

***“Enhancing Whole Genome Sequencing (WGS), national infrastructures and capacities for COVID-19 and surveillance of other respiratory viruses in Italy”
(SeCOV+)***

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Final Meeting SeCOV+ Project

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Relevance

The SeCOV+ project addressed the need to strengthen technical and scientific expertise in the field of genomic surveillance of SARS-CoV-2 and other respiratory viruses at the national level. The meeting provided an opportunity to share updates on the main results of national genomic surveillance, discuss methodological approaches, exchange regional experiences, and reflect on lessons learned to support future developments and strategic planning.

Aim and Objectives

The aim of the event is to strengthen national genomic surveillance by promoting the informed and efficient use of sequencing data and fostering knowledge exchange to support evidence-based public health decision-making.

- General Objective: to enhance the network of laboratories and infrastructures supporting SARS-CoV-2 and other respiratory viruses genomic surveillance activities by providing a forum for sharing updates and insights.
- Specific objectives: describe the structure and key indicators of the national genomic surveillance system for SARS-CoV-2 and other respiratory viruses; discuss approaches for ensuring data quality, integration, and analysis; promote networking and the exchange of regional experiences; address sustainability aspects of genomic surveillance systems; highlight the value of training and communication.

Working method

Oral presentations, round tables

Summary by Federica Bonetti

DAY 1 – 18th March 2026

Central Theme of Day 1

Day 1 focused on the transition from single-surveillance systems (clinical, genomic, environmental) to a fully integrated, model-supported public health intelligence system. The core idea was that no single data source is sufficient, and that epidemic intelligence improves when multiple systems are combined through standardisation, sequencing, and mathematical modelling.

Session I: Genome sequencing for SARS-CoV-2 and other respiratory viruses (Chairs: A.T. Palamara, P. Stefanelli)

1. HaDEA – EU Implementation Framework - P. D'Acapito

The European Health and Digital Executive Agency (HaDEA) represents the operational arm of the European Commission, responsible for implementing EU programmes through grants and procurements. While policy priorities are defined by Directorates-General (e.g. DG SANTE, Health Emergency Preparedness and Response Authority), HaDEA translates them into concrete actions by managing the full project lifecycle, from calls to monitoring and dissemination.

Within the health sector, HaDEA plays a key role in delivering the EU4Health Programme, which finances preparedness and surveillance capacities across Member States. Investments have focused on genomic sequencing, wastewater surveillance, and integrated surveillance systems.

The SeCOV+ project itself is an example of this mechanism in practice, supporting both the expansion of Whole Genome Sequencing (WGS) and Reverse Transcription Polymerase Chain Reaction (RT-PCR) capacity and the integration of these tools into routine surveillance.

Key message: EU preparedness is not only defined at policy level but enabled through structured funding and implementation mechanisms. HaDEA provides the financial and operational backbone that allows surveillance systems to be developed, scaled, and harmonised across countries.

2. DG HERA – Future perspectives – M. Goerlitz

The Health Emergency Preparedness and Response Authority (HERA) defines the EU strategic framework for health emergency preparedness, with a focus on strengthening the full value chain of medical countermeasures—from development to access. Established in 2021, HERA reflects a shift from reactive crisis management toward long-term preparedness and capacity building.

A central component of this strategy has been the investment in WGS through direct grants, which supported capacity building across 25 countries. These initiatives demonstrated the importance of genomics not only for COVID-19 but as a core tool for broader infectious disease surveillance.

However, key challenges remain: data sharing across countries is still limited, standardisation is lacking, and there is insufficient evidence on the cost-effectiveness of WGS. In addition, gaps in bioinformatics expertise highlight the need for sustained investment in workforce development.

Looking forward, HERA's priorities include consolidating existing capacities, improving coordination between countries, and promoting training and knowledge exchange.

Key message: WGS has become a strategic pillar of EU preparedness, but the focus is now shifting from rapid expansion to consolidation, sustainability, and better integration across countries.

3. ECDC - Future perspectives - L. Freschi

The European Centre for Disease Prevention and Control (ECDC) perspective emphasises that strengthening surveillance systems is not only a technical challenge, but a question of sustainability, data quality, and integration. Within the SeCOV+ context, efforts focus on reinforcing WGS capacity also for respiratory viruses while ensuring these systems are embedded into routine public health surveillance.

Key gaps identified include insufficient long-term funding, limited human resources, and persistent issues with data quality and reporting timeliness. These challenges directly impact the reliability of surveillance outputs and, consequently, public health decision-making. In addition, fragmentation between surveillance systems reduces the ability to generate a comprehensive view of epidemiological trends.

Proposed solutions highlight the need to integrate genomic surveillance into existing infrastructures, invest in standardised and automated data systems, and strengthen training across multiple professional roles. Collaboration is also central, both across sectors (One Health approach) and between countries, to improve efficiency and reduce duplication.

ECDC supports this transition by updating surveillance frameworks, enhancing data-sharing platforms (e.g. EpiPulse), and promoting innovation in areas such as wastewater surveillance and metagenomics, in collaboration with partners including HERA and HaDEA.

Key message: Effective surveillance depends on high-quality, timely, and integrated data systems. The priority is no longer expansion alone, but ensuring that surveillance is sustainable, standardised, and fully actionable for public health.

4. The Italian Ministry of Health - Contribution to the SeCOV+ project – A. Mammone

The Ministry of Health (MoH) provides the national governance framework for public health in Italy, grounded in Article 32 of the Constitution, which defines health as both a fundamental individual right and a collective interest. Its role combines regulatory oversight, system coordination, and strategic guidance, ensuring equity, quality, and preparedness across the healthcare system.

Within the area of communicable diseases, the MoH is responsible for epidemiological surveillance, pandemic preparedness, vaccination strategies, and coordination with regional authorities. This positions the Ministry as a key interface between national policy and operational public health activities.

In the context of SeCOV+, the MoH acts as an affiliated entity, ensuring alignment of project activities with national legislation and strategic priorities. It supports coordination between the Istituto Superiore di Sanità (ISS) and regional systems, contributes technical expertise, and plays a role in governance and evaluation. Operationally, it is involved in key project components, including participation in evaluation activities and coordination of periodic SARS-CoV-2 prevalence surveys within the genomic surveillance framework.

Key message: The Ministry of Health ensures that surveillance systems are not only technically robust but also institutionally embedded, coordinated across regions, and aligned with national public health strategy.

5. Fondazione Bruno Kessler - Bridging Surveillance Systems through Modelling to Enhance Epidemic Risk Monitoring – P. Poletti

The contribution from Fondazione Bruno Kessler highlights the central role of mathematical modelling in bridging fragmented surveillance systems. The core premise is that no single data source—epidemiological, genomic, or environmental—can fully describe an epidemic. Instead, modelling integrates these partial signals into a coherent picture, improving epidemic intelligence and risk monitoring.

Through case studies on COVID-19 variants in Italy, modelling demonstrated how combining genomic and epidemiological data allows estimation of key parameters such as transmissibility and growth advantage. For example, during the co-circulation of Alpha and Gamma variants in 2021, models showed that Alpha became dominant due to higher transmissibility, despite Gamma's partial immune escape. Similarly, the rapid expansion of Omicron was quantified through integrated analyses, revealing a strong transmission advantage and short doubling time.

These approaches extend beyond COVID-19 to influenza and vector-borne diseases, supporting tasks such as transmission reconstruction and epidemic forecasting. Genomic data, in particular, enhance modelling by enabling phylogenetic and phylodynamic analyses, although limitations remain due to incomplete data and missing epidemiological links.

Key message: Mathematical modelling acts as the integration engine of surveillance systems, transforming heterogeneous data into actionable insights on transmission dynamics, variant spread, and epidemic risk.

Session II: Methodological insights (Chairs: P. Stefanelli, A.T. Palamara)

1. Genomic surveillance: structure and key indicators - E. Giombini

Dr. Giombini's presentation outlined the structure of genomic surveillance in Italy, highlighting its evolution into a nationwide, integrated system supporting monitoring of respiratory viruses and public health response. The SeCOV+ framework contributes to strengthening WGS capacity, consolidating data systems, and enabling advanced analyses through integration with epidemiological data and modelling.

At the national level, surveillance is organised around two main platforms—I-Co-Gen (SARS-CoV-2) and I-Flu-Gen (influenza)—supported by the IRIDA-ARIES infrastructure for data management and analysis. A distributed laboratory network applies multiple sequencing technologies (Illumina, Ion Torrent, Nanopore), generating both raw and processed genomic data used for variant identification, mutation analysis, and phylogenetic tracking.

The system has evolved from periodic flash surveys to continuous surveillance, with increasing focus on severe and hospitalised cases and integration with sentinel and non-sentinel systems. This transition reflects a move toward more routine, sustainable monitoring, although data consolidation still requires time, introducing delays in analysis.

A central component is the definition of standardised indicators to assess data quality and system performance. These include metrics on sequencing quality (e.g. coverage, % missing data), raw data reliability, and completeness of metadata, which remains a key challenge. Improvements have been observed over time in sequencing output and data quality, though variability persists, particularly in epidemiological information.

Integrated analyses, such as those conducted for emerging variants like JN.1, demonstrate the value of combining genomic, epidemiological, and phylogenetic data to monitor spread and inform public health action.

Key message: Genomic surveillance in Italy is now a structured and mature system, but its effectiveness depends on data quality, standardisation, and integration with epidemiological information to fully support epidemic intelligence.

2. Mapping, prioritizing, and ensuring quality of epidemiological data - P. Pezzotti

Dr Pezzotti's contribution focused on the integration of epidemiological, genomic, and environmental data within SeCOV+, with the objective of strengthening surveillance through improved data mapping, indicator selection, and quality assessment. The approach involved mapping national data sources across disciplines (epidemiology, genomics, wastewater, microbiology) to identify how different systems can be connected and used jointly for epidemic monitoring.

A key component is the evaluation of data quality through standard attributes such as completeness, timeliness, representativeness, and consistency. The Italian system includes routine quality control mechanisms, such as weekly automated reports comparing different data sources and identifying inconsistencies or missing information. While core variables (e.g. sex, diagnosis date) show high completeness, significant regional variability persists, particularly in clinical and care-related data, highlighting structural heterogeneity across the system.

Timeliness remains a major challenge, as reporting delays directly affect key indicators such as transmissibility (R_t) and overall situational awareness. This creates a constant trade-off between speed, completeness, and comparability of data. Integration across systems—epidemiological surveillance, genomic data, wastewater monitoring, and vaccination registries—further increases complexity, especially given differences in data collection, reporting timelines, and interoperability.

Within SeCOV+, a set of priority indicators was identified to support integrated surveillance, including incidence, variant distribution, transmissibility, hospital burden, and mortality. However, not all indicators are equally feasible, and prioritisation is necessary to ensure sustainability and usability of outputs such as dashboards and bulletins.

Key message: Effective surveillance depends on high-quality, timely, and integrated data. Mapping systems, standardising indicators, and prioritising feasible outputs are essential steps toward building a sustainable and actionable integrated surveillance framework.

3. Dynamic transmission models and statistical inference approaches - M. Manica

This presentation focused on how genomic epidemiology combines genetic and epidemiological data to better understand transmission dynamics and variant spread. A key distinction was highlighted between phylogenetic trees (evolutionary relationships) and

transmission trees (actual infection chains), underlining that genetic data alone cannot fully reconstruct the transmission chain.

Dynamic transmission models, such as SIR-type models and renewal equations, provide a framework to describe how infections spread over time and to estimate key parameters like the reproduction number. These approaches are complemented by phylodynamics, which links viral evolution with population-level transmission processes, allowing inference on epidemic growth, origin, and spread.

Statistical inference, particularly through Bayesian methods and Markov Chain Monte Carlo (MCMC), enables estimation of transmission rates and evolutionary dynamics from incomplete and heterogeneous data. However, limitations remain, as genomic data alone may not uniquely identify parameters and are affected by sampling bias and partial observation of cases.

As an example, an application of the model to the JN.1 variant in Italy showed how integrating genomic, epidemiological, and phylodynamic analyses allows estimation of transmissibility, timing of emergence, and epidemic size, explaining its rapid spread and subsequent stabilisation.

Key message: Dynamic models and phylodynamic approaches are essential tools for integrating genomic and epidemiological data, transforming partial observations into quantitative insights on transmission, variant dynamics, and epidemic evolution.

4. Focus on environmental surveillance - G. La Rosa

Dr La Rosa's presentation highlighted the growing role of wastewater surveillance as a complementary tool to clinical and genomic systems. By capturing signals at population level, environmental surveillance enables monitoring of virus circulation and variant dynamics independently of testing strategies, providing an early and less biased indicator of epidemic trends.

In Italy, a national wastewater surveillance system was established during COVID-19, involving a broad network of treatment plants and laboratories coordinated by ISS, the MoH, and regional authorities. The system evolved from simple detection of viral presence to more advanced approaches, including quantification and sequencing for variant identification. Over time, it has generated a substantial volume of data and regular reporting, even continuing beyond the initial funded phase, albeit with reduced capacity in some regions.

Wastewater sequencing presents specific technical challenges, including low viral concentrations, fragmented RNA, and mixed populations, which complicate reconstruction of consensus sequences. To address these limitations, multiple complementary methods are used, such as targeted molecular assays and NGS, improving sensitivity and enabling detection of

emerging variants. Notably, wastewater data has in some cases identified variants earlier than clinical surveillance.

Key message: Environmental surveillance provides a valuable population-level and early warning signal that complements clinical and genomic data. Its full potential is realised when integrated into a broader surveillance framework, though sustainability and methodological challenges remain key issues.

Summary and conclusions of the first day - A.T. Palamara, P. Stefanelli

There is no single surveillance system that is sufficient on its own: clinical, genomic, environmental, and modelling approaches each capture only part of the epidemiological picture and therefore need to be integrated. Genomic surveillance is central for monitoring pathogen evolution and variant dynamics, but it becomes most informative when combined with epidemiological data and interpreted through mathematical modelling, which acts as the integration layer to estimate transmissibility, epidemic trends, and variant behaviour. Wastewater surveillance further strengthens the system by providing a population-level, early-warning signal that complements clinical detection.

Across all contributions, governance and coordination emerged as equally critical as technical capacity, requiring alignment between national ministries, regional systems, and EU-level structures, alongside sustained investment in infrastructure, standardisation, and interoperability.

There is a clear shift that has been marked from fragmented surveillance approaches toward an integrated, model driven, One Health framework in which genomic, epidemiological, and environmental data are combined into a unified and actionable system for public health decision-making.

DAY 2 – 19th March 2026

Central Theme of Day 2

Day 2 focused on the transition of Italy's SARS-CoV-2 genomic surveillance system from an emergency response structure to a sustained national public health infrastructure, involving national coordination, regional laboratory networks, governance, training, and expansion to other pathogens such as influenza, and RSV. A central theme across all sessions was how to preserve and institutionalise a system built during a crisis once emergency conditions subside.

Session III - National and Regional experiences (Chairs: A.T. Palamara; P. Stefanelli)

1. The Italian Sequencing Network for SARS-CoV-2 and Other Respiratory Viruses - L. Ambrosio

The Italian genomic surveillance system, coordinated by the ISS within the SeCOV+ project, aims to strengthen and sustain national sequencing capacity for SARS-CoV-2 and other respiratory viruses. Developed during the COVID-19 emergency, it now operates through a distributed network of around 70 laboratories (hospitals, universities, research institutes, private and veterinary labs), integrated via the national I-Co-Gen platform for sequencing data submission, analysis, variant tracking, and reporting.

Surveillance has progressively evolved from large-scale emergency sampling to more targeted, sentinel-based monitoring, reflecting a shift toward routine and sustainable genomic surveillance. Annual external quality assessments support standardisation and comparability across laboratories, with 45 participating in 2025 and most achieving satisfactory performance. Key challenges remain in harmonising workflows, bioinformatics pipelines, and metadata standards, alongside expansion toward multi-pathogen surveillance including influenza and RSV.

Key message: Italy is transitioning from an emergency-driven sequencing system to a coordinated, standardised, and sustainable national genomic surveillance infrastructure, where interoperability, quality assurance, and long-term integration are the main priorities.

2. Regional experience – Lombardia - E. Pariani

The Lombardia regional experience, presented by Prof. Elena Pariani of the University of Milan, illustrates how genomic surveillance was operationalised within one of Italy's most active regional networks. Starting in early 2021 from a limited and fragmented sequencing capacity, the region rapidly developed into a coordinated system involving 19 laboratories and over 41,000 SARS-CoV-2 genomes, later expanding to multiple respiratory viruses.

The national sequencing framework provided the structural backbone for this transformation, enabling shared objectives, centralised data platforms, and coordinated workflows. This facilitated the transition from isolated laboratory activity to an integrated regional network, supported by the adoption of NGS technologies, harmonised bioinformatics pipelines, and strengthened inter-laboratory collaboration.

Over time, the network evolved in both scale and maturity, improving sequencing speed, resilience under workload fluctuations, and overall coordination. However, operational challenges remained, particularly in managing variable sample volumes, ensuring timely

reporting, and standardising procedures across institutions. These were progressively addressed through continuous communication and trust-building between partners.

The scope of surveillance has also expanded beyond SARS-CoV-2 to include influenza and RSV, marking a shift toward multi-pathogen respiratory monitoring. Parallel initiatives, such as preparedness projects and One Health-oriented research frameworks, are further consolidating regional capacity into long-term infrastructure.

Key message: The Lombardia experience shows how fragmented laboratory capacity can be transformed into a resilient, high-output, and scalable regional genomic surveillance system through national coordination, technological adoption, and sustained inter-institutional collaboration.

3. Regional experience – Umbria - R. Spaccapelo

The Umbria regional experience, presented by Roberta Spaccapelo, illustrated how a relatively small regional system contributed to national genomic surveillance through sustained sequencing and integration with clinical and environmental data. Work from the University of Perugia demonstrated continuous monitoring of SARS-CoV-2 evolution, particularly during the Omicron phase, highlighting rapid variant turnover and the importance of updating shared genomic databases. The regional system combines next-generation sequencing with epidemiological interpretation and is increasingly extending to other respiratory viruses such as influenza.

A key element is the integration of multiple surveillance streams, including wastewater analysis, to maintain sensitivity even in low-incidence phases.

Key message: The Umbria experience reflects the broader transition from emergency sequencing efforts to a stable, multi-source surveillance infrastructure supporting long-term public health preparedness.

4. Regional experience – Sicilia - F. Tramuto

The Western Sicily reference laboratory, led by Dr Fabio Tramuto of the Giaccone University Hospital, acted as a regional hub for COVID-19 diagnosis and genomic surveillance, evolving from an emergency response centre into a stable component of Italy's surveillance infrastructure.

Initially established within the influenza surveillance network, the laboratory was rapidly designated during the pandemic as a reference centre for SARS-CoV-2 confirmation and later formalised as a regional genomic reference laboratory. It became fully integrated into national systems through collaboration with the ISS, contributing to the I-Co-Gen platform, flash

surveys, and the SeCoV+ initiative, as well as extending activity to influenza and other respiratory pathogens.

The laboratory operates as a multi-layer surveillance hub, combining clinical, genomic, environmental, and cross-pathogen monitoring (including viral and bacterial diseases). It supports continuous sequencing, variant tracking, and integration of data into national surveillance frameworks, while also contributing to scientific research on viral evolution and transmission dynamics.

Over time, its role expanded from emergency diagnostics to sustained genomic surveillance and regional preparedness capacity, embedded within national coordination structures and standardised sequencing frameworks.

Key message: The Western Sicily laboratory illustrates how an emergency diagnostic centre can be transformed into a long-term, multi-pathogen genomic surveillance hub, fully integrated into national systems and supporting both routine public health monitoring and outbreak preparedness.

Session IV – Sustainable sequencing capacities and communication aspects

1. Report on the distance learning training course - A. Mazzaccara

The SeCOV+ e-learning programme, coordinated by the ISS, is a capacity-building initiative aimed at strengthening genomic surveillance for SARS-CoV-2 and expanding it to influenza and RSV. Designed for a multidisciplinary audience of public health and laboratory professionals, the course combines technical training on sequencing workflows with practical applications for surveillance integration.

Delivered between March and July 2025, the course adopted a problem-based learning approach centred on real-world surveillance challenges, with structured modules, assessments, and certification requirements. It focused on harmonising genomic data collection and analysis at national level while improving understanding of sequencing technologies and their public health use.

Feedback indicated high satisfaction, particularly regarding clarity, accessibility, and teaching quality, although participants highlighted the need for more advanced, practice-oriented content and clearer differentiation between beginner and expert levels.

Key message: The e-learning programme represents a structured tool for workforce development in genomic surveillance, supporting the transition toward a harmonised,

multi-pathogen surveillance system, while highlighting the ongoing challenge of balancing accessibility with technical depth.

2. Sustainability as an Organizational Challenge: Insights from a Laboratory Network - F. Bolici

The study by Dr Francesco Bolici and Dr Alberto Varone (OrgLAB, University of Cassino; ECT Lab, European University of Technology) addresses the long-term sustainability of genomic surveillance networks established during the COVID-19 crisis, with a focus on the transition from emergency-driven expansion to stable infrastructure within SeCOV+.

It highlights a central tension: systems rapidly built during the pandemic benefited from exceptional funding and urgency, but now face the challenge of maintaining functionality, coordination, and participation under “normal” conditions. To address this, the authors developed a Sustainability Assessment Protocol and a composite indicator, the Network Performance Sustainability Index (NPSI), designed to evaluate laboratory networks across five dimensions: infrastructure resilience, human capital, operational performance, operational robustness, and institutional sustainability.

A pilot application across participating laboratories shows that sustainability is shaped not only by technical capacity, but also by governance, staffing, and network connectivity. Informal collaboration, peer support, and communication between laboratories emerge as key stabilising factors, alongside more formal coordination mechanisms. However, risks remain linked to funding instability, uneven capacities, and workload pressures.

Key message: Genomic surveillance networks are not only technical systems but organisational ecosystems, whose long-term sustainability depends on balancing infrastructure, human resources, governance, and especially the strength of formal and informal connectivity across the network.

3. The Value of Communication - P. Malloni

The presentation on the value of communication, delivered by Dr. P. Malloni of the ISS Press Office, emphasized that effective communication is a core pillar of public health surveillance systems, not a secondary function. Drawing on the experience of the ISS communication unit during the COVID-19 pandemic, he highlights how complex epidemiological and genomic data must be translated into clear, timely, and actionable information for different audiences, including policymakers, healthcare professionals, and the general public.

A central challenge identified is the management of “infodemics”, where misinformation can undermine trust, distort risk perception, and weaken public health

responses. In this context, communication becomes a strategic tool that supports surveillance by enhancing data usability, promoting transparency, and reinforcing institutional credibility.

Key message: Sustainable surveillance systems require not only robust data generation, but also structured communication frameworks capable of ensuring that evidence effectively informs decision-making and public behaviour.

Summary and conclusions of the second day - A.T. Palamara, P. Stefanelli

Day 2 portrays Italy's genomic surveillance system as a multi-level infrastructure spanning national coordination, regional implementation, and laboratory execution, currently undergoing a transition from an emergency-driven configuration to a more stable and sustainable governance model. Across the presentations, the system emerges as a socio-technical network whose performance depends not only on sequencing technologies and data platforms, but equally on human expertise, inter-institutional collaboration, and institutional stability. The overarching message is that the future of genomic surveillance will be defined less by sequencing capacity alone, and more by the ability to maintain coordinated, standardised, and collaborative networks over time.

Roundtable discussion (Chairs: P. Stefanelli, F. Riccardo) - P. D'Acapito (European Health and Digital Executive Agency, HaDEA); L. Freschi (European Centre for Disease Prevention and Control, ECDC); T. Lazzarotto (Scientific Coordinator of the Association of Italian Clinical Microbiologists, AMCLI); G. Delogu (President of the Italian Society of Microbiology, SIM); G. Antonelli (President of the Italian Society of Virology, SIV)

The roundtable discussion brought together leading experts and key stakeholders with complementary experience across genomics, microbiology, laboratory medicine and public health. The panel focused on the transition from emergency-driven genomic surveillance systems to stable, long-term national and European infrastructures, highlighting that this shift is as much organisational and governance-related as it is technical.

A recurring point was the need to ensure sustainability beyond crisis funding cycles, particularly through stable workforce development, harmonised workflows, and continued investment in digital and laboratory infrastructure. Participants also emphasised the importance of interoperability between epidemiological, genomic, and environmental data systems, as well as the role of modelling in translating these data into actionable public health intelligence.

The discussion further highlighted the value of network connectivity—both formal coordination mechanisms and informal collaboration between laboratories—as a key factor in maintaining system resilience. At the same time, challenges were acknowledged in balancing standardisation with flexibility across diverse regional and institutional contexts.

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