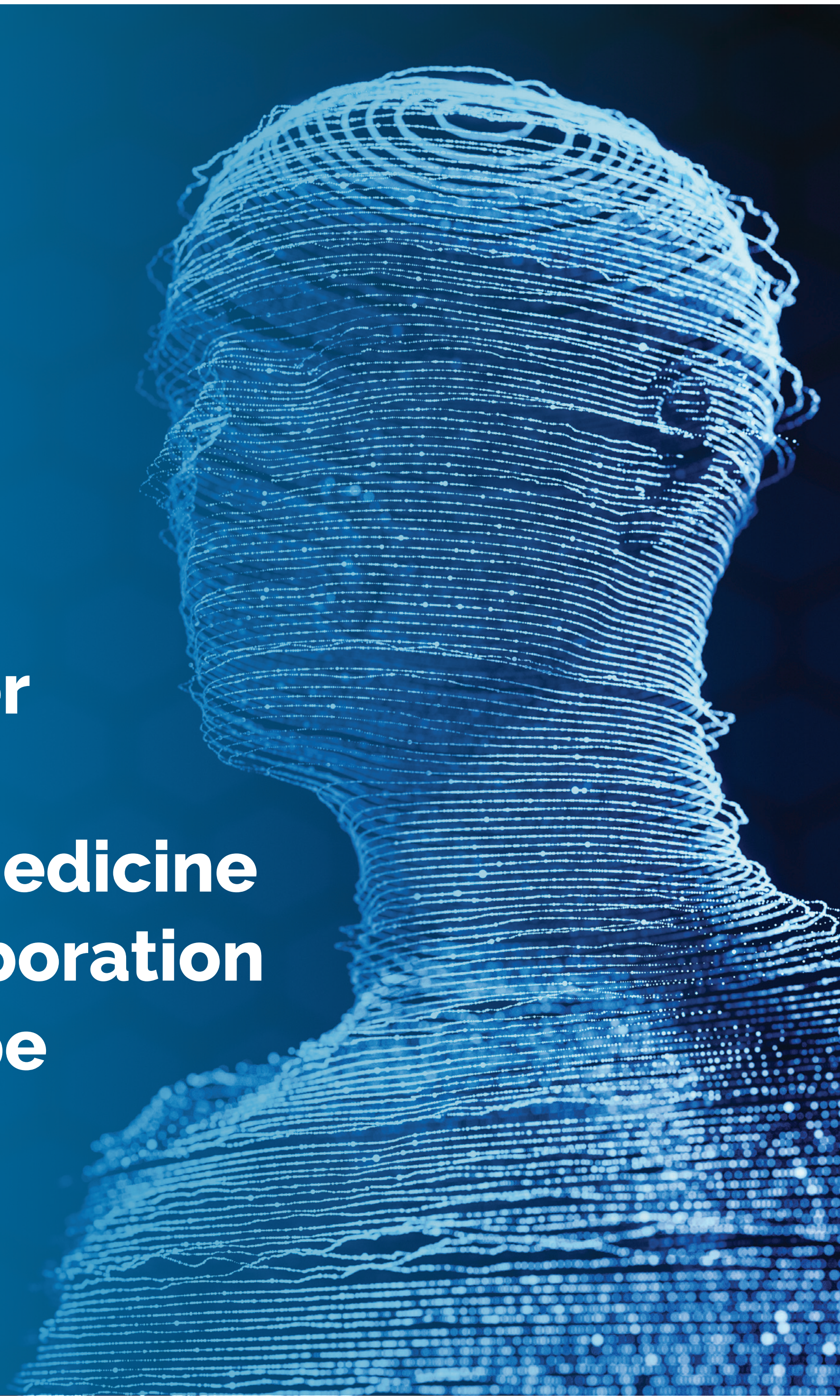
EU-Africa PerMed

Action Plan to facilitate, foster and promote Personalised Medicine research collaboration between Europe and Africa



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Executive summary and aim of the Action Plan

This document presents an Action Plan to facilitate, foster and promote collaboration in the field of Personalised Medicine (PM) between Africa and Europe. It includes PM research activities and supporting activities formulated as recommendations to be implemented at different levels and by different actors, to achieve the roadmap objectives:

- To foster, facilitate and encourage joint PM activities, projects and programmes between Africa and Europe
- To strengthen bilateral European Union and African Union (EU-AU) science, technology and innovation (STI) relations in the area of health, including PM.

The Action Plan proposes 26 concrete recommendations for actions at research and policy level, such as common funding opportunities and research topics for joint scientific agendas, structural recommendations (e.g. development of infrastructure, capacity building and training), and collaboration strategies supporting the future uptake of PM in healthcare systems. Each action (A) is presented as 1) a short description, 2) an outline for the mutual interests of Africa and Europe in the topic, 3) a description of the mode of collaboration, and 4) the expected objectives/impact. PM research activities, i.e. topics that can be pursued jointly via research consortia, are indicated in grey. PM supporting activities, i.e. topics on a strategic level that require co-ordinating and structuring collaborations, are indicated in blue.

A (NUMBER)	TITLE
Description	Description of the Action
Mutual African-European interest	Outline of the mutual interest
Mode of collaboration	Description of the collaboration and suitable support
Timing and objectives	Expected outcome and impact over the time

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Figure 1 : Structure of the research (grey) and research-supporting (blue) actions.

Recommendations for collaborative actions respond to common health challenges and needs identified through exchanges with African stakeholders, and the strategic findings of the International Consortium for Personalised Medicine (ICPerMed, i.e. the ICPerMed Action Plan, 2017[1] and Vision Paper[2], 2019), as well as the Strategic Research and Innovation Agenda for Personalised Medicine (SRIA for PM, 2023)[3]. The proposed actions take into account the differences between regions (Eastern, Western, Northern, Southern and Central Africa) and countries in Africa. Actions presented are furthermore identified to be of mutual interest for Africa and Europe.

The Action Plan is structured in two parts:

Part I "Personalised Medicine adopting environment" focuses on the entire PM system of health that considers all diseases or health conditions, and a broad range of technical and medical fields around diagnostics, treatment and prevention, as well as diverse stakeholders.

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[1] *https://www.icpermed.eu/en/activities-action-plan.php*

[2] *https://www.icpermed.eu/en/activities-vision-paper.php*

[3] *https://www.icpermed.eu/media/content/EPPerMed-SRIA.pdf*

Table 1 : List of proposed actions for part 1 of the Action Plan "PM adopting environment"

1) Infrastructure, Eduction and Technology Awareness	
Research supporting actions	
A1	Biobank infrastructure/cohort network
A2	Strengthening bioinformatics in research infrastructure
A3	Capacity building of Personalised Medicine data generators and users
A4	African-European multi-centres focusing on healthcare education and awareness
A5	Education and training programme for public healthcare forces
A6	Education and awareness activity for patients' associations
A7	Twinning programme
Research actions	
A8	Population studies support stations
A9	International multidisciplinary research programme addressing Personalised Medicine
A10	Research collaboration revealing cancer diversity
A11	Research projects on companion diagnostic and biomarker discovery
A12	Research projects on the Big Three Infectious Diseases (BTIDs) and molecular-based tests
2) Ethical and Legal Considerations	
Research supporting actions	
A13	Training course for ethical committees focussing on ethical, legal and social aspects (ELSA) in Personalised Medicine research
3) Access to Technology and Expertise	
Research supporting actions	
A14	A personalised medicine advocacy programme or initiative
A15	African-European (International) Personalised Medicine Conference
A16	Regional Personalised Medicine consortia/Hubs
A17	Personalised Medicine Meta-Cluster
A18	EU-Africa PerMed 2
A19	African-European personalised medicine research-supporting network (AE PerMed)

Part II "Genetics and genomics in personalised medicine" presents an example of a more specific PM field, with concrete actions focusing on this aspect. Considering that Africa is where the human species originated, and thus the most genetically diverse continent, with a wide range of ethnic groups and genetic variations, it is contradictory that there is a lack of representation of African populations in global genetic studies and databases.

Table 2: List of proposed actions for part 2 of the Action Plan "Genetics and genomics in personalised medicine"

1) Human Genomic Networks	
Research supporting actions	
A20	National Genome Archive
A21	Establish regional genomic hubs
A22	Genomic data network
A23	Genomics for global health – African contribution
2) Genomic Research Networks, Hubs and Projects	
Research actions	
A24	Characterisation of regional genetic populations' architecture
A25	Africa-Europe network for human genomic research
A26	Genome-wide association (GWAS) study

The Action Plan addresses all actors from Africa and Europe positioned to support the uptake and implementation of the presented recommendations: in particular, these include policy makers (STI and health); national, international and global funders, from the public and private sectors; the European Union (EU) and Commission (EC); the African Union (AU); the World Health Organisation (WHO); already existing joint actions such as the European and Developing Countries Clinical Trials Partnership (EDCTP); industry players; and actors contributing to the development and innovation of PM from academic and clinical fields.

The EU-Africa PerMed seeks and identifies synergies with ongoing bi-regional African and European research actions to initiate and promote collaboration in PM. This roadmap serves as a means to facilitate this collaboration, so that already existing initiatives and programmes, as well as local, national and international funders, can incorporate the proposed recommendations as action points in their agendas (e.g. EDCTP3, Horizon Europe, Cancer Mission, Global Action for Community Development (GACD), Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), etc.).

Introduction

Innovation is often supported particularly through digital technology. In the health sector, medical data of different sorts are increasingly available in digital format only. New diagnostic tools and technologies allow rapid data analysis, even in rural areas. Progress in machine learning (ML) and artificial intelligence (AI) enables the analysis of complex and diverse kinds of medical data, and their combination with the increasing pool of lifestyle data, e.g. as collected through smart watches or other trackers used by citizens.

The pool of medical data allows for more accurate and tailor-made provision of healthcare that places citizens or patients at the very centre of their healthcare. This future of medicine is also called Personalised Medicine (PM) and represents a promising new concept for dealing with challenges of health, healthcare and health systems. EU-Africa PerMed adheres to the definition of PM as stated in the PerMed Strategic Research and Innovation Agenda (SRIA): "Shaping Europe's Vision for Personalised Medicine" (2015)[4], adopted from the Horizon2020 Advisory Group[5]:

> ***"Personalised Medicine (PM)** refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."*

Synonyms for PM are used, such as precision medicine, 3P (predictive, preventive, personalised) or 5P (predictive, preventive, personalised, participatory, and population-based), as well as stratified medicine.

The PM concept is of increasing interest worldwide. PM has the potential to:

- Improve treatment outcomes and reduce adverse drug reactions,
- Help identify individuals at higher risk for certain diseases
- Enable early detection and apply preventive measures,
- Overall, reduce healthcare costs by avoiding unnecessary treatments and optimising resource allocation.

The steps to be taken to make PM a reality for society are understood, and comparable for all countries. While in principle this allows access to PM in every country, the diversity of healthcare systems and the different resources allocated to research, innovation, structural development and overall healthcare result in varied challenges when it comes to PM implementation. Collaboration in PM involves 1) facilitating access to new tools and technologies, and 2) contributing to minimising existing health disparities between countries. Full implementation is complex but could be realised in joining forces to ensure healthy lives for all at all ages, making healthcare more efficient and equitable (UN Sustainable Development Goal 3[6]).

PM is a topic with a clear global dimension in that cross-border and international collaboration is essential to enable the delivery of and access to precise diagnostics, therapies and prevention strategies for all citizens around the world3 . Particularly for the infectious disease field, it has been demonstrated that international collaboration is essential, successful and efficient, as diseases do not stop at borders.

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[4] *https://www.eppermed.eu/wp-content/uploads/2023/09/EPPerMed-SRIA.pdf*

[5] *European Commission. Advice for 2016/2017 of the Horizon 2020 Advisory Group for Social Challenge 1, "Health, Demographic Change and Wellbeing", July 2014: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AC%3A2015%3A421%3AFULL*

[6] *https://www.un.org/sustainabledevelopment/health/*

EU-Africa PerMed particularly aims to foster cross-border and international collaboration, with a focus on collaborations between Africa and Europe.

Therefore, this Action Plan refers only partially to African-African (within the continent) collaboration, and predominantly to African-European (South-North) collaboration.

This document does not discuss the overall hurdles of research and development (R&D) in Africa, or general hurdles for translation of R&D results into practice. Furthermore, it does not outline extensively the general needs and requirements to develop and implement PM, as this overall concept is already well described, e.g. through the PerMed SRIA: "Shaping Europe's Vision for Personalised Medicine" (2015) and the Strategic Research and Innovation Agenda for Personalised Medicine (SRIA for PM, 2023). The building blocks to enable PM in a health system are overall similar, independently of the location of the country, hence comparable between Europe and Africa. These include the need for ethical and legal frameworks to develop and implement PM, particularly around health data and their use; research and healthcare infrastructure; education and training for healthcare providers (skilled workforces) and citizens/patients; and the availability of sustainable funding, hence PM supporting strategies that, if aligned between different countries, could enable joint actions, ensuring the efficient use and sharing of available resources by avoiding duplications (see Part I). The time for implementation may depend on aspects such as the economic status of a country or the level of maturity of a functional healthcare system.

1) The EU-Africa PerMed project

Incorporating African countries into the global PM research agenda will contribute to shortening existing health disparities, as well as facilitating access of African countries to new tools and technologies that have the potential to make healthcare more efficient and equitable. The ICPerMed was launched in 2016, which brings together more than 50 health research funders, ministries and policy-making organisations, including organisations from Egypt and South Africa to co-ordinate research and health policy to advance the implementation of PM. While the majority of members are from Europe, several African organisations have shown interest in joining the ICPerMed.

In order to support the integration of non-EU countries in ICPerMed, the EU-Africa PerMed project was funded by the EU Horizon 2020 programme, and specifically supports the integration of African countries into ICPerMed activities as a means to contribute to the successful implementation of PM in the global context. It is intended to foster joint PM projects and programmes between Europe and Africa, as well as strengthen bilateral EU-AU STI relations in the area of health.

In comparing the continents of Europe and there are inherent differences and comparable challenges within healthcare systems that remain. it is apparent that healthcare systems differ from one country to another. In some countries, healthcare is managed by national regions. Furthermore, within a single country, access to healthcare may differ between highly populated and rural areas. Despite these differences, the overall challenges to developing and implementing PM, but also the benefits to society and healthcare systems, are comparable.

Mapping and analysing the African PM landscape

The mapping work carried out by EU-Africa PerMed to review the scientific and policy landscape of PM in Africa has shown that the African continent has to be seen in its diversity, and not as a whole, when it comes to discussions about health/biomedical research and opportunities for collaboration with Europe. Many cultural, political, social and economic differences exist between regions and countries in Africa that influence the opportunities and options for STI and health research collaboration within Africa and internationally and determine the models and programmes to support and strengthen this collaboration[7].

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[7] *Kamau L. et al., 2022, https://zenodo.org/records/7786300*

A scientific mapping of the African context has shown that over the past decade, there has been a notable increase in the number of research activities and publications in the field of PM across Africa, with South Africa and Egypt emerging as the highest contributors, accounting for nearly 50% of all PM publications on the continent. Tunisia, Nigeria and Kenya follow closely behind, with the top five countries contributing 64.5% of all PM publications in Africa[8].

Exchange with stakeholders and identification of needs and common interests

The recommendations in this Action Plan are the results of extensive exchanges with and consultation of stakeholders in Africa and Europe, through stakeholder workshops and African regional meetings (Western/ Central, Northern, Eastern and Southern Africa), as well as surveys. Based on these exchanges and with the overall goal to push joint actions between Africa and Europe, and also within African regions, the project identified a list of African PM needs and collected areas of mutual interest for PM between Africa and Europe. Broad areas for collaboration are 1) research on concrete diseases (e.g. cancer, cardiovascular diseases as well as diabetes/metabolic diseases and infectious diseases); 2) development and maintenance of sustainable infrastructure supportive of PM implementation (data repositories, biobanks, analytical platforms, etc.); 3) advocacy and sensitisation efforts directed at policy makers that will help to improve the knowledge base, increase advocacy and in turn help to guide political orientation; and 4) education and training activities. A report on gaps and a needs assessment of the African PM ecosystem has been prepared. The outputs of all regional engagements have initiated regional networking between interested and influential stakeholders who could support the further development of the African PM agenda in each region and foster specific activities to create an African PM strategy with concrete actions for the upcoming years.

The recommendations presented in this document are the result of diverse exchanges with stakeholders that validated and refined 1) areas of mutual interest for African and European collaboration; 2) gaps and needs identified; and 3) different models of collaboration, main challenges in international collaboration and the best ways to overcome them, especially in the area of PM and health.

In summary, the Action Plan aligns with the main project goals, which are:

- to integrate African countries into the ICPerMed activities and the EP PerMed
- to foster, facilitate and encourage joint PM projects and programmes between Europe and Africa
- to strengthen bilateral EU-AU STI relations in the area of health, including PM.

The recommendations within this document are therefore based on real evidence collected and analysed by the project and presented in different project documents, mainly the mapping work, the "List of African PM Needs" (D3.1[9]), the "List of Areas of Mutual Interest" (D3.2[10]) and the "Report of Gaps and Needs Assessment" (D3.3, under publication).

In order to determine the strengths, weaknesses, opportunities and barriers (SWOBs) to develop PM in Africa, as outlined in the "Report of Gaps and Needs Assessment" (under publication), EU-Africa PerMed has analysed the current status of African countries that could be positioned to drive growth within the region. Key aspects analysed include the competitive innovation ecosystem, technological, intellectual and physical assets, the interplay of government support – regulation, policy and research funding, academic areas of interest, health system environment and critical infrastructure that is important in developing a strategic direction, and ultimately an implementation plan. The analysis hinged on factors that determine a country's competitive advantages – such as infrastructure, research and innovation (R&I) programmes, activities and any unique standpoints that make the country special or competitive in the national and the African regional innovation ecosystem – juxtaposed with those internal or external factors that can keep a country from

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[8] *Sela E et al., 2021, https://zenodo.org/records/7934221*

[9] *https://www.euafrica-permed.eu/wp-content/uploads/2022/06/D3.1-List-of-African-PM-needs.pdf*

[10] *https://www.euafrica-permed.eu/wp-content/uploads/2023/06/Deliverable-3.2-List-of-areas-of-PM-mutual-interest-between-Europe-and-Africa.pdf*

realising its potential. The importance of determining these aspects was to uncover the gaps in and needs of each participating country, and to identify topics for cross-border collaboration. The following list shows the gaps and needs (GAN) identified in the African PM system of health, and the topics for concrete actions that are proposed in this document to be tackled by African-European collaboration, as they are of mutual interest (see detailed description of each topic also in Annex 1):

- GAN1: Genetic diversity
- GAN2: Infrastructure and resources
- GAN3: Access to technology and expertise
- GAN4: Data collection and sharing
- GAN5: Healthcare infrastructure and awareness
- GAN6: Ethical and legal considerations

The GANs were identified and complemented by and validated with stakeholders from both Africa and Europe.

Target group and stakeholders addressed by this Action Plan

The Action Plan is addressed to all actors from Africa and Europe positioned to support the uptake and implementation of the presented recommendations. These stakeholders can be individual organisations or initiatives. Two types of actors are needed: "drivers" and "implementors".

Actors who are "driving" PM development and innovation are, for example, researchers from the academic and clinical sectors, as well as representatives of the private sector. They will "do the job" by providing new insight through research, supporting evidence creation and accommodating or supporting the effective use of an innovation by practitioners.

Actors who are "enabling" PM development and innovation as well as supporting implementation activities are essential to establish a solid system of health and provide future system functionality by providing sustainability measures. "Enablers" work on two levels: they 1) bring visibility to the work that is necessary to support efficient development and delivery of future health requirements, e.g. in PM, through strategic documents and dedicated communication; and 2) provide support to "drivers", e.g. via dedicated funding measures. Typical "enabling" actors are:

- **Funders:** Funder support exploration via funding of research, proof of principle, proof of concept and other activities essential in understanding the needs of a healthcare system and exploration of potential solutions, and further evolution of existing processes. This stakeholder group can involve national, international and global funders, from the public and private sectors as well as the EU and AU. Non-governmental organisations (NGOs) such as the WHO and charities also play a strong role.
- **Funders and ministries and cross-border collaboration (AU/EU):** Policy makers from STI and health have a dual role as enablers and drivers, as they build the architecture for PM development on a national level, but in connection with strategic cross-border alignment. For example, the joint action "Developing Countries Clinical Trials Partnership" (EDCTP) is a consortium of funders with the common goal of funding activities in health, acting together as enablers.
- **Ministries:** This stakeholder type is essential for enabling the establishment of infrastructure supporting PM as an essential tool to build, enhance, connect and align the environments for the development, testing and deployment of PM approaches. Having ministries acting as enablers allows a sustainable and efficient pipeline for the development and implementation of health innovations.
- **Regulatory agencies:** Regulatory agencies (e.g. EMA, AMA), can be categorised as enablers for compliance, as well as managing processes such as verification, validation and approval steps. They could also support the alignment of activities and processes across borders, and support particularly the "drivers" in navigating the regulatory landscape, as well as proposing modification of regulations where needed based on research results and clinical outcomes.

Where possible, the actions presented in this Action Plan refer to drivers and enablers in the section "Mode of collaboration".

Part I: Personalised Medicine adopting environment

This first part of the Action Plan focuses on the entire PM "system of health" and on concrete suggestions for collaboration within Africa, but also between Africa and Europe, to develop a PM-endorsing environment acting on three levels that are linked to the previously identified gaps and needs (GANs, see above):

1. Infrastructure: Resources, education and technology awareness, corresponding to GAN2, GAN4 and GAN5
2. Ethical and legal considerations, corresponding to GAN6
3. Policy actions: Access to technology and expertise, corresponding to GAN3.

The Strategic Research and Innovation Agenda for Personalised Medicine (SRIA for PM (2023) demonstrates that healthcare systems are heterogeneous, depending on the (European and continental) region and country, but that health needs are comparable. Therefore, solutions could be found through transnational (on continental or on cross-continental level) collaborations that allow and even require the development of common strategies, standards, and principles of collaboration based on co-creation and frameworks.

The first cross-cutting component is the establishment of **ethics, policy and regulation**, as any use of large-scale data-gathering programmes will require a regulatory system and an ethics board to govern underlying policies on its structure and operation. Once the regulatory system is in place, the next major requirement is **infrastructure**, especially the capacity to localise omics technology platforms, high-speed internet connectivity, electrical supply, biobanking, hospital facilities and patient electronic health record systems, coordinated biobanking systems, etc. The data infrastructure coordination needs to address how the necessary data will be captured, stored, utilised and shared. This leads to the third requirement, **skilled people/personnel** who train others, develop studies (including clinical trials), collect samples and process the resulting data, and finally implement these aspects within the healthcare system. This group should also include medical aid payers for reimbursement strategies, given the strong presence of private healthcare in most African countries. Finally, **focused funding** is required to develop the PM system of health incrementally within a country or region.

Furthermore, the following aspects need to be developed: 1) omics sciences (genomics, proteomics, regulomics, metabolomics and epigenomics; 2) data sciences, including digital health and health systems (addressing healthcare delivery and public health); and 3) biobanks.

To support PM research, innovation and implementation overall, sustainable funding is required. This could be provided via programmes such as the EU's Framework Programmes (currently in the 9th edition: "Horizon Europe"), e.g. to initiate collaborations (such as financial support to allow the development and management of networks), or to launch first pilot studies and concrete research collaboration. As outlined above, to allow PM to be accessible to citizens and patients, sustainable and long-term investments are required, i.e. prioritisation and allocation of funds for health research and healthcare at the national level. Those national strategic settings are also the only means to enable co-creation, i.e. co-development of joint activities in which different countries invest. For example, these include regional hubs or centres of excellence, joint funding or education and training activities, i.e. reduction of duplication and more efficient use of available resources. In the African context, processes might still need to be initiated by external financial support, e.g. from the AU or EU or other global funders, as well as investment from the private sector.

Based on the work of the EU-Africa PerMed project, a set of research-supporting and research actions were identified, and are presented, that support the overall development, innovation and implementation of PM. These actions were identified as feasible recommendations that can be implemented to advance both genomics studies in Africa and future collaborations with Europe.

The actions are presented in the three levels (described above) of Part I, as follows:

I.1) Infrastructure: Resources, education and technology awareness	I.1.1) Infrastructure – collection and sharing	A1, A2
	I.1.2) Healthcare infrastructure and capacity building	A3
	I.1.3) Healthcare professionals and patients – training, education, and technology awareness	A4, A5, A6, A7
	I.1.4) Research support and network organisation	A8, A9, A10, A11, A12
I.2) Ethical and legal considerations		A13
I.3) Policy actions: Access to Technology and Expertise	I.2.1) Advocacy and awareness-raising activities	A14, A15
	I.2.2) Regional consortia	A16
	I.2.3) PM Meta-Cluster	A17
	I.2.4) African-European collaboration	A18, A19

Figure 1 : Structure of the research (grey) and research-supporting (blue) actions.

1) Infrastructure: Resources, education and technology awareness

Many countries face infrastructure and resource limitations, including inadequate laboratory facilities, limited access to advanced and novel technologies, and insufficient funding for research and implementation. The dedicated infrastructure supporting PM can enable access to healthcare, for well-developed as well as rural areas. Required infrastructure includes technology platforms, high-speed internet connectivity, electrical supply, biobanking, genomic archives, hospital facilities and patient electronic health record systems, coordinated biobanking, etc. The lack of infrastructure and resources hampers the collection and analysis of diverse types of health data needed to enable PM.

To support these aspects required to develop a PM-endorsing environment, a set of dedicated research supporting actions are presented in this section:

A1	Biobank infrastructure/cohort network
A2	Strengthening bioinformatics in research infrastructure
A3	Capacity building of PM data generators and users
A4	African-European multi-centres focusing on healthcare education and awareness
A5	Education and training programme for public healthcare forces
A6	Education and awareness activity for patients' associations
A7	Twinning programme

As well as concrete research actions:

A8	Population studies support stations
A9	International multidisciplinary research programme addressing Personalised Medicine
A10	Research collaboration revealing cancer diversity
A11	Research projects on companion diagnostic and biomarker discovery
A12	Research projects on the Big Three Infectious Diseases (BTID) and molecular-based tests

Infrastructure – collection and sharing

In the African context, but also in Europe, infrastructure, particularly that which is connected to bioinformatics, data systems, biobanks or central repositories, represents a huge gap and challenge within health systems. Data has to be operated ethically, captured, stored, used and shared easily. Highly skilled people are required and must be trained to implement PM aspects within the healthcare system.

A1	**Biobank Infrastructure/Cohort Network**
Description	Development of an African/European infrastructure/cohort network that: • Supports efforts in standardisation, harmonisation, quality assurance and validation of associated data. • Provides a basis to overcome the difficulty of undersized case studies, different samples and data as well as variations in datasets collected. • Maintains, further develops and integrates high-quality sustainable biobanks and population/disease cohorts. • Supports the development of processes to co-ordinate access to data. • Provides direct linkage to medical and public health systems in each country. • Is an essential aspect in fostering PM research collaboration.
Mutual African-European interest	The composition of populations is influenced by factors such as the presence of different ethnic groups/indigenous peoples within one country, mobility, immigration, migration, forced displacement and tourism, which implies the need: • For inclusive diagnostics and treatment strategies for all healthcare systems, including diseases largely affecting the local society, regionally located diseases (e.g. neglected tropical diseases, genetic disorders, communicable and non-communicable diseases, etc.), rare diseases and those related to lifestyle. • To develop adequate biobank infrastructure which 1) allows for powerful data generation tools employing highly trained staff, applying standardised and quality-controlled procedures with an elaborated data management system; 2) provides an important source for PM research, as it can provide high-quality samples (considering all aspects including collection, storage and data/sample management) that could be used to study e.g. genetic variation and other factors that may influence an individual's response. Centralised, connected and interoperable biobanks and health data repositories allow stratification processes in PM that are not only applicable in one specific population. Well-curated, easily accessible, high-quality data infrastructure and biobanks support e.g. decision support tools integrating AI and Machine Learning (ML) methodologies. In addition to human sample repositories, biobanks may include pathogen repositories.

A1	**Biobank Infrastructure/Cohort Network** (Continued)
Mode of collaboration	While biobanks are developed on local, national or regional level, co-ordination, e.g. in the form of a headquarters, is centrally organised and financially supported by the participating countries (i.e. support through membership, e.g. national buy-in for participation) and/or AU/EU (co-) funding (i.e. external support) to: • Support, manage and harmonise overarching platform aspects and processes such as data/sample collection, access, supporting and training activities • Connect national/regional medical centres and research infrastructure • Support linkage to medical and public health systems in each country, e.g. by linking (genomic) biobanks/databases and the clinical and public healthcare providers, or the integration of (genomic) databases in national health management information systems • Ensure financial support for the development and maintenance of biobanks. Sustainable funding is essential for, for example, a reliable source of electricity, and funding for infrastructure and equipment and for permanent well-trained staff. Besides African-European collaboration, it should be mentioned that there is a lack of long-term and sustainable transnational funding for South-South collaboration, e.g. for biobanking and cohort infrastructure, including the consensus-building process that is needed for data harmonisation and standardisation.
Timing and objectives	Short-term objectives: • Connect different biobanks that already exist in Africa and Europe • Create "learning" networks of existing local, national and regional biobanks, and supporting the set-up of new ones. Medium-term objective: • Install centralised co-ordination for the network on continental or international level. Long-term objectives: • Support the creation of new biobanks through knowledge transfer, i.e. harmonisation of data/sample quality and standards, safety, ethical and legal consideration and training, and funding models • Organise centralised co-ordination and access to existing biobanks • Exchange of e.g. samples between Europe and Africa, and vice versa.

A2	Strengthening Bioinformatics in Research Infrastructure
Description	Establishment and enhancement of a network of bioinformatics and research infrastructure across the African region that connects and strengthens already existing centres and supports knowledge sharing to create new bioinformatics units in already existing research infrastructures to: • Create a platform centrally supported for knowledge sharing and collaboration among researchers, fostering both regional and international scientific dialogue • Promote the implementation of advanced bioinformatic tools and techniques for data collection, analysis and interpretation (e.g. genomic data repositories) enabling PM research and innovation • Support co-operation between African and European research entities.
Mutual African-European interest	The development of bioinformatics in research infrastructure will act on two levels: technical, e.g. supporting the use of bioinformatics, data analysis, etc.; and the management/governance of health data, including aspects such as ethics, data sharing, data stewardship, etc. Overall, joint activities around this action: • Strengthen and enhance the research capacity of a country and a region • Harmonise strategies and processes, e.g. aligning roadmaps between Africa and Europe designed for secure and compliant transnational access to genomic data • Standardise guidelines for data infrastructure and data-sharing models • Improve security measures • Navigate regulatory frameworks • Facilitating the advancement of PM knowledge generation on Genome phenome connections within human populations. If this action is supported jointly, it may be a trigger to push different and especially independent centres to consider collaboration around bioinformatics and data sharing, e.g. if collaboration is indicated as requirement to receive funding.
Mode of collaboration	Implementing a regional cooperative network of centres (bioinformatics units in research centres). While the individual centres are supported locally, their collaboration is supported via joint funding provided from national authorities, or external funding (e.g. grants from EU/AU or global funders). Also, EDCTP network-like supporting actions could be applied.
Timing and objectives	Short-term objective: Creation of a bioinformatics platform for research collaboration and knowledge sharing. Medium-term objective: Establishment of sustained independent bioinformatics research, and enhanced collaboration capacity in Africa, scientific productivity and PM implementation in practice. Long-term objective: PM implementation in healthcare that leads to better patient outcomes.

Healthcare infrastructure and capacity building

Capacity building in fields related to PM is essential, e.g. through academic and certified training programmes, including for example genetic counselling, clinical/medical genetics, molecular biology, molecular medicine, ethics, functional genomics, clinical trials, genetic diagnosis, bioinformatics and other fields that support PM development, innovation and, especially, implementation. All of these aspects represent important challenges for healthcare systems and professionals, which raises difficulties in integrating PM into routine clinical practices.

One action specifically focused on capacity building of PM data generators and users is proposed in this document. Overall, low information and awareness regarding PM generates a lack of high-quality and comprehensive data needed for PM initiatives, such as biobanking repositories, resulting in insufficient funding for research and implementation. Of note: one challenge around the development of bioinformatics capacities in Africa is the lack of affordable ways of generating PM data that require a will to negotiate competitive pricing (e.g. higher costs due to import duties and taxes, middleman fees, smaller target market, the need for a reliable ecosystem that is sustainably funded, etc.).

A3	Capacity Building of PM Data Generators and Users
Description	Establish tailored short courses for stakeholders (both creators and users of health data), as well as exchange programmes to enhance skills in PM data management. The datasets generated are diverse in nature and form, ranging from administrative claims, medical records, pathology reports, analysis of health benefits or outcomes, data concerning provider or patient behaviour such as treatment objectives or preference, analysis/data on clinical utility, etc. Capacity building improves the quality of data collection and generation (also concerning data on patient behaviour or patient-reported outcomes from various structured and unstructured sources), and their integration and analysis. Some of the PM data generators or creators and users may include: • Healthcare delivery systems: hospitals, patient care teams, etc.[11] • Pharmacy benefits managers: services such as drug formulary development, manufacturer rebate negotiation and collection • Commercial health plans/insurance companies: generate data such as claims, billing and reimbursements for the covered services • Self-insured employers: data on enrollers' healthcare claims • Researchers: diverse types of biological and health-related data.

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[11] *e.g. UCSF TRANSPERS; https://pharm.ucsf.edu/transpers. Collaboration with the San Francisco Veterans Affairs Medical centre (SFVAMC; CA, USA) service and Cancer Care Ontario (CCO; ON, Canada).*

A3	Capacity Building of PM Data Generators and Users
Mutual African-European interest	Africa is believed to have unmined health data (in many cases still paper-based/non-digitalised records) that have not been curated or require completion to provide meaningful information for PM approaches. The European population is very diverse, with people originating from around the globe, while drugs and treatment decisions are based on research performed mainly on those of European origin. Both Africa and Europe stand to benefit from an arrangement using data-driven innovations and discoveries that will emerge from the existing data. European advancement in PM data management and infrastructure can provide mentorship and skills transfer to Africa, which lacks specialist skills and infrastructure for PM data management. To be integrated in collaboration between Africa and Europe, health databases must be harmonised and connected. One example of collaboration is the correlation between genotype and phenotype data, to solve the current gap: • Phenotype data and longitudinal cohort data collected in Africa are stored in diverse, not harmonised, databases through electronic health records (EHR). • Big genomics data archives of African population genomics data are not available. There is no infrastructure besides the H3ABioNet that holds African genomic data. Small datasets may previously have existed in Africa but were lost. They may exist in the European Genome Phenome Archive. To be noted and included in structuring efforts: there is a strong need for strengthening capacity to perform functional studies of African genetic diversity. Increased workforces will allow the analysis of African genetic diversity, to avoid the need for information retrieval of genomic data from different regions. The interpretation of the functional effect and the impact of genomic variation will require medical infrastructure to shift from paper to electronic medical (health) records (EHR), in order to be compatible with bioinformatics portals for data delivery and interpretation.
Mode of collaboration	Bilateral collaboration or international collaboration, to be fostered under the AU -EU Innovation plan and consider the recently developed EU Health Data Policy. In Africa, Europe and worldwide there is a need for agreed policies and mechanisms of Findable, Accessible, Interoperable, and Reusable- FAIR data principles[12] around data and fair data sharing. This will enable collaboration agreements between health databases in Africa and Europe.
Timing and objectives	Short-term objective: (online) courses for both creators and users of health data focusing on PM data management should be organised, and exchange programmes launched. Medium-term objective: enhanced skills in PM data management in Africa and Europe. Long-term objective: improved service delivery in the area of PM in healthcare.

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[12] *https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf*

Healthcare professionals and patients – training, education and technology awareness

In the African context, an inefficient public health sector combined with the incapacity of the private healthcare sector to train healthcare professionals plays a crucial role in the lack of expertise and commitment, which are factors that impact the specialisation of workforce development in the health field, leading to a brain drain, A similar context has also been reported in Europe, especially where there is a need to support interdisciplinary training in developing skills in areas such as ICT and specialised healthcare professionals for a PM workforce.

There are various stakeholders in the health ecosystem that need to be involved to ensure the impact of PM on clinical practice. Education and training actions should be directed to healthcare professionals, scientists and technologists, as well as patients and families.

A4	**African-European Multi-Centres Focusing on Healthcare Education and Awareness**
Description	The creation of a network of (national or regional) centres supporting healthcare education with a focus on PM to: • Create community outreach programmes • Raise awareness by organising PM topic-specific conferences, workshops and webinars • Increase dedicated communication via websites and other media, including regular newsletters, presence on social media, creation of video content on YouTube and TikTok, collaboration with influencers, publication of articles in journals, online advertising, directories and marketplaces • Create training programmes for health practitioners • Make PM part of curricula in medical and nursing schools.
Mutual African-European interest	Novel interventions are constantly being developed, and efforts are needed to administer them to people who can benefit from them. This process must be supported via improved knowledge and wider dissemination of those innovations. Most researchers understand the concept of PM, while there is still a lack of knowledge among healthcare forces, such as doctors and nurses, but also among the public, policy makers and funders. Most health practitioners (in Africa and Europe) do not have the knowledge to integrate rapidly emerging technologies or data resulting from new diagnostic tools into their daily work, hence those technologies lack direct clinical implementation. For the public, policy makers and funders, it is important that education and awareness campaigns are delivered in a lay format, which includes the use of native languages in comprehensible form. This leads to increased commitment, e.g. of patients/citizens to participate in clinical trials. Innovations in healthcare practice are more likely to be accepted when the public understands the scientific process and the benefit/value for them. Furthermore, public support for PM, including the allocation and use of public funds and taxes, is more likely to be sustained when people appreciate the value that PM brings to solving everyday as well as future healthcare problems. If citizens and patients (pull effect) and policy makers (push effect) understand the value of PM, the probability of leveraging funding for PM implementation increases. To support the pull and push effect requires communication (creating knowledge and improving education) on the value of and the increased quality of life for all supported by PM.

A4	African-European Multi-Centres Focusing on Healthcare Education and Awareness
Mode of collaboration	Local, national or regional centres collaborate in the form of a network to launch joint activities, support outreach to the local community and reduce individual effort by joining forces and sharing materials/activities. Many communication and training materials already exist, including online training courses that are already translated into several languages (English, French, Italian, Spanish, Portuguese), and could be translated/adapted to local languages rapidly, but also used internationally. Training materials need to consider local cultural aspects and have to be adapted to the respective target group.
Timing and objectives	Short-term objective: already existing online courses are made available and promoted in Africa. Medium-term objective: local, national or regional centres collaborate as a network to launch joint activities. Long-term objective: policy makers, the public and healthcare professionals are informed about PM and support its development and implementation.

A5	Education and Training Programme for Public Healthcare Forces
Description	Education and training programmes for public healthcare forces will raise PM awareness and share evidence on the benefit of PM approaches to the public healthcare system. Education specific to PM, but also, if possible, adapted and tailored to the respective countries' settings, is crucial for public health system workers to stay updated with the latest advancements, guidelines and best practices in the PM field, including the patient's perspective. Healthcare workers can be trained to proactively identify and manage disease outbreaks by the identification of individual (genetic) predispositions and environmental factors. With this internal support, the public health system is able to respond more efficiently to emerging health threats and improve the allocation of resources. **Key aspects of continued education for health system workers are:** • Academic education programmes: for example, revising and updating existing education programmes, allowing healthcare workers to specialise in PM with a dedicated and recognised curriculum and diploma • Professional development programmes focusing on PM: health systems can offer centralised professional development programmes that focus on specific areas of PM. These programmes could be delivered through workshops, conferences, seminars, online courses or in-house training sessions • Specialisation and advanced training: health system workers pursue specialised training or advanced degrees with a focus on PM • Collaborative learning and peer support: e.g. case discussions, journal clubs, or interprofessional team-based learning sessions • Cultural competency and health equity training programmes: these programmes address cultural competency, diversity and health disparities to ensure that health system workers provide equitable and patient-centred care to individuals from diverse backgrounds.

A5	Education and Training Programme for Public Healthcare Forces
Mutual African-European interest	In the African context, a poor public sector combined with the incapacity of the private healthcare sector to train healthcare professionals plays a crucial role in the lack of expertise and commitment, which are factors that impact the specialisation of workforces in the health field, as well as brain drain, particularly in African countries but also reported in Europe. An education and training programme for the public healthcare workforce leads to: • Healthcare improvement: both African and European countries have diverse populations and unique genetic backgrounds, with different environmental exposures and lifestyle factors. Building capacity in PM ensures the improvement of healthcare outcomes by tailoring interventions and treatments to individual patients, considering their specific genetic and environmental profiles. This leads to better disease prevention, more accurate diagnoses and more effective treatment strategies. • Reduction of disease burden and health inequalities: Africa and Europe face significant disease burdens, including communicable and non-communicable diseases, as well as inequalities in patient care (including aspects such as gender, age, societal status, as well as (non-)availability of healthcare in rural areas). • Health technology assessment (HTA) knowledge development: building capacity in HTA drives the implementation of new technologies and innovation in both Africa and Europe. • Public health preparedness: enhancing PM capacity strengthens public health preparedness in both Africa and Europe.
Mode of collaboration	Consortium with actors at the international level, e.g. Africa and Europe, that combines policy makers, researchers and healthcare workers.
Timing and objectives	Short-term objective: professional development programmes Medium-term objective: specialisation and advanced training Long-term objective: cultural competency and health equity training programmes

A6	Education and Awareness Activity for Patients' Associations
Description	Training courses or seminars focusing on and explaining the PM concept and benefits organised for patients' associations to raise awareness and increase knowledge.
Mutual African-European interest	Patients' associations are crucial in connecting patients and the general public with healthcare professionals, researchers, decision makers, etc. They push policy makers through a bottom-up approach to allocate increased funding for the development, innovation and implementation of PM and the training of healthcare professionals in PM. However, this requires an overall understanding of the PM concept and the value it provides for patients and citizens. This action brings representatives of patients' organisations from Europe and Africa together to enable the exchange and sharing of information that could support PM. This exchange improves education and awareness over different disease fields and PM application.
Mode of collaboration	Strong advocacy groups are mobilised in different modalities of disease awareness to drive PM approaches and their adoption (e.g. collaboration amongst the Spanish Association Against Cancer and Cancer Association of South Africa). Collaboration in this context requires a special consideration of the local context, culture and beliefs. This action also depends heavily on the existence of patient associations/organisations. In the case of a lack of patient organisations, patients and citizens could be targeted directly.
Timing and objectives	Short-term objective: training actions organised for and by patients' associations. Medium-term objective: build links between patients' associations from Africa and Europe. Long-term objective: associations are close to patients, patient families and the general public, and are drivers in knowledge sharing about PM.

A7	Twinning Programme
Description	The development of a twinning programme with a focus on PM applications to: • support knowledge exchange, mutual learning and collaboration of clinics between Africa and Europe • create a collaborative network of actors in the public and private medical sectors to discuss, develop and share new or refined tools and knowledge • showcase good examples in PM application • create an environment that connects researchers/clinicians across Europe and globally for knowledge exchange and exchanges of personnel.
Mutual African-European interest	• Demonstrate efficiency of a method/technology or approach in different environments, e.g. in countries/hospitals in Africa and Europe • Reduce duplication of efforts and harmonisation of access to novel technologies – instead of starting the development of a PM approach in each clinic or country, the knowledge is transferred from one setting to the other (e.g. for exchanges between Africa and Europe). Within a region, e.g. in the African context, this could support the development of excellence centres accessible for more than one country (for very specific technology or expertise needed) • Implement and use new technologies: increase the market of new technologies outside of one continent • Develop expertise and facilitate knowledge sharing among different bodies/agencies in Africa and Europe.
Mode of collaboration	African-European consortium with actors of different countries and both continents, which: • Is mainly driven by actors of the health sector as clinicians, academics and industry. • Should be supported financially to be able to meet and organise exchanges. • Is requested to exchange with policy organisations like regulatory agencies and ministries to improve government support in the long-term. Alternatively: Already existing initiatives integrate the launching of Twinning Calls as activity.
Timing and objectives	Short-term objective: development of exchange programmes, e.g. through twinning calls to harmonise the understanding and sharing of knowledge (capacity building) Medium-term objective: larger pilots are started for knowledge transfer and transfer of practices from one centre to another Long-term objective: a highly connected clinical network and harmonised access to high-quality care and novel technology, facilitated resource sharing.

Research support and network organisation

EU-Africa PerMed analysis has shown that a notable trend in African PM research is a marked interest in infectious diseases, cancer, the immune system and nervous system diseases. Treatment options and diagnosis methods clearly dominate the research landscape of European and African collaboration, and prevention-related research is significantly underrepresented, with only 8.4% of PM publications dedicated to this crucial aspect.

One major trend in Africa's PM research landscape is the rapid growth of international collaboration. The proportion of collaborative research increased from 29% in 2012 to 75% in 2020. African-European collaboration, as evidenced by the number of publications co-authored with African researchers, increased significantly starting in 2013, and reached its peak in 2019, with more than 350 co-authored publications. Until 2013, the total number of co-authored publications was less than 50 articles per year. Out of 4 340 PM publications, 1 973 have at least one collaborative European institution, which represents 45.5%.

The co-authorship network between six European countries and their top collaboratively engaged African nations is shown in Figure 2. The thickness of the line between the European countries and the African countries is proportional to the total number of co-authored publications.

Activities presented in this section on "Research support and network organisation" are research actions. It should be noted that PM can be applied to all disease fields and to diverse medical areas. The main areas for African-European research collaboration identified by EU-Africa PerMed are outlined in Deliverable 3.29 and comprise "disease areas" and "thematic areas". In this Action Plan, two disease fields are proposed that were identified as of high interest for both Africa and Europe, with great potential to be supported with sustainable as well as accessible funding opportunities: cancer (A10) and infectious diseases (A12). Collaboration in other disease fields is also considered important.

It is essential to underline that budget invested in research and PM development or innovation is not to be seen as an expense (spending) but an investment, i.e. research provides value.

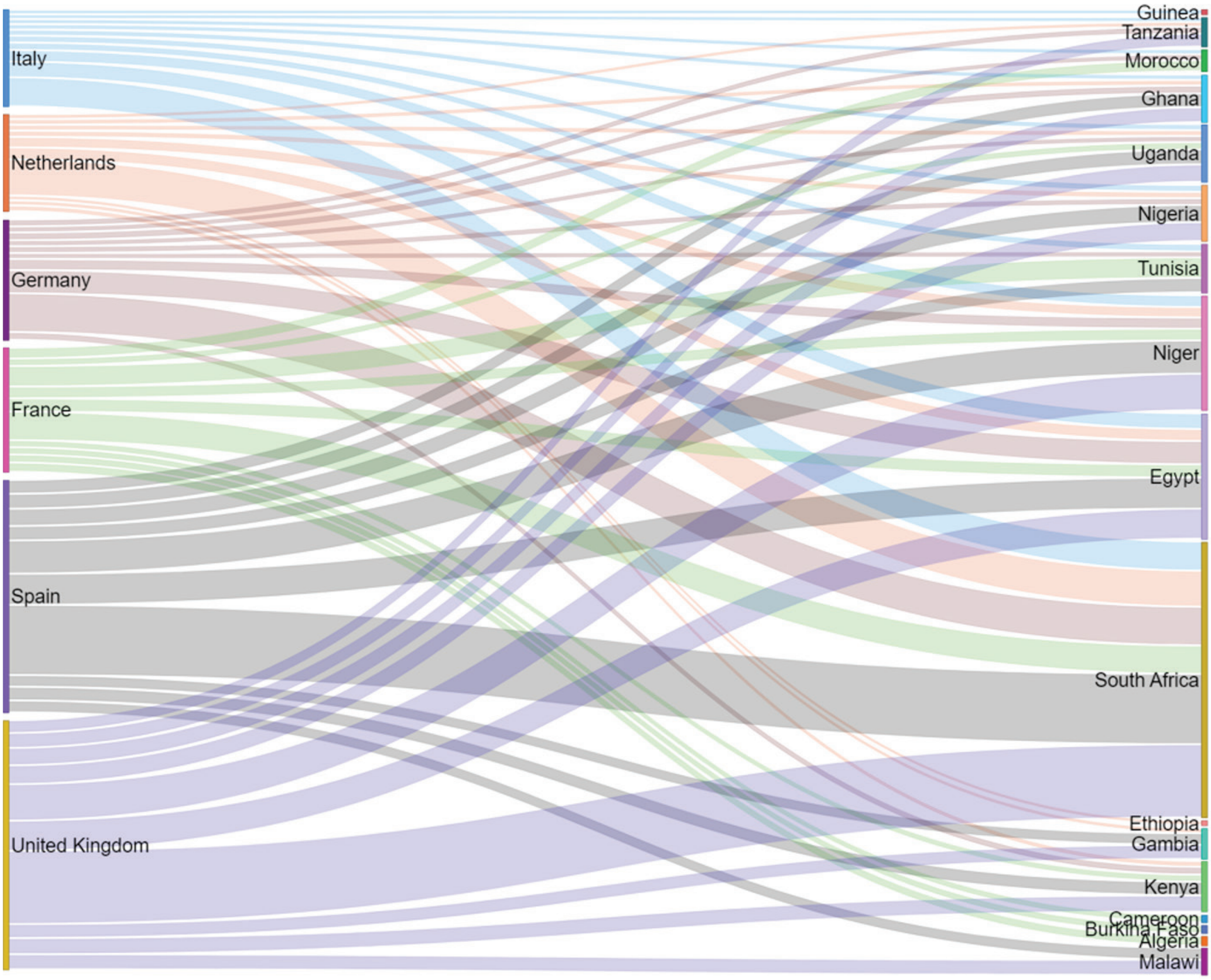

Figure 2: Co-authorship network between the highly active European countries (United Kingdom, France, Germany, Italy, Spain and the Netherlands) with their top African collaborating countries (visualised through a Sankey Diagram).

A8	**Population Studies Support Stations**
Description	Implementation of a sociodemographic, phenotypic, clinical and genomic longitudinal data sites network that supports the establishment and expansion in scope of demographic surveillance systems to identify comprehensive clinical, phenotypic, lifestyle, environmental and genomic data.
Mutual African-European interest	Comprehensive and reliable data on diverse populations increase the power of association studies and enable big data analysis beyond the question posed at a specific moment of data collection, or the limitations of the hypothesis. A network of stakeholders from Africa and Europe supports harmonisation of processes and studies that could be conducted individually at national or regional level, e.g. standardisation of data collection across African and European borders.
Mode of collaboration	Establishment of a network of clinical and research centres, the major drivers when it comes to health data generation and collection, but also of the private sector, particularly for the consideration of lifestyle and real-world data. The network can integrate already existing structures such as pan-acting medical societies (often focusing on a specific medical or disease field), and thus strengthen those already existing initiatives and broaden their scope/outreach. Specialisation, as bioinformatic expertise is required to support the analysis of multiple data sets from the very beginning. Ethical, legal and social issues expertise is required to respect ownership of data and strategies for the use of research outcomes, as well as to consider implementation research for the future use of data in clinical practice, e.g. for prevention strategies.
Timing and objectives	Short-term objective: identification of comprehensive clinical, phenotypic, lifestyle, environmental and genomic data to be collected (e.g. define minimum data sets). Medium-term objective: harmonisation of processes and standardisation of data collection across African and European borders. Long-term objective: availability of comprehensive and reliable data on diverse populations and use of the data to support PM.

A9	International Multidisciplinary Research Programme Addressing PM
Description	A research programme that fosters multi/international collaboration among researchers, with active participation of African and European actors from diverse disciplines such as genomics, bioinformatics, pre-clinical and clinical research, epidemiology and biostatistics to align a comprehensive insight for conducting research, rigorous methodologies and improved study design, e.g. considering the FAIR principles. Collaboration among researchers from different countries promotes cross-cultural exchange, which: • fosters a global perspective in research programmes • leads to a broader understanding of healthcare challenges, cultural influences and regional variations, ultimately improving the relevance and impact of research outcomes. In addition to clinical studies, it is crucial to discover incentives and promote increased set-up of pre-clinical studies to effectively evaluate stratification and therapeutics before advancing to PM clinical trials. This approach is essential for reducing the number of inconclusive trials, and guiding researchers and patients toward PM trials that have a higher probability of success. One further aspect supported by the research programmes is research on PM implementation and adoption, including: • the development of comprehensive and standardised data collection methods • research on the privacy and security of sensitive genetic information • research on socioeconomic and ethical considerations • health economics/socioeconomic evaluation of PM demonstration projects in low-resource settings at population level. The set of aspects to be considered can be only assured comprehensively if the research programme is established at the international level.
Mutual African-European interest	Considering the diverse diseases to be addressed by PM: African and European collaboration in PM research allows researchers to explore shared genetic variations, environmental factors and disease patterns. Individual research centres or clinics do not have the entire set of disciplines at hand, and (international) collaboration could fill those gaps via joint projects, and in the medium term, expand the local skilled workforces. Considering a public health point of view: Enhancing international research collaboration in PM can strengthen public health preparedness in both Africa and Europe. Research programmes that promote collaboration among researchers from diverse disciplines and countries establish the groundwork for long-term progress within public healthcare systems, and for the consideration of PM research as a major driver for knowledge development and sharing, innovation and implementation of PM. Through such programmes, research findings can support evidence-based decision-making and contribute to the development of healthcare that is more efficient and patient-centred.

A9	International Multidisciplinary Research Programme Addressing PM
Mode of collaboration	Collaboration can be established at two levels: 1. public-private collaboration at international level 2. collaboration between policy makers, researchers and healthcare workers at national level, in that not only do research outcomes feed into clinical applications, but also there is a feedback loop from clinical practice back into research. To establish sustainable and more impactful collaboration for a long-term transformation, funding mechanisms over a 10-year duration could be considered. The typical funding cycles of 3 – 5 years do not fit with the need for infrastructure. Due to short funding periods or lack of continued funding, many data, cohorts and materials are wasted or not optimally used.
Timing and objectives	Short-term objective: • build relationships and create a conducive environment for collaborative research • establish effective partnerships and communication channels • create platforms for knowledge exchange, organising interdisciplinary workshops or conferences, and facilitating networks that can result in collaborative projects. Medium-term objective: • Establishment of early-stage career fellowships to support researchers to acquire specific skills in clinical management research • identification of research priorities through placements in clinical or academic affiliated research organisations or product development partnerships (PDPs) • research funding programmes for proof-of-concept studies (POC, research investigations conducted to demonstrate the feasibility and potential effectiveness of a new concept, idea, or intervention). Long-term objective: Collaborative research programmes that fund projects: • on exploring strategies to overcome PM implementation challenges, to improve the uptake of innovative PM approaches and to evaluate the impact of implementation efforts on patient outcomes • that analyse the effectiveness, efficiency and equity in the implementation of PM research outcomes in different healthcare settings, including the evaluation of the related healthcare policies and interventions, and identifying new areas for PM research.

A10	Research Collaboration Revealing Cancer Diversity
Description	Multinational and intersectoral research project focusing on the detection of new genetic polymorphisms linked to cancer and considering different cancer characteristics such as localisation in the body or formation of metastases, as well as the impact of infectious diseases like human papilloma virus (HPV) and Epstein-Barr virus (EBV). The project should compare mutations that are known in Africa and Europe and correlate the results with geographic zones and environmental conditions.
Mutual African-European interest	Understanding the differences in cancer epidemiology, aetiology and management between African and Europe creates important opportunities for generating new knowledge for accurate diagnosis and appropriate interventions. Discoveries made in Africa, due to its high genetic and environmental diversity, could be applicable to the rest of the world. Improved knowledge of loco-regional polymorphism of genes related to cancer represents an opportunity for new and innovative therapies. As a result of the science performed, targeted innovations are developed, and existing targeted therapies from Europe adapted to the African context (e.g. immunotherapy and neoadjuvant drugs). For Europe, collaborative research revealing cancer diversity results in better health coverage of people with a migration background living in Europe. For both continents, the outcome of the research feeds into improved prevention policies, hence, has great potential to reduce healthcare costs.
Mode of collaboration	Transnational and intersectoral research projects with teams from Africa and Europe. Funding is provided through joint national funding from the participating countries, from funding programmes like EDCTP or directly from funders such as the AU/EU or global funders.
Timing and objectives	Short-term objectives: • shared methodology (e.g. in a genomic network) • training courses and post-doc exchanges. Medium-term objectives: • use of platforms and development of biobanks • big data and bio-informatics infrastructure establishment. Long-term objective: • cohorts for research purposes will be constituted • diverse genetic and molecular factors associated with disease development are revealed.

A11	Research Projects on Companion Diagnostic and Biomarker Discovery
Description	Funding of research projects that support the development of companion diagnostics (CD) supported through biomarker identification and validation. Projects funded can focus on early discovery of companion biomarker(s) or sets of biomarkers to stratify patients into groups for targeted treatments, monitoring of treatment efficacy and outcomes, drug administration, guiding clinical studies, prediction and timely monitoring of disease progression or remission. Inclusive models of biomarker profiles or signatures/patterns could be tested in clinical trials, e.g. to verify their potential to support the monitoring and assessment of several relevant biological pathways in complex pathological processes, or to verify the potential of early detection of treatment failures.
Mutual African-European interest	Companion diagnostic and biomarker research is a means of evidence-based funding and supports the decision on precision treatments. Companion diagnostics emerge as a very specific in vitro diagnostics group among the different technologies shaping the personalised healthcare spectrum. They provide highly valuable information for health professionals and payers to take evidence-based decisions, i.e. higher certainty on the potential benefits of a treatment or care pathway. Increased stratification potential and decreased uncertainty, e.g. of the efficacy of a treatment (considering the origin of the patient, sex gender and age, etc.), result in more efficient treatment care that can be targeted to those subpopulations that are most likely to benefit from a treatment. In order to incorporate CD into routine clinical practice, policy makers and funders in Africa and Europe need to gain stronger evidence on the value of CD, e.g. its potential to increase cost-effective healthcare delivery. This can be achieved through joint collaborative research activities in this field.
Mode of collaboration	This action requires longitudinal studies as well as implementation and entrepreneurial skills. Funding for transnational and intersectoral research projects with teams from Africa and Europe will be provided through joint national funding from the participating countries, from funding programmes such as EDCTP or directly from funders such as the AU/EU or global funders.
Timing and objectives	Short-term objective: small-scale research projects funded for the discovery of new biomarkers or validation of known biomarkers in clinical practice Medium-term objective: launch of clinical trials to test combination of different biomarkers/set of biomarkers for complex pathological processes Long-term objective: treatment decisions and follow-up of therapies are combined with companion diagnostics. Non-effective treatments are avoided, and healthcare costs reduced.

A12	Research Projects on the BTIDS and Molecular-Based Tests
Description	Treatment drug resistance threatens the gains made in the past decades in the treatment of the BTIDs. A better understanding of drug resistance mechanisms is crucial for the development of rapid methods of drug resistance detection.
Mutual African-European interest	The world's deadliest infections, tuberculosis, malaria and HIV/AIDS are considered the "big three" infectious diseases (BTIDs). Treatment drug resistance threatens the gains made in the past decades in the treatment of the BTIDs. A better understanding of drug resistance mechanisms is crucial for the development of rapid methods of drug resistance detection. The majority of these infectious diseases are poverty driven, hence highly prevalent in the lower-income and middle-income countries of Africa. Targeted treatment for the main infectious diseases into clinical routine in African countries will contribute to increased efficiency of current medical African and European co-operation funds. But BTIDs affect both developed and developing countries; therefore, there is a clear joint interest in more clinical trials that allow early detection of treatment failures and resistance origins.
Mode of collaboration	Discovery and understanding of the BTIDs, supported by early-stage research projects and molecular-based tests (e.g. discovery of host/pathogen interaction) and advanced research, e.g. on aspects such as multi-medication (drug-drug interaction) or overtreatment through joint and cross-border clinical trials, as a means of evidence-based funding decision and development of personalised treatment. A specific focus should be on PM implementation research in this area to leverage on already existing research results. Therefore, alignment with other initiatives on international as well as on African, European and national levels needs to be considered, e.g. EDCTP or WHO activities.
Timing and objectives	Short-term objective: small-scale research projects funded for the understanding of disease mechanism and host-pathogen interactions Medium-term objective: launch of clinical trials, e.g. for testing drug-drug interactions, optimisation of multi-medication and overtreatment to avoid drug resistance Long-term objective: evidence-based funding decision and development of personalised treatment.

2) Ethical and legal considerations

Healthcare systems are heterogeneous, especially concerning ethical aspects and the way ethical boards operate. PM research (health/biomedical research, including clinical trials) and implementation requires the development of ethical guidelines and policies that are appropriate to each healthcare system and the African context concerning privacy and personal information, as well as informed consent and clinical trial files.

Ethical and legal considerations face several weaknesses for the development of PM in African countries, especially the lack of accredited labs, independent ethics committees trained in PM requirements, regulatory authorities as well as ethical and regulation laws and procedures across health innovation.

Several countries lack supportive regulations adapted to PM health innovation, e.g. related to genomics, and infectious and rare diseases.

In addition, many cultural, political, social and economic differences exist between regions and countries in Africa that influence the opportunities and options for STI and the implementation of ethical and legal models.

This activity (A13) presents a research-supporting action:

A13	**Training Course for Ethical Committees Focusing on Ethical, Legal and Social Aspects (ELSA) In PM Research**
Description	Courses for members of national ethics committees to learn about PM research and its specificities in ethical, legal and social implications. The courses could be organised internationally, with the participation of members of African and European ethical committees, to share experience and best practices. It is essential to consider local context, cultural practices and norms. For example, African countries have different levels of sensitisation, knowledge and legal enabling ecosystems. Especially in the African context, the course could inform participants about European practices and universal ethical principles but should include input from local (African) ethicists, legal experts and health professionals.
Mutual African-European interest	For African-European collaboration, mutual understanding and appreciation would be essential to advance PM and implementation. Sharing research standards and good practices around ethical, legal and social issues related to PM facilitates the collaboration of African and European researchers in multinational research projects and programmes. It furthermore supports institutional capacity building.
Mode of collaboration	(Free) online or onsite training courses are organised via joint agreements between European and African countries, and include at least the following modules: • capacity building and strengthening programmes • multilateral and bilateral funding.
Timing and objectives	Short-term objective: (online) training courses are available in different languages and are promoted Medium-term objective: ethical committees are aware of PM and consider its perspectives when revising research proposed, and outcomes Long-term objective: institutional capacity in ethical, legal and social issues is built and strengthened.

3) Policy actions: Access to technology and expertise

The findings from the EU-Africa PerMed policy mapping have provided a picture of African countries that shows their level of maturity for the development and implementation of PM, based on their rating on a set of six dimensions or capacities: 1) governance of health research; 2) financing of health research; 3) resources for health research; 4) health research outputs; 5) international collaborations in health research; and 6) PM/genomic research. The result of this rating in five groups is presented in Table 3 for the African countries for which information was available.

Access to cutting-edge technologies and expertise, e.g. in novel diagnostic tools and health data analysis, is limited in many African countries. The high cost of e.g. genomic and other novel technologies, limited availability of specialised equipment and a shortage of e.g. trained health personnel and bioinformatics experts pose barriers to PM implementation. This vast gap may only be addressed by a PM-endorsing policy environment that enables the development of scaled projects and centres of excellence to disseminate necessary know-how through developing programmes of R&I, fostering the development of skills and reversing the brain drain in Africa as well as in Europe.

Developing, installing and strengthening transformative policies supporting the PM system of health, and establishing respective regulatory frameworks, will stimulate (sustainable) public and private funding to flow in and drive PM development, innovation and implementation. Effective policies and a regulatory framework will ensure that countries have an objective approach to funding R&I from national budgets and address prioritised areas.

Table 3: Classification of African countries based on the results of the EU-Africa PerMed mapping framework.

Group 1	Countries with very high values for genomic/PM research, and ratings very high or high for the other capacities. There is evidence that PM is a relevant issue for the governments, with specific programmes funding research and infrastructure available in the country.	South Africa, Egypt
Group 2	Countries with PM research capacity in place, normally associated with a high level of health/biomedical research. R&I governance is well established, funding for health/biomedical research exists (mainly from external sources) and countries participate in international research. PM is an issue of interest for the governments.	Algeria, Cameroon, Ghana, Kenya, Morocco, Nigeria, Tanzania, Uganda, Tunisia, Zimbabwe
Group 3	This group of countries have, in general, good performance in health research, but their capacity in PM/genomic research is low compared to group 2 with potential to grow in the future if funding exists, as there is already some baseline activity.	Botswana, Burkina Faso, Ethiopia, the Gambia, Malawi, Senegal, Zambia
Group 4	These countries have a low level of PM/genomic capacity, and an average performance in STI/health research, though high in some cases (i.e. Mauritius), but low in comparison to other groups in most of the dimensions/capacities analysed.	Benin, Mali, Mozambique, Congo, Cote D'Ivoire, Democratic Republic of Congo, Eswatini, Gabon, Guinea, Guinea Bissau, Mauritius, Namibia, Rwanda
Group 5	Countries with low/very low capacities in PM/genomic research, and low in the rest of the dimensions. In some cases, scoring was not possible due to lack of data to measure the selected indicators.	Angola, Burundi, Cabo Verde, Central African Republic, Chad, Comoros, Djibouti, Equatorial Guinea, Eritrea, Lesotho, Liberia, Libya, Madagascar, Mauritania, Niger, São Tomé and Príncipe, Seychelles, Sierra Leone, Somalia, Sudan, Togo

Alignment of policies could be achieved through collaboration efforts on different levels, for example via regional consortia, meta-clusters and international initiatives to enhance African and European collaborative engagement actions (presented in this section in form of actions). For sustainable cross-border collaborations and joint research and policy agendas, it is essential to create equal and trustful partnerships such that the voices of all countries, independent of their size or level of advancement, are heard, and their diverse needs are considered. This enables the closing of equity gaps.

Despite continuous growth in R&D expenditure in the last decade, most African countries face several weaknesses when it comes to the transmission of and access to information. Regional networks can generate the required understanding of the regional context of the R&I ecosystem. More commitment is required for the establishment of platforms, actions and synergies, e.g. via events, that allow researchers, clinicians, healthcare providers and other stakeholders of the PM system of health to access information and develop capacities in the field of PM.

To support access to technology and expertise, the following research supporting actions are proposed in this section related to "Policy actions: Access to technology and expertise":

A14	A personalised medicine advocacy programme or initiative
A15	African-European (International) Personalised Medicine Conference
A16	Regional Personalised Medicine consortia/hubs
A17	Personalised Medicine meta-cluster
A18	EU-Africa PerMed 2
A19	African European Personalised Medicine Research Supporting Network (AE PerMed

Advocacy and awareness-raising activities

To enhance awareness around PM, and therefore create opportunities to leverage funding and accelerate the access of PM implementation, advocacy programmes are needed.

A14	**A Personalised Medicine Advocacy Programme or Initiative**
Description	Launching of an African-European PM project or initiative engaging governments and their science granting councils, particularly in the African context, to develop common strategies for the support of PM.
Mutual African-European interest	Engaging organisations responsible for implementing science in Africa: • enhances the capacity of countries to fund and regulate PM means, particularly if the respective governments are engaged • drives translation into practice, i.e. healthcare, particularly if ministries of health are engaged. The development of capacity of African countries and organisations to lead and fund PM will provide the potential to: • initiate further collaboration with external players on more level ground • achieve less dependence, and increase capacity to contribute to the common goal of improved global health • allow more effective evidence production and translation into practice and policy.
Mode of collaboration	The project or initiative brings together actors such as research councils, ministries of health, science and education, and funders from different countries to develop and align strategies as well as investments (research funding) in the field, e.g. by jointly managing research grants, designing and monitoring research programmes, supporting knowledge exchanges between the public and private sectors and strengthening partnerships between funders and ministries. The initiative facilitates the connection of policy makers with researchers and clinicians (actors from the field) but also healthcare professionals and the public/patients from the end-user perspective to advocate for the development and implementation of PM. Examples of existing (not PM-related) advocacy initiatives are GloPID-R (Global Research Collaboration for Infectious Disease Preparedness, https://www.glopid-r.org/) or SGCI (Science Granting Councils Initiative, https://sgciafrica.org/), but also the ICPerMed (International Consortium for Personalised Medicine, https://www.icpermed.eu/). Participation in the initiative could be in kind (no budgetary commitment needed), but members joining agree to work towards the same objectives. At the launch of the initiative, it would be a support if funding were provided to allow the organisation of meetings or activities such as events, communication and dissemination.
Timing and objectives	Short-term objective: a first meeting takes place where organisations of different countries come together to agree on a modus operandi for a PM advocacy group Medium-term objective: an initiative is launched, and a roadmap (common strategy) is developed Long-term objective: PM is incorporated into national strategies.

One specific activity proposed as concrete example to support advocacy is a conference:

A15	**African-European (International) PM Conference**
Description	Raising awareness among policy makers and end users is a first step to be taken to enable the integration of PM into clinical practice by PM-supporting healthcare policies. An international conference on "PM implementation in healthcare systems: Challenges and opportunities for African countries", to be organised at regional or pan-African level, will Serve to advance knowledge and raise awareness among health policy makers in Africa on PM and the benefits of advancing PM-supporting technologies, and to establish infrastructure in healthcare systems. Alternatively, online conferences could be organised[13]. The first event might focus on the status of PM in Africa and Europe, considering local differences. Following events could focus on suitable and feasible co-operation measures supporting the development of the field, or on the implementation of PM. Events should aim for clear impacts, and bring together the right initiatives, organisations and experts as well as stakeholders, including policy makers and funders. A specific session topic suggestion is "Genomics". Following the "WHO 2022" recommendations, promotion of the adoption or expanded use of genomics in all countries through advocacy strategies is needed to make the use and benefits of genomics more widely known among health policy makers.
Mutual African-European interest	Sharing good practices and real benefits of PM applications in Europe is a means to increase awareness among African policy makers. Means of PM promotion is part of the AU-EU innovation agenda, as long-term public health actions. They are part of the political agenda for STI collaboration between Africa and Europe.
Mode of collaboration	Multilateral and bilateral funding AU-EU collaboration Co-ordination and support action (CSA) topic in Horizon Europe Work Programme (Africa Initiative)
Timing and objectives	Short-term objective: policy makers and end users are to be informed about and to understand the PM concept. The status of PM in Africa and Europe is presented/ discussed. Medium-term objective: support for and organisation of an annual PM conference at international level. Long-term objective: PM-supporting technologies are available in every country, and PM-supporting infrastructure in healthcare systems established.

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[13] *International Partnerships InfoPoint: https://international-partnerships.ec.europa.eu/knowledge-hub/infopoint_en*

Regional consortia

The EU-Africa PerMed mapping has shown that despite positive trends in the evolution of international collaboration, there is still a significantly low scientific outcome in the form of publications that solely involve African countries. Bilateral collaboration within Africa is less than 2%, with an even smaller number of publications involving more than two African countries without any non-African collaborators. This figure drops dramatically when considering collaborations involving more than three African countries with no non-African partners. South Africa stands out with the highest number of African collaborations (based on first and co-authored publications). Other countries that show significant activity include Nigeria, Ghana, Zimbabwe, Algeria and Tunisia.

> The African continent cannot be seen as a whole. When it comes to health/biomedical research and opportunities for collaboration with Europe, diversity across countries and regions has to be considered.

There is a strong need to develop clusters of excellence within individual countries, and to work in a collaborative way between different countries, e.g. by leveraging stronger well-resourced partners within a region through regional consortia to close the gaps concerning access to infrastructure.

A16	**Regional Personalised Medicine Consortia/Hubs**
Description	Creation of regional consortia/hubs and regional communities that are composed of stakeholders essential to advance PM in the respective region. In the African context, regional consortia could comprise Northern, Eastern, Southern, Central and Western Africa. Regional consortia represent a solution to: • foster access to technological innovation • pool resources and enable infrastructure and/or technology and/or data sharing, depending on the need • collect health data, establish cohorts and organise their follow-up and maintenance • align regulations related to the access to clinical studies, data collection and ethical consideration regarding their use and sharing.
Mutual African-European interest	Regional PM consortia/hubs facilitate collaboration within the African context between different regions, but also with Europe. The mapping work carried out by EU-Africa PerMed to review the scientific and policy landscape of PM in Africa has shown that the African continent cannot be seen as a whole. When it comes to health/biomedical research and opportunities for collaboration with Europe, diversity between countries and regions has to be considered. The cultural, political, social and economic differences between regions and countries influence the opportunities and options for STI and health research collaboration within Africa and internationally and condition the models and programmes to support and strengthen that collaboration.
Mode of collaboration	Multidisciplinary network based on terms of reference (ToRs) and working methods between countries collaborating in the respective regions.

A16	Regional Personalised Medicine Consortia/Hubs
Timing and objectives	Short-term objective: PM regional consortia are started at regional level Medium-term objective: regional consortia start joint activities, e.g. research projects/funding or education and training activities Long-term objective: countries participating in regional consortia adopt PM strategies at national level.

Personalised Medicine meta-cluster

In addition to the activities described above, there is a need to develop infrastructure programmes to co-ordinate and support infrastructure development within countries, regions and at continental level, in a harmonised manner based on common principles. These will allow countries and regions to collaborate with each other, including between Africa and Europe.

A17	Personalised Medicine Meta-Cluster
Description	Implementation of a meta-cluster as a strategic move towards enhancing the PM ecosystem in Africa, i.e. a cluster of local clusters, networks or regional hubs that connects the PM system of health in Africa and Europe. A PM meta-cluster represents a platform to: • delve into the concept of connecting existing hubs, excellence centres, networks, clusters and regional hubs, drawn together through a well-structured overarching meta-cluster • foster knowledge exchange, sharing of best practices and setting up of tailored training to the needs of the cluster members • discuss the potential benefits, challenges and practical steps toward achieving the integration of different tools, capacities and capabilities to boost the efficiency of PM research and application in Africa.
Mutual African-European interest	A PM meta-cluster plays a strategic role in influencing policy making. By serving as an advocacy platform, it aims to: • enhance equitable collaboration between Africa and Europe, as exemplified by the Africa-Europe Clusters of Research Excellence • pool resources, knowledge and expertise from both continents, but also among local/regional hubs in Africa, following a network-of-networks approach • serve as an advocacy platform • provide a unified voice to influence policy changes and optimise the implementation of PM by aggregating networks • lay the groundwork for building future partnerships. By pooling together scientists, clinicians and policy makers from Africa and Europe, a meta-cluster could: • create a collaborative environment, fostering relationships that could lead to co-creation and sharing of knowledge, and potentially forming new initiatives and projects • provide a platform for researchers to collaborate on shared research projects and joint training programmes • create opportunities for translational and implementation research by leveraging the collective expertise of the network, thus further advancing PM.
Mode of collaboration	Scientific network, with funding available for meetings, conferences, short-term scientific missions and training. Co-ordination and Support Action (CSA) model.
Timing and objectives	Short-term objective: offer tailored training programmes to healthcare professionals to transmit the necessary competencies and skills for implementing and integrating PM into practice. Sharing knowledge by connecting existing hubs, networks and clusters will facilitate the exchange of research findings, best practices and lessons learned across different regions and healthcare systems Medium-term objective: build new partnerships by fostering collaboration among researchers, healthcare professionals and decision makers Long-term objective: enhance the capacity of the African healthcare system and improve patient outcomes.

African-European Collaboration

PM innovation can both support capacity building of the health workforce, e.g. through virtual learning, and increase service delivery through, for example, e-health, telemedicine, point-of-care diagnostics and self-care medical innovations. International partnerships, including with the private sector, can support the development and use of new technologies for health. These must consider the need to address cultural and regulatory differences, the importance of building trust and the potential for increased efficiency and cost-effectiveness through shared resources and expertise..

A18	**EU-Africa PerMed 2**
Description	A project comparable to a CSA comprising partners from Africa and Europe to: • support the integration of African organisations into existing PM initiatives such as the ICPerMed and EP PerMed • support the creation of regional PM groups or hubs in Africa • carry out awareness raising among African countries and African stakeholders of the value of PM to better address health challenges in Africa • carry out pilot training actions. This will be a starting point for a larger and more effective African-European PM partnership: "AE PerMed".
Mutual African-European interest	The EU-Africa PerMed demonstrated important achievements, and has underlined the importance of engaging and exchanging information with stakeholders in Africa to raise awareness of and interest in PM. Activities such as networking, workshops, bilateral meetings and focus groups are a means to advance PM research and innovation in the African and Europe collaboration, as well as to raise interest on the policy level. Regional PM groups or hubs in Africa can work towards a better understanding of PM in countries where the level of maturity in the PM field is still low, as well as facilitate inter-country/intra-regional collaboration in Africa, and in future, collaboration with Europe. The above-mentioned activities began within the first EU-Africa PerMed project, and their impact will increase if the project continues for another period of 3 - 4 years. Considering the size of the African continent, the effort might be too substantial to be taken up as a whole by other running initiatives.
Mode of collaboration	Coordinating and Support Action (CSA) or network. A project carried out by partners from Africa and Europe that receives funding, e.g. via EU/AU or global funders.
Timing and objectives	Short-term objective: Organise workshops and (bilateral) meetings to raise awareness about PM and engage stakeholders to participate in regional consortia. Medium-term objective: Logistical support for the establishment of regional consortia. Long-term objective: Organise joint activities to bring together representatives of the different regional consortia and international organisations, with a focus on Europe.

A19	African European Personalised Medicine Research Supporting Network (AE PerMed)
Description	A partnership supporting African and European PM R&I collaboration, i.e. a joint funding initiative to support PM research, development of infrastructure, resources, training and ethical guidance. Funders of different countries from Africa and Europe align funding strategies as well as pool personnel and funding resources to launch joint calls for proposals in the PM field. National funding commitment is mandatory to join the action, while EU/AU co-funding can support management and other implementation activities. Funding could be directed to research projects as well as training activities, such as mentoring programmes for post-docs or PhD candidates. To be innovative and avoid "brain drain", these programmes could support mentors and trainees onsite instead of moving trainees to other sites, and thus strengthen local research capacity on topics that are relevant to the host countries and institutions.
Mutual African-European interest	Effective transnational, European-African R&I networking, co-ordination and synergies between national, international and EU research programmes relevant to PM. The preparation and implementation of joint calls for collaborative R&I project proposals between African and European partners will contribute to the co-ordination and increase of joint activities between R&I institutions and their programmes across African countries and the EU member states (including associated countries) in the area of PM. To have successful R&I projects, the research funder community agrees on applying similar (e.g. FAIR) principles. More specifically, the AE PerMed will support the public health thematic priority of the AU-EU innovation agenda, i.e. to demonstrate the opportunities that PM can bring to public health and prevention policies.
Mode of collaboration	European Research Area Network -ERA-Net- are instruments to promote cooperation between scientific research funding agencies, ministries and/or research institutes (acting as program managers) of the Member States and associated countries of the European Union (EU), as well as third countries. Therefore, the ERA-NET like model maybe used to support the partnership though co-funding for calls, but most importantly, financial support for management and implementation of activities. This action could be set up following the examples of already existing AU-EU research and innovation partnerships that focus on: • food and nutrition security and sustainable agriculture (FNSSA) under the green transition priority • climate change and sustainable energy (CCSE) under the green transition priority • innovation under the innovation and technology priority (e.g. Africa-Europe Innovation Partnership (AEIP).
Timing and objectives	Short-term objective: funders of countries from Africa and Europe join calls launched by the European Partnership for Personalised Medicine Medium-term objective: a joint African and European roadmap for collaboration in PM is developed Long-term objective: African and European partners launch African European Personalised Medicine research supporting network (AE PerMed).

Part II:
Genetics and genomics in PM – example study

Particularly in the first stages of PM development, patient genetic information and its analysis was the major driver to support research for tailored diagnosis and treatment for certain diseases. Cancer and rare diseases treatments benefited most from this stage. Today, the field of PM has advanced rapidly, and the range of technologies, methodologies and information utilised is much broader, supporting improved diagnostics and tailormade treatments and prevention strategies (see also SRIA for PM, 2023).

As outlined in the gaps and needs analysis of EU-Africa PerMed (GAN1: Genetic diversity): As previously described, Africa is the most genetically diverse continent, with a wide range of ethnic groups and genetic variation. However, there is a lack of representation of African populations in existing genetic studies and databases, which primarily focus on populations of European descent. This leads to a limited understanding of genetic variation specific to African populations, hindering the development of PM approaches tailored to the unique genetic profiles of Africans. There is a strong need to enable population genomics projects to close the gaps in scientific knowledge on the African genome.

While PM is disease non-specific and considers a wide range of health data (diverse omics, imaging data or lifestyle data), genome analysis presents an example for PM-supporting data/information that are of particular importance for Africa.

Although therapeutic drugs on the market have demonstrated their value in generally improving health, their efficacy differs from individual to individual. Variability in the treatment response is mainly due to differences in the genome, i.e. genetic variants affecting the pharmacokinetics and pharmacodynamics of medications. As outlined in Part I of this Action Plan, initiatives between Africa and Europe could focus either on the entire system of health or, alternatively, focus on a specific subtopic.

Considering the importance of genetics for Africa, Part II focuses on actions related to this topic, including genomics analysis and connected framework supporting actions.

It should be noted that analysis of large-scale genomic data is a crucial component of PM, with high potential to inform disease research and clinical care. Therefore, large-scale genomic studies will benefit the global population and not only individuals living in Africa if a significant portion of the African genome is included. If African genomic data is not considered, there remains the disease burden in Africa, and the global risk from mechanisms such as population disease re-infection, drug and vaccine inefficacy and non-inclusive clinical trial results. It is suspected that an under-represented population may serve as a reservoir for some lethal diseases, which may spread through globalisation [14].

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[14] *Omotoso, O.E., Teibo, J.O., Atiba, F.A. et al. Bridging the genomic data gap in Africa: implications for global disease burdens. Global Health 18, 103 (2022). https://doi.org/10.1186/s12992-022-00898-2*

Based on the work of the EU-Africa PerMed project, a set of research-supporting actions specifically focused on the area of genetics/genomics in PM were identified and are presented here. These actions were identified as feasible recommendations that can be implemented to advance both genomics studies in Africa and future collaboration with Europe.

Research-supporting actions supporting the consideration of genetics/genomics in PM are presented in chapter 1, “Human genomic networks”:

A20	National genome archive
A21	Establish regional genomic hubs
A22	Genomic data network
A23	Genomics for global health – African contribution

Concrete research actions proposed for genetics/genomics in PM are presented in chapter 2, “Genomic research networks, hubs and projects”:

A24	Characterisation of regional genetic populations’ architecture
A25	Africa-Europe network for human genomic research
A26	Genome-wide association (GWAS study

1) Human genomic networks

As already shown in Part I, the organisation of activities can be performed stepwise and on different levels:

- A national strategy and activities should be set up and (sustainable) resources (personnel and financial allocated) (A20).
- To avoid duplication and to share efforts, activities can be supported at regional level, i.e. neighbour countries can launch joint activities to use existing resources, personnel and infrastructure more efficiently, but also to build capacity and align activities (A21).
- Different hubs, national or regional centres can form networks at continental level, or with international outreach (A22).
- Overarching policy initiatives support and connect the entire value chain (A23).
- As indicated above, the activities presented below are research-supporting actions.

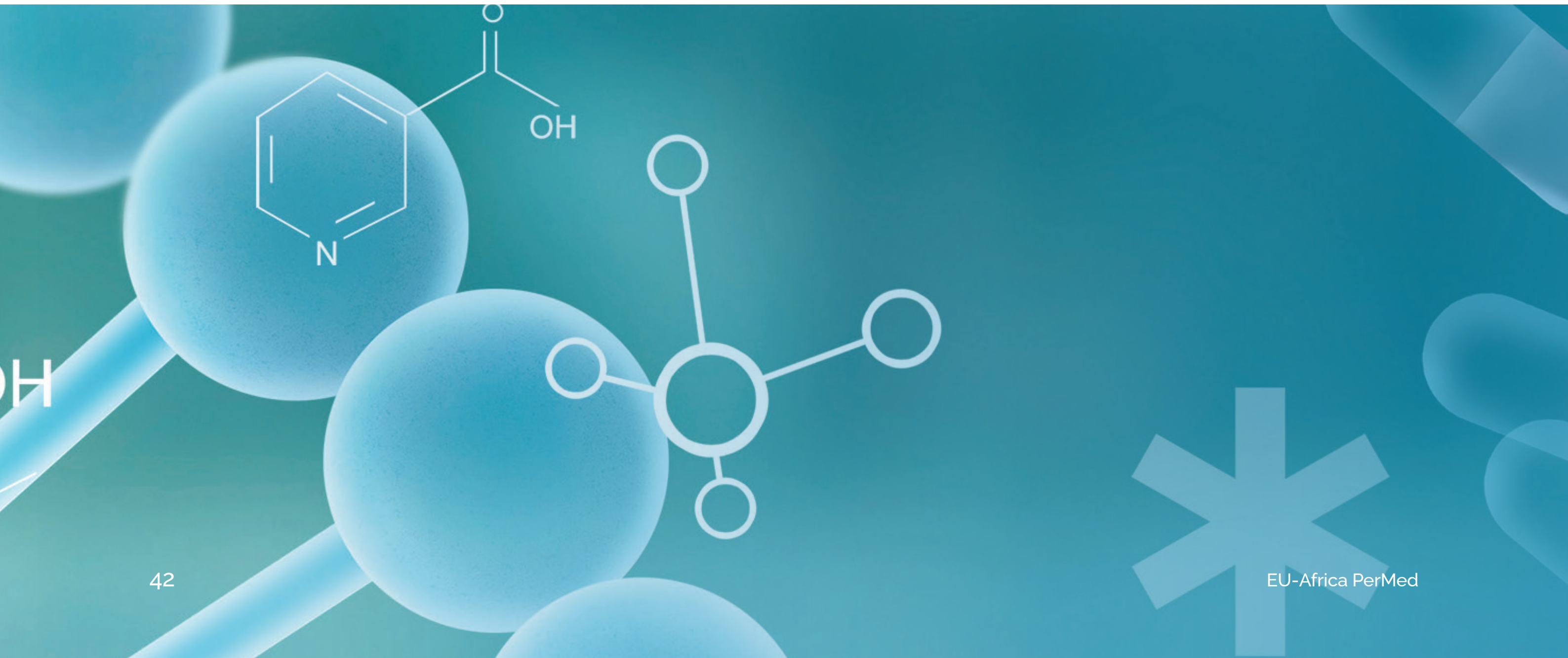
A20	National Genome Archive
Description	The role of a national genome archive is to support: • the storing of large-scale robust genomic data, e.g. from population genomics programmes (PGPs) to create population-level knowledge. PGPs aim to overcome the lack of diversity of genomes analysed through whole genome sequencing (WGS). More complete and diverse data are needed, e.g. to assess which variations are associated with disease or drug metabolism • interpretation of the functional impacts of genomic variation, and to integrate data to relate complex interactions with phenotypes • advancing technologies (e.g. next-generation sequencing, NGS) to obtain a combination of short and long read sequences that allow the development of population genomics scaffolds. This will help to alleviate the current high level of variation seen in African genomes compared to the current reference genome. Better algorithms to analyse African genome data are needed, as is the development of new, advanced methods for novel single nucleonic polymorphism (SNP) discovery and improved quality control metrics (e.g. use of proteomic signatures and their correlation to genome variation).
Mutual African-European interest	To apply PM approaches as broadly as possible, and in the best case, worldwide, diverse data sets of different populations are to be considered, particularly when it comes to genomic analysis. GWAS through Whole Genome Sequencing (WGS) analysis are already running even though at a limited scale, but they often focus on a specific population. National genome archives could be a starting point to collect local data. In a second step, they could be combined by having collaborations established between different national genome archives. As an example: Europe has launched actions such as the "1+ Million Genome" initiative that focuses predominantly on incorporating genomic diversity in Europe. But European countries have a strong migrant population, which so far has not been sufficiently considered. African-European collaboration could support the analysis of functional population diversity and heterogeneity, both essential to enable PM for all. Therefore, more knowledge about African genomics needs to be gained through population genomic programmes comparable to those run in Europe. GWAS analysis needs larger sample sizes, hence collaboration between archives from different countries and even continents will increase the chances of understanding causal genomic variants of disease to develop PM. Partnerships could: • be developed for different cancer types to understand causal variants and validate these in different populations • provide access to databases for researchers from Africa and Europe • create capacity development, as researchers can share knowledge and training. Mining genomic data is complex, and since Europe has been active in genomics analysis, the inception of the human genome is a tangible point of collaboration to analyse and mine genomic data, develop algorithms and analysis models and create bioinformatic tools • utilise world class genomic labs that are already set up, and generate data collaboratively, while Africa could focus on building capacity in data warehousing and storage to perform data analysis. Both pathogen genomics and human genomics should be considered, but both need training, skills and a critical mass of workforces.

A20	**National Genome Archive**
Mode of collaboration	National genome archives are to be established in each country. In some countries, this process has already started, and could be further developed. Their installation could be supported by external funding resources, while it is essential that the follow-up maintenance receives national funding. Alternative sources of funding such as fees for services could be considered but should be carefully chosen so as not to impact accessibility to the broader community.
Timing and objectives	Short-term objective: from mapping activities launched in countries and regions, comprehensive knowledge is gained about the data registries and health data information available Medium-term objective: central national genome archives are established for collecting/connecting local data Long-term objective: data can be combined by having collaborations established between different national genome archives.

A21	**Establish Regional Genomic Hubs**
Description	One country is selected from each region to hold the (research) hub, with the aim of serving as a reference centre for genomic sequencing and preparing the implementation of research projects on PM. The regional genomics hubs will centrally: • co-ordinate the establishment and later on the management of region-specific databases that researchers can query and consult for the identification of prevalence of variants • organise the generation of and access to health-related data (e.g. for WGS or amplicon-based marker genes, etc.). • organise training of research staff on sequencing technologies and bioinformatics • foster access to technology and innovation • establish networking activities between stakeholders from Europe and Africa • initiate PM-specific research projects for diseases of interest.
Mutual African-European interest	Regional genomics hubs facilitate collaboration on PM research in diseases of mutual interest among countries in one region (e.g. in Africa: Western, Central, Southern, Northern and Eastern Africa). They can also support collaboration between different regions and also internationally (in African-European collaboration) as a central contact point.
Mode of collaboration	A Multidisciplinary network based on Terms of Reference and working methods between countries collaborating in the respective region.
Timing and objectives	Short-term objective: exchanges between stakeholders within one region are initiated to define the framing of a regional genomic hub Medium-term objective: a co-ordinated approach for the establishment of regional specific databases, including the alignment of standards and processes Long-term objective: co-ordinated management of regional specific databases and access for (international) researchers.

Part II: Genetics and genomics in PM – example study continued

A22	**Genomic Data Network**
Description	An international genomic data network for data dissemination among Europe and Africa, including information technology (IT) specialists, researchers, genetics specialists from both Africa and Europe to: • support data collection and sharing across European and African borders • strengthen collaboration between African and European IT systems • launch research studies finding solutions to overcome challenges and providing evidence for opportunities resulting from genomic data sharing (e.g. sharing of existing methods and practices, SWOB analysis, legal considerations) • mobilise funding to establish advanced data-sharing systems or informatic tools (e.g. via algorithms) to combine different data sets in one study without the need to provide full access to data • identify and share best practice examples on an international level.
Mutual African-European interest	For Africa, given the vast genomic diversity and the high burden of disease, it is crucial to accelerate the development of PM based on the region's unique genetic profiles. By fostering a collaborative approach to PM research, this action will help to address the current gaps in African genomic data, promoting better understanding and treatment of diseases in the African population. The network will support the identification of challenges but also of opportunities for data sharing in both Africa and Europe, based on previous live examples and scientific proof. Progress and concepts in data sharing between different countries obtained from previous or current European initiatives could be shared with African stakeholders, to ease the process of initiation of data-sharing concepts among African countries. The network will support African-European genomics data exchange, which will lead to more effective implementation and increase the success rate of PM in Africa by considering African genetic backgrounds. The data exchange opens more job opportunities in Africa. European countries benefit from the availability of African genomic data to improve PM research outcomes and their application in care worldwide.



A22	Genomic Data Network
Mode of collaboration	A network consisting of experts in genomics, IT specialists, researchers and experts in molecular biology from Africa and Europe, but also more broadly internationally. The network will co-ordinate and support data sharing among members of the consortium or in support of other initiatives. It will organise frequent meetings to support the implementation process, e.g. via a constant dialogue with regulatory and political authorities, considering that data are highly connected to political matters. Sustainable funding mechanisms are needed, including national funding, e.g. via membership fees or centrally via funding (e.g. from the AU or EU), or support through sponsorship from industry. The latter is comparable to the “Together for Change” initiative, a big pharma consortium looking at closing a key gap in developing a population-level data registry on African genomics, including the development of core training programmes in human genomic data analysis. Multinational pharma consortia can act as driving partners, leveraging significant investments. The funding mechanism should be carefully balanced between public and private sector interests.
Timing and objectives	Short-term objective: detect challenges for data sharing between regional and international stakeholders by issuing documented studies Medium-term objective: strengthen collaboration and communication among African and European data specialists to support data sharing and to overcome the challenges already identified in order to ease data sharing Long-term objective: initiate genomic data sharing between Africa and Europe. Identification of newer therapeutic targets for African patients.

A23	Genomics for Global Health – African Contribution
Description	A project or initiative that supports organisations at national and regional level to advance PM through genomics, including policy dialogue, advocacy and awareness raising, funding of research projects, infrastructure and training. The initiative provides support to, for example, African regional PM committees focusing on genomics.
Mutual African-European interest	The current genomics data gap in Africa has implications for the global disease burden. Considering the diverse population genetics of the African continent could improve global disease prevention efforts. To attract international cooperation funds to support PM genomics initiatives in Africa, it might be necessary to change the wording and to adopt the WHO phrase "genomics for global health", or the new terminology: "public health genomics" (PHG). PHG is a new multidisciplinary field focusing on effective and responsible translation of genome-based knowledge and technologies to improve population health. The information gathered on genomics and risk for disease can be linked to other individual-specific factors such as behaviour and lifestyle, climate, access to healthcare and nutrition, exposure to pathogens, etc. Thus, truly personalised approaches combining different parameters can be developed, e.g. explaining why two people from a comparable genetic background but living in different environments have different risk of developing a disease.
Mode of collaboration	The work of a "Genomics for global health – African contribution" initiative, comprising organisations from Africa and Europe, could fit, and be supported by EU strategic programmes such as the Neighbourhood, Development and International Cooperation Instrument – Global Europe[15] (NDICI-Global Europe), and specifically the "Global challenges" thematic programme, and Horizon Europe under the specific objectives: 1) health; and 3) strengthened local authorities at global level. Team Europe is the backbone of global Europe (the main financial tool for EU international co-operation from 2021 to 2027). The Team Europe Initiatives ('TEIs') include the EU, EU member states, including their implementing agencies and public development banks, as well as the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). Building on and strengthening existing networks or initiatives such as the H3Africa (Human Heredity and Health in Africa) and the 1+ Million Genomes initiative could be considered.
Timing and objectives	Short-term objective: stakeholders (funders, ministries, researchers, clinicians, industry) from countries in Africa and Europe join efforts to prepare a roadmap for a "Genomics for global health – African contribution" initiative Medium-term objective: a joint African and European roadmap for collaboration on human genomics is published, including indications concerning its relevance for PM Long-term objective: African and European partners launch a "Genomics for global health – African contribution" initiative.

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[15] *https://international-partnerships.ec.europa.eu/system/files/2022-01/mip-2021-c2021-9157-global-challenges-annex_en.pdf*

2) Genomic research networks, hubs and projects

Infectious diseases such as malaria, HIV and tuberculosis (TB) as well as non-communicable diseases such as cancer, cardiovascular diseases and diabetes are increasingly becoming the main cause of mortality in sub-Saharan Africa, affecting around 1 billion people (WHO 2019[16]). Several genetic studies are currently taking place in African countries, especially in oncology, hypertension, cardiovascular disease, diabetes, neurogenetics, the human immunodeficiency virus (HIV), malaria, COVID-19 and TB. Strong research programmes and institutions in human genetics (including microbial genomics and cancer genetics) in various African countries are ongoing. Expansion of existing pharmacogenomics programmes addressing adverse drug reactions is essential. Big data infrastructure in national genomic archives are essential, as well as formal programmes on data sciences and digital health. To better involve genomics and the African perspective in PM research and other collaborations, co-creation is essential, as are robust funding programmes.

Beside the more supportive activities proposed in section 1 of Part II, this section 2 outlines concrete research actions performed by networks or individual research projects.

A24	**Characterisation of Regional Genetic Populations' Architecture**
Description	Research studies launched within Africa to develop population cohorts at national/regional level, including different ethno-linguistic groups. The projects launched will collect biological samples and phenotypic data to be stored locally or supported from regional hubs in high-quality biobanks. The results of the projects will support the development of PM approaches and support their implementation in local healthcare practices. African regional networks (see also Action A16 and A21) can provide support to those studies and co-ordinate standardisation, harmonisation, quality assurance and validation of biobanks and associated data.
Mutual African-European interest	Collaboration between existing (regional) genomic networks in African and Europe for: • mentoring • knowledge transfer • staff training and exchanges • sharing methodology and procedures • aligning regulations and ethical guidelines related to genetic data collection, storage, mining and sharing.
Mode of collaboration	Large-scale projects on population genomics that study the genetic structure of African populations. These require sustainable and large-scale investments. The required awareness and readiness on the African continent for this research needs to be created and could be, for example, supported by regional networks (see also Action A16 and A21). Various genomics studies should be supported in different African regions, including, for example, participation of stakeholders of several countries and ethnic groups within countries in each project. The stakeholders could vary or even overlap/be similar between different studies, i.e. one ethnic group across and in multiple studies if represented in more than one country, or multiple ethnic groups in the same country. While each study might solely focus on specific regional genetic populations in Africa, a consortium can be constituted of teams from different African and European countries. Currently running initiatives could be considered, such as the pan-African research network models (e.g. MalariaGen) or the recently launched African Population Cohort Consortium (APCC).

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[16] *https://www.who.int/publications/i/item/9789241565707*

A24	Characterisation of Regional Genetic Populations' Architecture
Timing and objectives	Short-term objective: an increased understanding of the value of having knowledge about local genomic diversity as a starting point for networking and large-scale research studies to connect local centres with other centres in the same or other regions, as well as internationally, e.g. Europe Medium-term objective: availability or efficient use of already existing local or regional biobanks and data platforms that can collaborate at regional, continental and international level Long-term objective: support the development PM approaches for people of African origin.

A25	Africa-Europe Network for Human Genomic Research
Description	A scientific network of researchers from Africa and Europe working on genomic research linking with relevant international PM communities to: • stimulate interactions between stakeholders to form and connect a PM-endorsing system of health • promote, support and facilitate information and international knowledge exchange, future collaborative research projects as well as the organisation of workshops and training activities • accelerate the careers of young researchers through networking. Networking activities for the next generation of researchers facilitate the development of new research collaborations, which can help in career development.
Mutual African-European interest	Collaborative networks are relevant means to align strategies and develop joint funding activities, in order to: • initiate and consolidate research collaborations • facilitate the participation, especially of African researchers in European projects and international consortia, but also vice versa • facilitate capacity-building activities • transfer knowledge and good practices. PM research, innovation and implementation in Africa will be advanced through strategic partnerships with countries that are more experienced in the field of genomics, as well as through the engagement of concerned communities at local, national, regional and international level. Sharing the experience of Africa in managing infectious disease through the use of genomic tools (genomic disease surveillance), as shown in the COVID-19 pandemic, is added value for Europe.
Mode of collaboration	Establishment of a scientific network, with necessary funding for meetings, conferences, short-term scientific missions and training. The project could be constructed as a CSA model, supported through the EU framework programmes.
Timing and objectives	Medium-term objective: build new collaborations and pave the way for future interdisciplinary research collaborations. Long-term objective: new research leadership skills and experience for less-connected researchers.

A26	Genome-wide Association (GWAS) Study
Description	International research collaboration between Africa and Europe, with the goal of: • integrating and promoting common standards • promoting and facilitating international knowledge exchange programmes for clinicians and researchers • attaining a critical amount and more diverse types of data to develop and train algorithms and models in PM approaches • developing approaches that could be applicable to a large range of disciplines and populations, i.e. not limited to a local genetic context • establishing high-throughput labs to sequence at a faster rate (currently not available in every country). Research collaborations can focus on specific aspects of PM, or disease fields. Highly relevant are (in addition to other disease and application areas) infectious diseases and pharmacogenomics.
Mutual African-European interest	GWAS and NGS collaborations (disease and population studies) have been identified by EU-Africa PerMed as an area of mutual interest for collaboration between Africa and Europe (Deliverable D3.2). In the SRIA for PM (2023), specifically transnational genomic studies for PM have been identified as one of the actions to be supported by international collaboration. Furthermore, genomic medicine was identified as a relevant area for public health within the AU-EU Innovation Agenda and is expected to contribute to the implementation of PM approaches. Large African/European sequencing (NGS) and genotyping (GWAS) studies using GWAS and NGS techniques allow the integration of African genetic variants into international medical genomic research, with the identification of biomarkers for human disease diagnosis/testing. The inclusion of diverse populations and human variations in genomic studies is critical to achieve a more complete understanding of human genomics variation, and for the elucidation of the underpinnings of complex diseases. It also contributes to increase the representation and consideration of African genomics in health genomic research: “The unique discoverability potential from African genomic studies promises invaluable contributions to understanding the genomic and molecular basis of health and disease” (Pereira L. 2021).

A26	**Genome-wide Association (GWAS) Study**
Mode of collaboration	This action can be supported via international co-operative research projects. Funding strategies (of bilateral and multilateral funding schemes) that will enable smaller, locally relevant genomics studies as well as large-scale genomics initiatives and genomic data science are needed to comprehensively address African genomic data shortages and apply the findings to improving health around the world. International collaborative research grants that bring together a diverse group of researchers from different countries, continents and research niches will be particularly useful to complement and address skills and experience gaps[17] [18].
Timing and objectives	Short-term objective: peer-reviewed co-created publications Medium-term objective: facilitating international co-operation among research scientists and institutions Long-term objective: increased scientific knowledge and innovation contribute to capacity building and knowledge exchanges.

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[17] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9201791/*

[18] *Pereira L, Mutesa L, Tindana P, Ramsay M. African genetic diversity and adaptation inform a precision medicine agenda. Nat Rev Genet. 2021 May;22(5):284-306. doi: 10.1038/s41576-020-00306-8. Epub 2021 Jan 11. PMID: 33432191.*

Annexes to the Action Plan

Annex 1: Reference to Deliverable 3.3: GAPS and NEEDS Analysis (Under Publication)

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Gaps and needs in the African PM system of health and topics proposed to be tackled by African-European collaboration as they are of mutual interest.

> **Genetic diversity:** Africa is the most genetically diverse continent, with a wide range of ethnic groups and genetic variations. However, there is a lack of representation of African populations in genetic studies and databases, which primarily focus on populations of European descent. This leads to a limited understanding of genetic variations specific to African populations, hindering the development of PM approaches tailored to the unique genetic profiles of Africans. There is a need to enable population genomics projects to close the gaps in scientific knowledge on the African genome.

- **Infrastructure and resources:** Many African countries face infrastructure and resource limitations, including inadequate laboratory facilities, limited access to advanced genomic and other novel technologies and insufficient funding for research and implementation. The lack of infrastructure and resources hampers the collection and analysis of genomic and other diverse types of health data needed for PM initiatives. There is a need to leverage stronger well-resourced partners within each region, e.g. through regional consortia, to close the gaps in access to infrastructure, and a need to develop infrastructure programmes to co-ordinate and support any infrastructure developments within each region and foster regional collaboration to develop the PM system of health.

- **Access to technology and expertise:** Access to cutting-edge technologies and expertise, e.g. in genomic research and health data analysis, is limited in many African countries. The high cost of, for example, genomic and other novel technologies, the limited availability of specialised equipment and a shortage of trained personnel and bioinformatic experts pose barriers to PM implementation. This vast gap may only be addressed by developing scaled projects and centres of excellence to disseminate skills and know-how, through developing programmes of R&I to foster the development of skills and reverse the brain drain in Africa.

- **Data collection and sharing:** The collection and sharing of high-quality, comprehensive data are essential for PM. However, there is a scarcity of large-scale genomic and clinical datasets in Africa. This gap is further exacerbated due to limited data collection infrastructure, lack of genomic data generated on African populations, challenges in data harmonisation and standardisation and concerns about data privacy and security. These hinder the development of robust data repositories necessary for PM.

- **Healthcare infrastructure and awareness:** Healthcare systems in Africa face numerous challenges, including inadequate healthcare facilities, a shortage of healthcare professionals and limited access to healthcare services in remote areas. These challenges hinder the integration of PM into routine clinical practice. Additionally, there is a need to raise awareness and educate healthcare professionals and the general public about the benefits and implications of PM.

- **Ethical and legal considerations:** PM raises ethical and legal concerns related to privacy, informed consent, data ownership and potential stigmatisation or discrimination based on genetic information. Developing appropriate ethical frameworks, guidelines and policies tailored to the African context is crucial to ensure the responsible and equitable implementation of PM.

Annex 2: List of actions proposed in this Action Plan

Main Section	Chapter	Sub-Topic	Action
I. PM adopting environment	I.1) Infrastructure: resources, education and technology awareness	I.1.1) Infrastructure – collection and sharing	A1 Biobank infrastructure/cohort network A2 Strengthening bioinformatics in research infrastructure
		I.1.2) Healthcare infrastructure and capacity building	A3 Capacity building of PM data generators and users
		I.1.3) Healthcare professionals and patients – training, education and technology awareness	A4 African-European multi-centres focusing on healthcare education and awareness A5 Education and training programme for public healthcare forces A6 Education and awareness activity for patients' associations A7 Twinning programme
		I.1.4) Research support and network organisation	A8 Population studies support stations A9 International multidisciplinary research programme addressing PM A10 Research Collaboration Revealing Cancer Diversity A11 Research projects on companion diagnostic and biomarker discovery A12 Research projects on the Big Three Infectious Diseases BTIDs and molecular-based tests
	I.2) Ethical and legal considerations		A13 Training course for ethical committees focussing on Ethical, Legal and Social Aspects ELSA in PM research
	I.3) Policy actions: Access to Technology and Expertise	I.2.1) Advocacy and awareness-raising activities	A14 A PM advocacy programme or initiative A15 African-European (international) PM conference
		I.2.2) Regional consortia	A16 Regional PM consortia/hubs
		I.2.3) PM meta-cluster	A17 PM meta-cluster
		I.2.4) African-European collaboration	A18 EU-Africa PerMed 2 A19 AE PerMed

Main Section	Chapter	Sub-Topic	Action
II. Genetics and genomics in PM – example study	II.1) Human genomic networks	A20 National genome archive	
		A21 Establish regional genomic hubs	
		A22 Genomic data network	
		A23 Genomics for global health – African contribution	
	II.2) Genomic research networks, hubs and projects	A24 Characterisation of regional genetic populations' architecture	
		A25 Africa-Europe network for human genomic research	
		A26 GWAS study	

Impress

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Conflict of interest

The authors declare no competing interest for this work.

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