities, clinical institutions, research organizations and industrial partners, ensuring a seamless transition from algorithmic innovation to clinical translation. The adoption of a co-creation approach, engaging surgeons as end-users throughout the design and development process, has been essential to align system functionalities with real surgical workflows and ethical standards.

STRATUM's heterogeneous HPC architecture, which combines GPUs, FPGAs and PIM accelerators, has been developed to support deterministic, energy-efficient computation directly at the PoC. The touchless 3D GUI developed using Qt, VTK, and MediaPipe, provides safe and intuitive interaction during surgical procedures, fully compliant with IEC 62304 and ISO 13485 standards.

In terms of future developments, STRATUM will establish the basis for a new generation of AI-assisted decision-support systems that have the potential to be extended to other clinical domains. The project's outcomes, which include instrumentation, accelerated algorithms, datasets and architectural guidelines, are expected to foster future research and industrial innovation in the field of trustworthy, real-time computing for healthcare.

ACKNOWLEDGMENT

This work has been developed under the STRATUM project which received funding from the European Union's Horizon Europe Programme HORIZON-IA action under grant agreement No 101137416. Finally, the members of the STRATUM Consortium are detailed in <https://www.stratum-project.eu/stratum-consortium-members/> and <https://zenodo.org/records/15105148>.

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