ORIGINAL ARTICLE

Biobanking of Salivary Gland Tumours: Insights from the Polish Salivary Gland Network Towards Future Digital Integration and Image-Based Research

Małgorzata Wierzbicka[1,2ABDE], Wioleta Pietruszewska[3ABDE], Hanna Klimza[1ABDE], Dominik Stodulski[4ABDE], Jarosław Markowski[5ABDE], Aleksandra Piernicka-Dybich[5ABDE], Katarzyna Radomska[6ABDE], Alicja Chańko[6ABDE], Paweł Burduk[7ABDE], Daniel Majszyk[8ABDE], Bogusław Mikaszewski[4ABDE], Patrycja Gazińska[9,10ABDEF]

[1]Department of Otolaryngology, Regional Specialist Hospital Wroclaw, Research & Development Centre, Wroclaw, Poland
[2]Institute of Human Genetics, Polish Academy of Sciences, Poznan, Poland
[3]Department of Otolaryngology, Head Neck Oncology, Medical University of Lodz, Poland
[4]Department of Otolaryngology, Faculty of Medicine, Medical University of Gdansk, Poland
[5]Department of Laryngology, Faculty of Medical Sciences in Katowice, Medical University of Silesia in Katowice, Poland
[6]Departament of Otolaryngology, Pomeranian University of Medicine Szczecin, Poland
[7]Department of Otolaryngology, Phoniatrics and Audiology, Collegium Medicum, Nicolaus Copernicus University, Bydgoszcz, Poland
[8]Department of Otorhinolaryngology, Head and Neck Surgery, Medical University of Warsaw, Poland
[9]Biobank Research Group, Lukasiewicz Research Network – PORT Polish Center for Technology Development, Wroclaw, Poland
[10]Department of Hematology and Oncology, Faculty of Medicine, Wroclaw University of Science and Technology, Wroclaw, Poland

ABSTRACT:

Introduction: Salivary gland tumours (SGTs) remain poorly represented in large-scale research due to low incidence and anatomical heterogeneity. Biobanking and data integration for SGTs remain particularly limited, as these tumours are often excluded from malignant tumour registries; even when data are collected centrally, they frequently lack sufficient detail and standardization, hindering harmonization and meaningful analysis.

Aim: To present the design and early implementation of the Polish Salivary Gland Network (PSGN), a multicentre initiative linking standardized clinical data with ISO 20387-compliant biobanking infrastructure for SGTs.

Materials and methods: The PSGN collects harmonized clinical, surgical, and pathological data from eight academic university departments across Poland (2017–2025). The data are managed using NorayBanks software, ensuring full traceability, regulatory compliance, and standardized data governance. This infrastructure lays the foundation for future digital integration, image-based research, and AI-supported analyses. Additional efforts focus on data quality assurance, process mapping, and dataset harmonization to enable multicentre interoperability and research scalability.

Results: As of 2025, the PSGN holds data on 3,654 patients with SGT (mean age: 58.3 years; 62% female), including >70 clinicopathological variables per case. While parotid tumours dominate, ~3.7% involve rare sites such as the parapharyngeal space. The registry includes treatment details and key outcomes such as DFS, OS, and recurrence. Early findings suggest potential to inform clinical decision-making and uncover diagnostic challenges.

Conclusions: The PSGN is the first structured platform for SGT biobanking. It provides a foundation for data-driven research and sets the stage for future digital and molecular advancements in rare cancer studies.

KEYWORDS: BBMRI, biobanking, PSGN, rare cancers, salivary gland tumours, SGT, translational research

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CORRESPONDING AUTHOR:
Patrycja Gazińska; Biobank Research Group, Lukasiewicz Research Network – PORT Polish Center for Technology Development; Stablowicka street 147, 54-066 Wroclaw, Poland; E-mail: patrycja.gazinska@port.lukasiewicz.gov.pl

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The authors declare that they have no competing interests.

ABBREVIATIONS

AI – artificial intelligence
ASCO – American Society of Clinical Oncology
ASR – age-standardized incidence rate
BAC – Biopsy-Assisted Cytology
BBMRI-ERIC – Biobanking and BioMolecular Resources Research Infrastructure – European Research Infrastructure Consortium
CNB – Core Needle Biopsy
DFS – disease-free survival
ECD – extracapsular dissection
ESGS – European Salivary Gland Society
EURACAN – European Reference Network for Rare Adult Solid Cancers
FAIR – Findable, Accessible, Interoperable, Reusable
FNA – Fine-Needle Aspiration
HDI – Human Development Index
HP – histopathology
IO – intraoperative
Ł-PORT – Łukasiewicz–PORT Polish Center for Technology Development
OS – overall survival
PPS – parapharyngeal space
PSGN – Polish Salivary Gland Network
RCPath – Royal College of Pathologists
SGC UK – Salivary Gland Cancer UK
SGM – salivary gland malignancy
SGT – salivary gland tumour
WHO – World Health Organization

INTRODUCTION

Biobanking in rare diseases plays a critical role in overcoming the limitations of traditional research approaches, particularly where patient numbers are too low to support large-scale clinical trials. In the field of precision oncology, biobanking has become a cornerstone for advancing biomarker discovery, genomic profiling, and the development of individualized therapeutic strategies [1]. For rare head and neck tumours – where heterogeneity is high and clinical evidence is sparse – integrated biobanks linked with robust clinical metadata are essential. They provide the infrastructure needed to uncover patterns in tumour biology, treatment response, and disease progression that would otherwise remain elusive.

SGTs are rare and biologically diverse neoplasms, accounting for less than 5% of all head and neck tumours; of these, 70 to 90% are benign. Salivary gland malignancies (SGM) are uncommon, representing 1–6% of head and neck malignancies [2]. Despite ongoing research, significant gaps remain in global population-level data on SGMs, particularly in rare anatomical subtypes and underrepresented regions. A large-scale population-based analysis by Huang et al. (2024) reported an age-standardized incidence rate (ASR) of 0.57 per 100,000 for SGMs with notably higher rates in high-Human Development Index (HDI) countries, particularly among women. The highest incidences were observed in North America, Northern Europe, Japan, and UK, while the lowest were recorded in Polynesia [3]. Complementing these global trends, a national study from Poland [4] analysed 230,589 cases of salivary gland pathologies over a decade. The majority of cases were non-neoplastic (85.5%), followed by benign tumours (11.5%) and malignancies (2.9%). While the overall incidence was 59.94 per 100,000, benign tumours showed a steady increase (mean: 6.91/100,000), and malignant tumours declined over time (mean: 1.78/100,000). Non-neoplastic lesions remained stable. These findings indicate a shifting epidemiologic pattern – characterized by a growing burden of benign tumours and a declining trend in malignancies – which calls for updated diagnostic workflows and revised strategies in healthcare planning.

Among notable international efforts, the Mayo Clinic's salivary tissue-organoid biobank and Salivary Gland Cancer UK (SGC UK) represent important initiatives advancing both translational research and clinical standardization in salivary gland disease. The Mayo Clinic's salivary tissue-organoid biobank provides cryopreserved, clinically annotated samples from over 200 donors – including both healthy individuals and patients with diseases such as cancer, Sjögren's syndrome, and COVID-19. These organoids are rich in salivary stem/progenitor cells and are being used to study regenerative therapies for conditions such as xerostomia and radiation-induced damage [5]. In parallel, SGC UK has launched a national working group focused on improving diagnostic pathways, treatment planning, and pathology standardization across the UK [6].

Nevertheless, diagnosing SGTs remains a clinical and pathological challenge due to their broad morphological diversity and frequent histological overlap between benign and malignant entities. To address these complexities, the Royal College of Pathologists (RCPath), in alignment with the 5th edition of the WHO Classification of Head and Neck Tumours, has recently revised its dataset for salivary gland carcinomas [7]. These updates incorporate newly recognized tumour entities, refined grading criteria, and standardized reporting frameworks that emphasize the use of molecular diagnostics and immunohistochemistry. The revised RCPath dataset introduces harmonized protocols for specimen handling and diagnostic workflows, aiming to enhance diagnostic precision and support more consistent clinical decision-making across institutions [7–9]. SGMs are histologically and molecularly heterogeneous due to the complex embryological origin of salivary tissue [10]. Risk factors include radiation exposure, Epstein-Barr virus [11], tobacco, and alcohol use, while links to mobile phone radiation and air pollution remain inconclusive [12]. Despite the publication of the 2021 ASCO guidelines, optimal approaches to surgery and systemic therapy for salivary gland malignancies remain insufficiently defined [13]. A review by Bishop (2022) underscores how newly emerging SGT entities are being reclassified based on novel molecular alterations, such as characteristic gene fusions and mutations. These discoveries are transforming traditional diagnostic frameworks and allowing for more refined tumour subtyping [14].

There is growing momentum – particularly through international and pan-European collaborations – to harmonize data sharing, biospecimen access, and research infrastructure for rare cancers like SGMs. Consortia like BBMRI-ERIC and EURACAN promote standardized procedures and cross-border integration to enhance collaborative research and patient care [15].

Together, these initiatives represent a growing ecosystem of national and international collaborations aimed at improving outcomes in rare SGT and SGM, which, due to their rarity, are often excluded from major clinical trials, leaving a knowledge gap in evidence-based treatment. As hypothesized, standardized ISO 20387-compliant biobanking and centralized clinical data management across the Polish Salivary Gland Network enable robust identification of clinicopathological and molecular patterns, thereby supporting stratified treatment planning and advancing translational research. In this context, we present the design and early implementation of the Polish Salivary Gland Network (PSGN) – a national initiative that integrates standardized clinical data with ISO 20387-compliant biobanking infrastructure for rare SGTs.

AIM

The aim of this study is to present the concept and structure of the PSGN clinical-digital platform and to evaluate its potential to support research on rare salivary gland tumours. The central hypothesis is that integrated biobanking and clinical data collection can improve the quality of translational research and facilitate the identification of risk groups and clinically relevant biomarkers.

MATERIALS AND METHODS

Study Design and Collaborative Framework

PSGN is a national, multicenter initiative designed to improve the diagnosis, treatment, and research of salivary gland tumours. It includes eight university-affiliated otolaryngology and oncology centres and covers primary SGT cases diagnosed between 2017 and 2025. The work is ongoing and continues to expand as additional cases and data are incorporated. PSGN has completed high-quality clinical and pathological data, including rare and anatomically challenging subtypes such as accessory parotid and parapharyngeal tumour entities often underrepresented in broader studies.

Through standardized reporting and biobanking protocols, the PSGN has established itself as a foundational resource, providing well-organized, high-quality data suitable for future research. Its contributions are advancing knowledge in multicenter epidemiological studies on surgical outcomes, minimally invasive techniques, and the behavior of rare tumours – addressing critical evidence gaps and supporting more informed clinical decision-making.

PSGN uses a biobanking infrastructure housed at the Biobank Research Group, Center for Population Diagnostics, Łukasiewicz Research Network – PORT (Ł-PORT) Polish Center for Technology Development, Wrocław, Poland. The biobank is certified by the BBMRI-ERIC (Biobanking and BioMolecular Resources Research Infrastructure – European Research Infrastructure Consortium) and operates under ISO 20387:2018 standards for biobanking, ensuring high-quality, ethically compliant, and standardized biospecimen and data management. The platform enables large-scale research through secure and interoperable systems and supports multi-institutional collaboration.

The operational framework of the network is built on grassroots efforts, including systematic data collection at each participating university clinic, monthly remote meetings to ensure coordination, the establishment of key analytical topics, and the submission of proprietary material for biobanking. The data collection template was initially developed in 2017 and refined in 2020 and 2022 following the identification of data gaps. The initiative operates without external financial support and relies entirely on the internal resources of participating departments.

Database Design and Data Collection

All clinical, demographic, and laboratory data associated with each donor were securely stored and managed using the NorayBanks software (NorayBio, Spain), a specialized biobank data management platform. The system supports structured data entry, full traceability, and controlled user access, ensuring standardized data handling across all participating centres. NorayBanks is designed to comply with international biobanking standards, including ISO 20387, which emphasizes quality management, data integrity, and operational transparency. Its implementation contributed to maintaining high-quality data governance, essential for the reproducibility and reliability of multicenter biobanking research. Data entry is centralized and includes structured variables covering demographic, clinical, histopathological, therapeutic, and outcome-related information for over n = 3,654 patients. Key n = 70 categories include: patient demographics, exposure history, clinical and pathological data, treatment details, outcome data (Tab. I.). Free-text fields are included to capture nuanced information such as histopathological comments, treatment timelines, and narrative descriptions of disease progression.

Data Quality and Standardization

Data are entered by trained clinicians or research coordinators at each center using a standardized template. Internal data validation procedures are applied periodically to ensure consistency, including logic checks (e.g., date sequences), range validations (e.g., age, survival months), and categorical harmonization (e.g., histological classifications).

Additional Dataset: Process Mapping

An auxiliary sheet captures institutional practices and data flow logistics, focusing on continuity of care, completeness of clinical data, and surgical context (e.g., gland involved, procedure type). This tool is used to audit institutional participation and identify procedural variations that may affect data comparability across centres.

Dataset Harmonization

In addition, a standardized data dictionary defines all fields, formats, and permissible values - ensuring consistency in variable naming, coding systems, and data entry across participating sites. This standardization supports interoperability, facilitates multicentre analyses, and reduces the risk of misclassification or missing data. Controlled vocabulary and predefined field structures enable accurate aggregation of epidemiological, clinical, and pathological information across diverse institutional workflows.

Tab. I. Clinical and Biobank Data Overview for Salivary Gland Tumour Patients.

DOMAIN	VARIABLES
Demographics	Patient ID, Sex, Occupation, Date of Birth, Hospital Location, Population Size
Initial Clinical Information	Diagnosis Date, Age at Diagnosis, Tumour Location, Number of Patients, Tumour Size (cm), Tobacco Use, Alcohol Use, Mobile Phone Use (yrs, daily), Handset Side, Chemical Exposure, Radiation Exposure
Tumour & Recurrence	Recurrent Tumour, First Surgery Date, Recurrence Size, Tumour Presence Duration (mo), Symptom Duration (mo)
Imaging & Diagnostics	Facial Nerve Palsy, Imaging Modalities (USG, CT, MRI), FNA Taken, BAC Taken, BAC Result
Pathology	WHO 2017 Histopathology, Malignancy Classification, Malignant Tumour Type, Tumour Grade, pT, pN, Clinical Stage
Surgical & ESGS Data	Surgery Date, Surgery Extent, ESGS Tumour Location, Parapharyngeal Involvement, ESGS Surgical Extent (x2), Margins, Bilateral/Multi-focal/Satellite Tumours, Intraoperative HP, Compatibility (BAC/HP, CNB/HP, IO/HP)
Malignancy Indicators	Clinical Malignancy Signs, Radiologic Malignancy Signs, Tumour Presence (mo, 2nd instance), Symptom Duration (mo, 2nd instance)
Follow-up & Outcomes	FU Date, FU Facial Nerve Palsy, FU Palsy Status, Wound Healing, Healing Quality, FN Palsy Extent, FN Palsy Deterioration (x2), Neck Dissection, Additional Treatment (RT, CT, IO), Last Visit, DFS (mo), OS (mo), Death Due to Malignancy

Digital Pathology and Imaging Integration

Although the current database primarily focuses on clinical and epidemiological variables, the PSGN is actively expanding its infrastructure to support digital integration. Participating centres are equipped with whole-slide scanners and a digital slide management system to enable digital biobanking and future image-based research. Planned upgrades will allow seamless linkage between digital pathology and clinical data, creating a foundation for AI-driven analysis and collaborative multicenter image annotation.

RESULTS

Cohort Overview and Database Composition

As of 2025, PSGN database includes detailed clinical, pathological, and demographic data from over n = 3,654 patients with SGTs, positioning it among the largest known registries focused on salivary gland neoplasms. The mean patient age was 58.3 years (range: 18–93), with a female predominance (~62%). The most common primary tumour sites were the parotid glands. Notably, the database also captures rare tumours in challenging locations such as the parapharyngeal space and accessory parotid lobe, which together represent approximately 3.7% of all cases. Archived data includes treatment modalities: types of surgical resection, adjuvant radiotherapy, or chemotherapy. Longitudinal outcome data include disease-free survival (DFS) and overall survival (OS), as well as recurrence patterns and secondary malignancies.

Published Outcomes and Impact

PSGN-based research focuses on identifying high-risk cancers, informing surgical strategies, and advancing rare cancer research through real-world evidence.

Complementing these findings, recent PSGN studies have expanded the scope of SGT research into less-studied populations and high-risk tumour locations. A rare subset of six pregnant patients were diagnosed with SGTs, most of which were benign and managed expectantly. One malignant tumour, however, required urgent resection during the third trimester, illustrating the need for case-specific intervention strategies during pregnancy [16]. In parallel, other analysis revealed that parapharyngeal space (PPS) involvement is associated with a significantly higher rate of malignancy and facial nerve dysfunction, particularly in tumours >4 cm. These tumours frequently require advanced surgical access and carry a greater risk of incomplete resection [17]. Clinical red flags such as facial nerve palsy are increasingly recognized as key indicators of malignancy in parotid gland tumours. A study from Marszał et al. found that irreversible facial nerve palsy may serve as an early clinical manifestation of parotid gland carcinoma, underlining the importance of prompt oncological assessment [18]. Moreover, emerging data emphasize the diagnostic complexity of tumours in the accessory parotid gland (region V). These lesions, while often clinically benign, carried a malignancy rate of up to 40% and were misclassified preoperatively in nearly 38% of cases, demonstrating the limitations of standard imaging and the urgent need for heightened oncologic vigilance [19].

Digital Biobank Infrastructure and Centralized Slide Archiving for Rare Tumour Research

To support the next phase of translational research, the PSGN has initiated the acquisition and digitization of histopathological slides using whole-slide imaging systems, including Hamamatsu S60 (Hamamatsu, Japan) and Pannoramic 480 (3DHISTECH, Hungary) digital scanner. All slides will be centrally scanned and archived at the Biobank Research Group, Ł-PORT ensuring uniform quality control and metadata capture across institutions. The creation of a federated digital biobank is underway, with image data integrated into the clinical database through the NorayBanks biobank management system. Image analysis is being conducted using both commercial tools (e.g., StrataQuest by TissueGnostics) and open-source platforms for bioimage analysis such as QuPath, enabling standardized annotation, quantification, and AI-based image processing. This digital ecosystem lays the groundwork for scalable, reproducible, and collaborative research, though full integration into

a unified biobanking infrastructure remains a strategic objective. Linking digitized slides with histopathological reports, diagnostic imaging, biospecimens, and clinical metadata will enable real-time collaboration, cross-validation, and retrospective audit (phase 1), support the harmonization of histopathology reporting (phase 2), inform surgical planning (phase 3), and facilitate biomarker discovery in rare tumours (phase 4). The resulting infrastructure will streamline workflows, enhance data quality, and position PSGN for active participation in international computational pathology initiatives.

DISCUSSION

This publication presents the framework and outcomes of a multicenter, grassroots initiative founded not on formal obligations or grant funding, but on a shared commitment to collaboratively analyze a defined set of medical data. The primary aim was to collect cases of rare salivary gland tumors, which are absent from the National Cancer Registry and remain underrepresented in other central databases. Data derived from the PSGN and associated national registries underscore the clinical heterogeneity and management challenges of salivary gland tumours (SGTs), particularly in rare anatomical locations and special populations. Building upon retrospective registry insights, clinical audits have provided further granularity into how SGTs present and are managed in high-volume tertiary centers. A prospective analysis, based on 585 patients treated for benign major salivary gland neoplasms at a tertiary center, highlighted several key patterns in tumour behavior and surgical approach [20]. Pleomorphic adenomas were the most common histologic subtype (58.8%), followed by Warthin tumours (37.1%), with a notable age difference – patients with Warthin tumours were, on average, 13 years older than those with adenomas. The vast majority of tumours (96.2%) arose in the parotid gland, with most measuring between 2 and 4 cm. Tumour size strongly influenced surgical technique: extracapsular dissection (ECD) was preferred for lesions <2 cm, while larger tumours (>4 cm) often required partial superficial parotidectomy. These findings underscore the importance of stratifying surgical planning by tumour size, histology, and anatomical site. Importantly, the study also raises concerns about underreporting to national registries, suggesting a need for improved data integration across institutions. Long-term surgical outcomes are also being examined in other national cohorts. For instance, a single-center study of revision parotidectomies over a 10-year period identified key indications, surgical techniques, and recurrence risks, offering valuable contributions to the PSGN's surgical strategy dataset [21].

This highlights not only the clinical relevance of harmonized data but also the necessity of coordinated infrastructures capable of capturing nuanced pathological and procedural details across sites. Together, these studies affirm the PSGN's critical role in identifying high-risk tumour profiles, informing surgical strategies, and advancing rare tumour research through comprehensive clinical evidence. Continued integration of these datasets with digital pathology and biobanking infrastructure will enable even deeper insights into clinical outcomes, recurrence risk, and long-term prognosis. Additional data on parotid cancer therapy further support this approach. A 10-year retrospective study from the National Institute of Oncology in Rabat found that patients with resectable tumours had significantly better locoregional control and overall survival when treated with surgery followed by adjuvant radiotherapy, compared to those receiving radiotherapy alone. Unresectable tumours, nodal involvement, high-grade histology, and the adenoid cystic carcinoma subtype were linked to poorer prognosis [22]. These findings reinforce the importance of surgery as the cornerstone of treatment and highlight the limitations of radiotherapy in isolation.

Biobanks for rare diseases are vital for overcoming the limitations of conventional clinical research. Biobanks dedicated to rare diseases, including rare tumours such as SGTs, play an essential role in overcoming the limitations of traditional clinical research. SGTs exhibit low incidence – ranging from 0.4 to 2.6 per 100,000 annually – results in underrepresentation in clinical trials and insufficient statistical power for biomarker validation or treatment standardization. In this context, rare tumour biobanking enables the aggregation of well-annotated biospecimens across institutions, allowing researchers to explore disease mechanisms, treatment response patterns, and molecular heterogeneity that would otherwise remain inaccessible. When coupled with digital tools and advanced analytics, biobanking becomes a powerful enabler of personalized medicine in rare tumour settings.

A recent example of such an initiative is the establishment of a salivary tissue-organoid biobank by Aalam et al. (2025), which enabled the characterization of salivary gland stem/progenitor cells and the identification of novel differentiation markers such as PSMA/FOLH1 [5].

The complexity of rare tumour biology requires synergistic infrastructures combining high-quality biospecimen management with digital tools such as artificial intelligence. These technologies support the identification of subtle histopathological patterns and the development of decision-support models that could revolutionize personalized care in oncology. Importantly, rare tumour biobanks serve as hubs for translational science, offering access to deeply phenotyped tissue linked to real-world clinical outcomes – critical for understanding disease progression and therapeutic resistance in rare subtypes [23]. Furthermore, harmonization efforts like ADOPT BBMRI-ERIC demonstrate that pan-European standardization is feasible and essential [24]. Unified SOPs, interoperable data formats, and cross-border governance frameworks can transform fragmented biobanking systems into integrated platforms that facilitate large-scale studies, ensuring the scientific utility and ethical stewardship of rare disease samples [25].

In sum, the integration of standardized biobanking with prospective clinical datasets, such as those collected by PSGN, represents a cornerstone for rare tumour research in the digital era. Together, these developments underscore that rare disease biobanks are not merely repositories, but strategic infrastructures that drive discovery, foster innovation, and facilitate global collaboration. These studies also affirm the PSGN's pivotal role in identifying high-risk tumour profiles, guiding surgical decision-making, and advancing rare tumour research through real-world evidence.

Continued integration of these datasets with digital pathology and biobanking infrastructure will enable deeper insights into clinical outcomes, recurrence risk, and long-term prognosis.

CONCLUSIONS

The PSGN constitutes a pioneering initiative, uniquely integrating digital pathology, standardized clinical biobanking, and harmonized data governance to advance research in rare salivary gland tumours. Its multicentre structure, encompassing comprehensive clinical, histological, and epidemiological data, provides a fertile foundation for translational investigations in a field that has long suffered from data scarcity and underrepresentation.

Overcoming persistent challenges – ranging from ethical and procedural heterogeneity to limited tissue availability and fragmented workflows – will be essential for unlocking the full analytical value of this resource. Through the implementation of unified protocols, digital slide repositories, and FAIR-aligned data architecture, the PSGN is well-positioned to evolve into a functional model for rare tumour biobanking. Integration of omics-ready biospecimens and image-linked metadata will enable high-resolution phenotyping and support AI-driven pathology at scale.

Realizing this vision will require sustained institutional commitment and strategic alignment with European frameworks such as BBMRI-ERIC and EURACAN [15, 26]. We encourage national stakeholders and international partners to engage with this effort, as the PSGN transitions from a national registry to a dynamic platform for innovation in rare cancer diagnostics, biomarker discovery, and precision therapeutics.

These results confirm the initial hypothesis of this study – that a unified, digital, and clinical infrastructure such as PSGN can effectively support the collection, integration, and analysis of data on rare salivary gland tumours. The PSGN platform has demonstrated its potential to facilitate evidence-based decision-making, generate meaningful clinical insights, and serve as a valuable foundation for national and international collaborative research.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Independent Bioethics Committee for Scientific Research, Poznan (approval No. KB – 666/23).

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