

D3.3 Report on Gaps and Needs Assessment

RIZWANA MIA (SAMRC) AND WP3

DATE OF SUBMISSION: 2nd June 2023

Project Acronym	EU Africa PerMed	
Project Title	BUILDING LINKS BETWEEN EUROPE AND AFRICA IN PERSONALISED MEDICINE	
Grant Agreement no.	964333	
Start date of the project	01/02/2021	
End date of the project	31/12/2021	
Work Package number	WP3 – CROSS BORDER COLLABORATION AND IDENTIFICATIONS OF FUTURE ACTIONS IN PM BETWEEN AFRICA AND EUROPE	
Deliverable Number	D3.3	
Deliverable title	Report on Gaps and Needs Assessment	
Lead Beneficiary	SAMRC	
Due date	M27 (April 2023)	
Date of delivery	2 June 2023	
Nature	R (Report)	
Dissemination level	PU (public)	
<p>DISCLAIMER This document reflects only the author's view. Responsibility for the information and views expressed therein lies entirely with the authors. The European Commission is not responsible for any use that may be made of the information it contains.</p>		
Version	Contributors	Comments
3.0 DEF	Monika Frenzel (ANR), Erika Sela (Innovatec), Rizwana Mia (SAMRC)	Third draft -Review
2.0	Rizwana Mia (SAMRC), Raphaëlle Ripoche (INSERM), Teresia Nyawira (NACOSTI), Badara Cisse, Rokhaya Ndiaye (IRESSEF), Amr Radwan (ECTID)	Second Draft - Regional contribution from regional representatives
1.0	Rizwana Mia (SAMRC)	First draft

Table of Contents

Abbreviations and Acronyms	3
Executive summary	4
1. INTRODUCTION	6
2. METHODOLOGY OF THE REGIONAL ANALYSIS	9
2.1 BACKGROUND: MAPPING THE SCIENTIFIC AND POLICY LANDSCAPE OF PERSONALISED MEDICINE IN AFRICA	9
2.2 THE SWOB ANALYSIS RATIONALE	11
3. THE AFRICAN REGIONAL ANALYSIS	12
3.1 EAST AFRICAN REGIONAL ANALYSIS	13
3.1.1 The East African Scientific and Policy Landscape	13
3.1.2 Strengths, Weaknesses, Opportunities and Barriers to Develop PM in East Africa.....	14
3.2 THE SOUTHERN AFRICAN REGIONAL ANALYSIS	17
3.2.1 The Southern African Scientific and Policy Landscape	17
3.2.2 The STRENGTHS, WEAKNESSES, OPPORTUNITIES & BARRIERS to Develop PM in Southern Africa.....	19
3.3 NORTHERN AFRICAN REGIONAL ANALYSIS	24
3.3.1 The Northern African Scientific and Policy Landscape	24
3.3.2 The STRENGTHS, WEAKNESSES, OPPORTUNITIES & BARRIERS to Develop PM in NORTHERN Africa	25
3.4. THE WEST & CENTRAL AFRICAN REGIONAL ANALYSIS	29
3.4.1 The West & Central African Scientific and Policy Landscape	29
3.4.2 The STRENGTHS, WEAKNESSES, OPPORTUNITIES & BARRIERS to Develop PM in West & Central African Regional Analysis	32
4. THE AFRICAN CONTINENTAL GAPS & NEEDS	35
Table 5: Summary of the PM gaps and needs from East Africa	35
Table 6: Summary of the PM gaps and needs from Southern Africa	37
Table 7: Summary of the PM gaps and needs from North Africa	38
Table 8: Summary of the PM gaps and needs from West and Central Africa	39
5. Gaps-and-needs in the African personalised medicine system of health	41
6. References	43
Annex 1: SWOB Analysis methodology and critical questions used for landscape analysis.	44

Abbreviations and Acronyms

AU	Africa Union
AiBST	African Institute of Biomedical Science and Technology
ANR	French National Research Agency (France)
CDC	Centres for Disease Control and Prevention
D2.1.	Deliverable Report 2.1: “Mapping the scientific and policy landscape of PM in Africa”
D2.2.	Deliverable Report 2.2: “The EU-AFRICA PerMed stakeholder mapping report”
D3.1.	Deliverable Report 3.1: “List of African PM needs”
D3.2.	Deliverable Report 3.2.: “List of areas of mutual interest between Europe and Africa”
DSI	Department of Science and Innovation (South Africa)
DS-I Africa	Data Science and Innovation for Africa
EDCTP	European and Developing Countries Clinical Trials
EU	European Union
HIV/AIDS	Human Immunodeficiency Virus, acquired immune deficiency syndrome
H3 Africa	Human Hereditary and Health in Africa
ICPerMed	International Consortium for Personalised Medicine
ISCIII	Instituto de Salud Carlos III (Spain)
INSERM	Institute nationale de la santé et de la recherche médicale (France)
LMIC	Low and Low Middle-Income Countries
MakBRC	Makerere Biomedical Research Center
MoH	Ministry of Health
NCDs	Noncommunicable diseases
NEPAD	New Partnership for Africa's Development
NHLS	National Health Laboratory Service
NIH	National Institutes of Health
NGOs	Non-Governmental Organisations
NGS	Next Generation Sequencing
PABIN	Pan-Africa Bioethics Initiatives
PerMed	Personalised Medicine
PGx	Pharmacogenomics
PM	Personalised Medicine
R&I	Research and Innovation
SA	South Africa
SAMRC	South Africa Medical Research Council
SDG	Sustainable Development Goals
STI	Science, Technology, and Innovation
SWOB	Strengths, Weaknesses, Opportunities, Barriers
TB	Tuberculosis
WHO	World Health Organisation
WP	Work Package
UN	United Nations
UCT	University of Cape Town

Executive summary

In order to foster joint personalised medicine (PM) projects and programmes between Europe and Africa, as well as strengthen bilateral EU-AU science, technology and innovation (STI) relations in the area of health, the EU-Africa PerMed project, initiated several core stakeholder engagement initiatives from February 2022 to January 2023. These activities, and particularly the regional workshops, allowed for in-depth regional analysis and engagements across the African continent, as a mode to advance PM in Africa on various levels: for developing the PM agenda, for fostering collaborations, structuring of platforms and scientific hubs, for strengthening regulatory frameworks and for developing regional strategies. On the other hand, a national approach was considered to be more relevant for priority setting, implementation and allocation of resources.

As part of the activities of Work package 3 (Cross Border collaboration and identification of future actions in PM between Africa and Europe), it was planned to carry out a Gaps and Need Assessment in African PM ecosystem, that could provide as outcome, a preliminary list of gaps in the African PM ecosystem that can help us define the needs to address those gaps.

This document D3.3 describes the African PM gaps and needs identified by EU-Africa PerMed through consultation of diverse African stakeholders conveying a regional perspective. The deliverable considers outputs from the project's scientific and policy mapping activities (WP2-Deliverable 2.1); the conclusions of regional engagements in the East, South, North, West and Central regions of Africa; as well as the outcomes concluded in Deliverable reports 3.1 and 3.2, and the finalised regional feedback reported in the 2nd stakeholder workshop organised by EU-Africa PerMed (20-21 February 2023). Regional workshops were conducted using an analysis which involved determining Strengths, Weaknesses, Opportunities and Barriers (SWOB) to the development of PM in Africa. This enabled a stakeholder led analysis of the landscape to derive the gaps and needs for the development of PM in Africa, including the potential for collaborations between Africa and Europe.

The idea of the regional approach come up as results of the mapping work carried out in WP2 and the first feedback received from the first stakeholder engagements, i.e. the 1st stakeholder workshop and surveys, that showed that it is more appropriate to approach the engagement and interviews with stakeholders on regional level, i.e. bringing together stakeholders of north, south, central, west or east Africa each in individual joint meetings, instead of approaching the analysis solely at the African-continental level.

Regional engagements have taken place in all regions but at different level and with different approaches. This is mainly due to the i) availability of partners from only a set of African countries in the consortium (South Africa, Kenya, Tanzania, Senegal and Egypt) so not all regions are represented in the EU-Africa PerMed consortium; ii) already existing linkages between some African and European countries that have facilitated the engagement (the case of North-African francophone countries with close links to France); iii) important differences in the level of development of health/PM research across African countries (as found out by the mapping work) that implies that not all African countries have been considered for the detailed gaps and needs analysis (focusing mainly on those at a certain level of development) and iv) difficulties in identifying and engaging with some relevant stakeholders to attend the organised meetings. Nevertheless, the information collected can be seen as valuable to understand the situation at African regional/country level and to come up with a set of common and important gaps and connected needs for advancing PM development in Africa.

The outputs of all regional engagements have fostered regional networking of interested and influential stakeholders that could support the further development of the African PM agenda in each region and foster specific activities to create an African PM strategic roadmap/ action plan. This can be seen as an important outcome of the project that was not initially planned, but that will contribute to advance the PM agenda in some countries and regions, especially for those in that EU-Africa PerMed project partner organisations have their origin (Egypt, Kenya, South Africa and Senegal).

During the regional exchanges, the advantage to develop collaboration with countries of the EU that already advanced in PM was endorsed as Africa has to foster a momentum of research and innovation (R&I) that can drive PM on the continent; develop African specific population genomic knowledge and develop mechanisms

to enhance funding; harmonise ethical and legal considerations to enable PM research innovation and implementation; develop R&I programmes in PM from low hanging precise diagnostics; to enhance infrastructure and data as well as biobanking repositories; and address workforce development to reverse the brain drain within the science and innovation sector on the continent.

1. INTRODUCTION

To explore and analyse the potential and advantages of collaboration in Research and Innovation (R&I) in the field of personalised medicine (PM) between Africa and Europe, a full landscape analysis was performed in Africa. In this deliverable, we utilised a stakeholder engagement model of determining a SWOT or rather SWOB analysis - Strengths, Weaknesses, Opportunities, and we substitute Threats to determine Barriers for the development of PM in Africa. This analysis assisted in robustly engaging key participants, to identify and prioritise the PM gaps and needs for Africa. The Scientific and Policy landscape in PM were identified through extensive mapping activities in work package 2 (WP2) and complemented via a direct engagement with African PM stakeholders through a series of regional meetings that allowed engagement with research active African countries within the 5 Africa Union (AU) regions of the continent, namely: Eastern, Southern, Northern, Western and Central African regions and a Stakeholder workshop in South Africa According to the World Health Organisation (WHO), the African continent is experiencing a comparatively high burden of disease, particularly in infectious diseases such as malaria, HIV/AIDs, and non-communicable diseases like cancer, hypertension, cardiovascular and diabetes. Precision or personalised medicine approaches could be one of the solutions to manage this disease burden.

The analysis uncovered components of the R&I ecosystem that could drive the development of PM in Africa. Regional meetings were hosted outside the planned activities of the project, yet necessary to generate the required understanding of the regional context. This deliverable D3.3 will feed into the general EU-Africa PerMed objective 2, (see also Fig. 1): *To explore and analyse with relevant stakeholders, the potential for and advantages of collaboration in PM between Africa and Europe, identifying areas of mutual interest and added value for both regions and building sustainable links between both regions, to integrate the African continent in the global PM agenda.*

The regional analysis has furthermore contributed to work package 3 (WP3) specific objectives:

- Explore and analyse the potential and advantages of collaboration of Africa and Europe in the field of PM.
- Identify gaps and the needs/ requirements to close these gaps and areas of mutual interest and added value for future collaboration.
- Build sustainable links between Africa and Europe in PM research, development, innovation and implementation to better integrate the African continent in the global PM agenda.

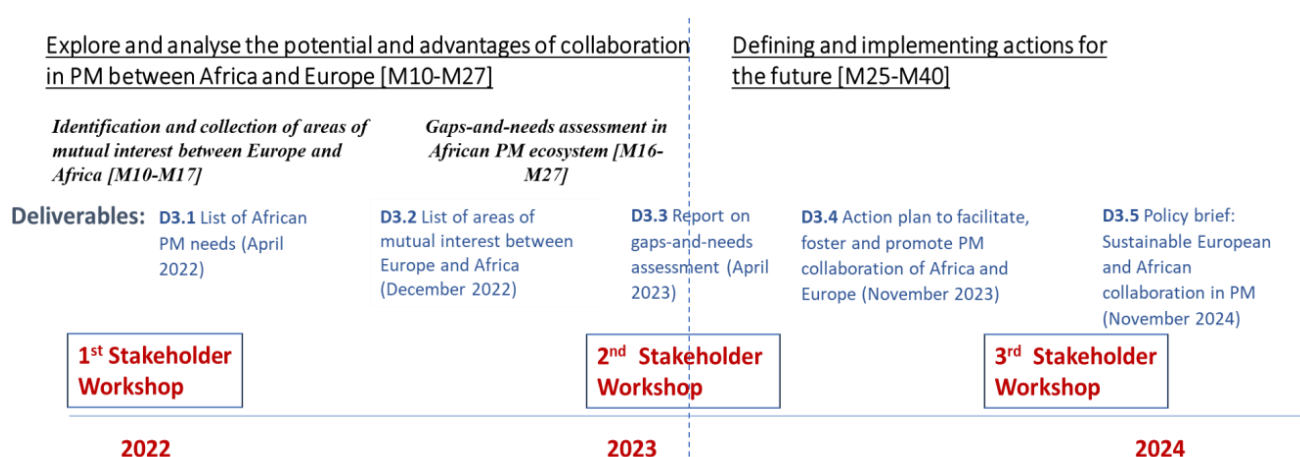


Figure 1: A visualisation of the EU-Africa PerMed work package 3 structure and timing, including workshops as well as outcomes presented in dedicated deliverables.

After the WP2 mapping exercises, WP3 aimed to establish sustainable collaboration and foster direct exchanges with African stakeholders to:

D3.3 Report on gaps-and-needs assessment FINAL

- 1) validate and further specify the information collected in WP2,
- 2) to explore and analyse the potential and advantages of collaboration in PM between Africa and Europe,
- 3) to define and implement actions for the future.

For this purpose, in total three African-wide stakeholder workshops are planned, but also other means of exchange such as regional workshops were implemented, to collect contribution of the different kind of stakeholders, this includes, individual interviews or surveys for supporting the further development of the PM agenda in Africa.

This deliverable report 3.3 (D3.3) is the third of five, interconnected deliverable reports within WP3. The first three deliverable reports (D3.1-D3.3) contribute to the overall topic “Explore and analyse the potential and advantages of collaboration in PM between Africa and Europe”- developed in the first half of the EU-Africa PerMed project (see also Fig. 1). Hence, D3.3 will finalise findings from D3.1-D3.2 and feed into the second half of the project, whereby, WP3 will concentrate on “Defining and implementing actions for the future” and will result in two deliverables reports in this context (D3.4 and D3.5). In more detail, the contents of the different deliverables and its relation to WP objectives are presented below:

To explore and analyse the potential and advantages of collaboration in PM between Africa and Europe

- D3.1 “List of African PM needs”: Outlined the first observations regarding the African needs in the field of PM identified by EU-Africa PerMed through mapping activities in WP2 and collected through direct exchanges with African stakeholders, i.e. the preparatory workshop survey and the 1st Stakeholder Workshop.
- D3.2 “List of areas of mutual interest between Europe and Africa”: Outlined the outcome of discussions with African stakeholders regarding areas of mutual interest between Europe and Africa in the field of PM and has stepped further than D3.1 by reflecting not only on the African PM areas of interest but highlighting those areas of interest of Europe from the ICPeMed Action Plan to align the potential for collaboration in the field of PM.
- D3.3 “Report on gaps-and-needs assessment”: is primarily focused on the African perspective with a gaps-and-needs assessment, setting the African needs (D3.1) in PM in the context of existing frameworks in the status of the African PM ecosystem. The regional approach enabled structured discussions with the most relevant stakeholders and therewith the development of D3.3 report. EU-Africa PerMed has validated the results hereto presented in D3.3 through the second stakeholder workshop that took place on 20-21 February 2023.

Defining and implementing actions for the future

- D3.4 “Action Plan to facilitate, foster and promote PM collaboration of Africa and Europe”: will be based on the outcome of EU-Africa PerMed and more specifically on D3.1-D3.3 and will further develop an action plan/roadmap to facilitate, foster and promote PM collaboration of Africa and Europe. This will include a prioritisation of the gaps previously identified and the identification of topics of collaboration in research, research supporting activities and on strategic level. EU-Africa PerMed will seek the validation as well as promotion of the action plan presented in D3.4 through the third stakeholder workshop organised in 2024.
- D3.5 “Policy Brief”: will include outcomes of the third stakeholder workshop and overall observations collected during the EU-Africa PerMed project in form of a policy brief “Sustainable European and African collaboration”.

Regional workshops have all been carried out – A two-day East African engagement took place in July 2022, followed by a similar approach taken in Southern Africa on 5-6th December 2022. Virtual and hybrid meetings took place for Northern Africa (French speaking countries) on the 9th January 2023, and then the West and

D3.3 Report on gaps-and-needs assessment FINAL

Central African engagement took place on 23th January 2023. These regional engagements convey a comprehensive African stakeholder perspective and African regional analysis. The outcomes were validated at the 2nd stakeholder workshop on 20-21 February 2023 in Cape Town, South Africa.



2. METHODOLOGY OF THE REGIONAL ANALYSIS

2.1 BACKGROUND: MAPPING THE SCIENTIFIC AND POLICY LANDSCAPE OF PERSONALISED MEDICINE IN AFRICA

The project recognised the importance of understanding the research and innovation landscape in Africa and to engage with relevant stakeholders to drive the development of the PM ecosystem within the continent. Hence, to understand the level of R&I and commence engagement of the project with African stakeholders, it was essential to conduct an extensive scientific and policy mapping of African competencies, collaboration capacities, capabilities and to identify supporting policies and programmes for PM in Africa. Furthermore, to build a database and classify stakeholders regarding their ability to drive the PM ecosystem development in Africa became an essential tool. This work was performed in WP2 and presented in two deliverable reports: **D2.1. “Mapping the scientific and policy landscape of PM in Africa”** and **D2.2. “The EU-AFRICA PerMed stakeholder mapping report”** (available at <https://www.euafrika-permed.eu/project-deliverables/>)

To elaborate, the first deliverable report, D2.1, utilised scientific bibliometric mapping to provide an overview of the countries in Africa that have publication outputs in PM research and innovation. This analysis also identified countries collaborating with African nations in PM research. This mapping exercise helped outline the research capabilities and collaborations in the field of PM within Africa. The policy mapping component aimed to identify and analyse the policies and programmes in African countries that support and promote health R&I. It focused on identifying specific policies, programs, and initiatives that specifically support PM activities, including research projects, training, infrastructure, innovation, and the existing industry. The report mapped these policies and programmes, to highlight the existing support for PM in various African countries. A metric was used to rank active countries with R&I policy, this assisted in guiding the inclusion of interested countries for the regional engagement and development of country level SWOB analysis. The extensive stakeholder database, classified stakeholders according to their level of involvement and influence to drive R&I within the continent. This database provided a core resource to guide the identification of relevant and influential participants to engage during regional and continental stakeholder engagements. The data collected through WP2 shows that African countries are developing PM R&I capacity at varying levels.

The D2.1 bibliometric study, with PubMed as primary data source (2011-2020), was performed to support answering key questions on the basis, themes and trends of PM in Africa including collaboration capacities, identification of competencies and key actors, and generating insights for mutual areas of interest with European institutions. A significant increase of the number of PM related literature was observed since 2015. The collaboration among African countries or interregional African collaboration (North, South, East, West, Central) is in general low but increasing with around 16% of publications co-authored by at least two African countries.

In terms of research topic, almost 82% of the articles found were related to 13 disease categories, predominantly infectious diseases, followed by cancer, immune and nervous system related diseases (D2.1). The majority of publications were in the field of diagnosis (58.5%) and treatment (56.8%) while prevention as topic was only 8.4%. In general, international cooperation in PM was increasing over time with a peak in 2020 (75%). European collaboration increased significantly in 2013 and reaching its peak in 2019 with more than 350 co-authored publications with African institutions.

The scientific mapping showed a high number of scientific publications for South Africa and Egypt, both having dedicated PM research programmes. Furthermore, Egypt showed to have a high number of collaborations with Europe while South Africa showed to have research supported to a high extent through the national budget.

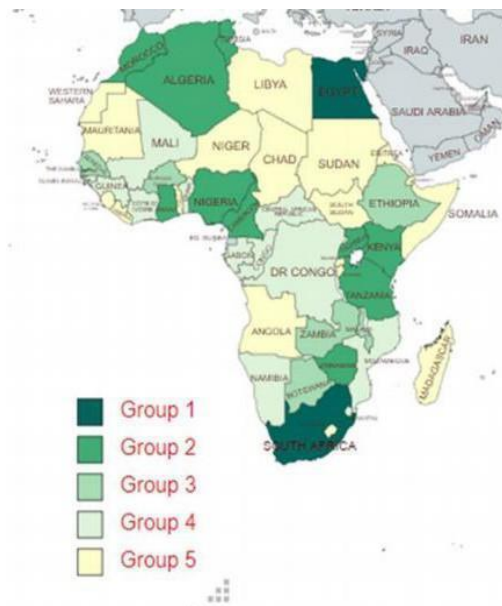


Figure 2. Representation of the results of the PM/genomic capacities in African countries, following the policy mapping framework of EU-Africa PerMed (Source: Sela E. et al., 2021)

PM research initiatives have been also identified in Algeria, Cameroon, Ethiopia, Ghana, Kenya, Morocco, Nigeria, Tanzania, Tunisia, and Uganda. Other countries had limited PM research. It was noted that a high number of countries were facing limitations such as poor infrastructure, lack of technical capacity, and no funding for genomic/genetic research, all important aspects needed for PM implementation. WP2 outlined that the status of PM R&I divides the African countries into five groups based on their strength defined through six dimensions (Figure 2): Governance of health research, financing of health research, resources for health research, health research outputs, international collaborations in health research, and PM/genomic research. For group 1 countries, PM is a relevant issue for the governments, dedicated PM programmes and infrastructures, respective governance, research funding, capacities and international collaboration are in place. In contrast, group 5 countries only show very low or no activities in the above mentioned 6 dimensions.

The policy mapping parameter of measurement contributed to a contextual understanding. These are listed as follows:

1. **Governance of Health Research** assesses the level of governance of health research in each country. Countries with low governance may have limited structures or regulations in place to guide and oversee health research activities, while those with high governance are likely to have well-established frameworks and institutions to support and regulate research.
2. **Financing:** The level of financial investment in health research within each country. Countries with higher financing are likely to allocate significant resources to support health research, including funding for research projects, infrastructure, and human resources. Those countries with lower investment/national funding may not be in an equitable position to finance research or collaboration at a bilateral level.
3. **Health Research Resources** is the measure of the availability and accessibility of resources for conducting health research. Countries with high resources are likely to have well-equipped research facilities, advanced technological infrastructure, and adequate research personnel.
4. **Health Research Outputs:** represents the level of health research outputs generated by each country and correlates to the number of publications shown per country. Countries with high research outputs are likely to produce a substantial amount of scientific publications, patents, innovations, and evidence-based knowledge.

5. **International Collaborations in Health Research:** to evaluate the extent of international collaborations in health research for each country. The levels are categorised as low, medium, or very high. Countries with high international collaborations are likely to engage in partnerships, joint projects, and knowledge exchange with researchers and institutions from other countries.
6. **PM/Genomic Research,** focuses specifically on policy mapping related to personalised medicine and genomic research. The levels are categorised as low, medium, or high. Countries with high PM/genomic research are likely to have dedicated policies and resources to support advancements in precision/personalised medicine and genomic research.

An in-depth analysis of the continent and the mobilisation of stakeholder groups became a necessary feat to truly unpack the African Gaps and Needs to foster mutual collaboration in PM.

2.2 THE SWOB ANALYSIS RATIONALE

In order to determine the Strengths, Weaknesses, Opportunities and Barriers (SWOB) to develop PM in Africa, one had to analyse what each African country possesses that could be leveraged to build capacity for growth within the region including 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 the strategic direction and ultimately an implementation plan. Therefore, the analysis hinged on factors to determine a country’s competitive advantages—such as infrastructure, R&I programmes, activities and any unique stand points that make the country special or competitive in the national and the African regional innovation ecosystem — juxtaposed against those internal or external factors that can keep a country from realising its potential. The importance in determining these aspects was to uncover the gaps and needs of each participating country and to ensure synergies may form for a stronger regional network. Countries within a region could assist each other, form stronger consortia in solving their barrier to developing PM in their regions and fostering international collaboration to fast-track the development of PM. Consequently, it also uncovered the gaps and needs for developing areas of mutual interest within each African region and potential for international collaboration with Europe. Therefore, the SWOB framework helped in gaining an understanding regarding the level of PM in each region. The building blocks of the country’s ecosystem are based on a sound framework with a clear foundation to enable the R&I landscape to establish the PM ecosystem, with several interlinked areas of focus that need to be integrated (Figure 3):

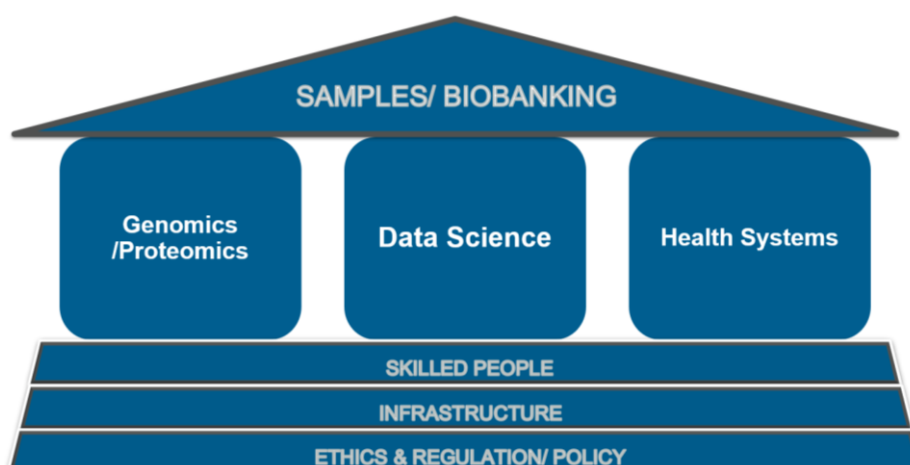


Figure 3: The components that enable a Personalised Medicine system of health

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 will be **infrastructure** especially the capacity to localise omics technology platforms, high-speed internet connectivity, electrical supply, biobanking and hospital facilities and patient electronic health record systems, co-ordinated biobanking etc. The data infrastructure co-ordination needs to address how the necessary data will be captured, stored, utilised and shared. This leads to the third requirement, **skilled people/ personnel** that train, develop studies, collect samples and process the resulting data and finally implement these aspects within the healthcare system. This group should also include the medical aid payers for reimbursement strategies, given the strong presence of private healthcare in most African countries. Finally, **Focused Funding** to develop the PM system of health incrementally within a country or region.

These foundational ecosystem enablers feed into the three main thematic areas or pillars of PM. These are the omics sciences (Genomics, Proteomics, Regulomics, Metabolomics and Pharmacogenomics); Data Science including Digital Health and Health Systems (addressing healthcare delivery and Public Health). These pillars essentially hold up the 'roof', which is to ensure samples that are collected or bio-banked are used to create new knowledge within the three pillars of the field. These samples are quite important given the unknown genetic diversity within the African population amid keen global interest which needs to be leveraged to create Africa's PM system of health. This framework was a guiding resource to develop the regional analysis, shows the in-depth questions to develop the SWOB analysis at a national level and determine the gaps and needs analysis.

More information on the SWOB analysis methodology used is available in ANNEX1.

3. THE AFRICAN REGIONAL ANALYSIS

The African Union (AU) is a continental union consisting of 55 member states located on the continent of Africa. The most important decisions of the AU are made by the Assembly of the African Union, a semi-annual meeting of the heads of state and government of its member states. The AU's secretariat, the African Union Commission, is based in Addis Ababa. The largest city in the AU is Lagos, Nigeria, while the largest urban agglomeration is Cairo, Egypt. The African Union has more than 1.3 billion people and an area of around 30 million km² and includes world landmarks, such as the Sahara and the Nile. The continent is demarcated into 5 regions with a distribution of primary working languages such as Arabic, English, French, Portuguese, Spanish, and Swahili (Africa Union). Thus, the continental analysis considered the AU member states divided into five geographical regional demarcations of the African Union.

To establish an understanding of the African PM landscape in each participating country in Africa, the SWOB framework was utilised. This conveyed the necessary information to derive the GAPS and NEEDS to be addressed in order to establish goals, that are typically required to build the PM system of health in a stepwise manner. The central questions addressed were the short-, medium- and long-term requirements to map out a path to develop the local PM ecosystem at a national level hence the following analysis, undertaken within each region in Africa was completed at a country level utilising the mapping activities of the EU-Africa PerMed project reports D2.1 and D2.2 as well as the methodology described in section 2. The aim was to engage all countries with an active R&I agenda to help steer the level of PM and potential to develop the PM R&I agenda within each region.

3.1 EAST AFRICAN REGIONAL ANALYSIS

3.1.1 The East African Scientific and Policy Landscape

The regional engagement in East Africa with over 70 participants from health systems policy makers, researchers, funding agencies, scientific societies, regional technology developers and international organisations in the field of PM and health research institutions met in Nairobi, Kenya, to discuss PM and identify specific regional needs around the area of PM for potential collaboration with other African Sub-Regions and Europe. Considering the activity of countries in East Africa according to the mapping exercise of the EU-Africa PerMed Project, Algeria, Cameroon, Ethiopia, Ghana, Kenya, Morocco, Nigeria, Tanzania, Tunisia, and Uganda have shown initiatives in PM research. However, considering the policy landscape within the Eastern region, the following countries were analysed: Kenya, Tanzania, Uganda, Rwanda and Ethiopia. These countries showed a relatively higher research output in PM, with Kenya leading followed by Uganda, Tanzania and Ethiopia. The analysis from the policy evaluation implied that sources of funding to support the R&I activity within the region vary. The landscape of institutions funding African R&D is complex and include the public sector, with significant proportions of financing in many countries coming from international funding. As an example, in Kenya which has one of the highest health research financing as a percentage of GDP (0.234% in 2015), most of the funding came from external sources (83.46%), with only 16.54% of the financing realised from domestic sources (EAHRC., 2018). Therefore, with the current outputs in PM research and the supportive policy landscape, East Africa is in a good position to drive PM R&I.



COUNTRY	Number of publications 2010-2020	First author publications	Percentage of first author publications
Kenya	205	110	63.58
Uganda	180	75	49.34
Tanzania	141	9	7.20
Ethiopia	111	57	64.04
Rwanda	18	4	33.33

Figure 4: A regional view of the East African Countries with an active R&I ecosystem and PM research outputs. Kenya, Tanzania, Uganda (Ranked in Group 2), Ethiopia and Rwanda (Ranked in Group 3)

Table 1: Showing the policy mapping output in Eastern Africa (D2.1)

COUNTRY	GOVERNANCE OF HEALTHRESEARCH	FINANCING HEALTH RESEARCH	RESOURCES FOR HEALTH RESEARCH	HEALTH RESEARCH OUTPUTS	INTERNATIONAL COLLABORATIONS IN HEALTH RESEARCH	PM/GENOMIC RESEARCH
Comoros	low	no data	No data	low	No data	very low
Djibouti	no data	no data	No data	low	No data	very low
Ethiopia	high	medium	medium	low	high	high
Kenya	very high	very high	high	high	Very high	high
Rwanda	Very high	high	low	medium	low	low
Somalia	no data	no data	No data	very low	No data	very low
Sudan	no data	no data	low	medium	low	medium
South Sudan	low	no data	very low	very low	No data	very low
Tanzania	very high	high	low	medium	very high	high
Uganda	high	high	medium	medium	very high	high

East Africa has high economic disparity with some countries that have sound policy, regulations, and resources to develop PM whilst others have developmental issues and even no real data available to understand the R&I

D3.3 Report on gaps-and-needs assessment

landscape. Countries ranked very high to high in research governance were Kenya, Rwanda and Tanzania ranked very high with Uganda and Ethiopia also ranked high. Whilst others such as South Sudan and Comoros ranked low, showing the need for formal structures of governance in terms of R&I. Financing in R&I is seen to be very high in Kenya, and also significant in Uganda, Rwanda, and Tanzania toward developing PM research and this correlates to the current scientific outputs. Resources for health research was shown to be high in Kenya and Rwanda suggesting a good availability of laboratories, equipment, and infrastructure for health research. Ethiopia and Uganda have medium resources, indicating the availability of necessary facilities and skilled personnel for conducting health research. In contrast to these countries, the remaining countries in the region ranked low in resources indicating a need for improvement in infrastructure and facilities for research. Ethiopia, Kenya, Rwanda, Sudan, Tanzania, and Uganda have varying levels of outputs, ranging from low to medium, indicating some research productivity. This directly correlates to the level of international collaboration, indicating active partnerships and knowledge sharing and genomic research outputs. Therefore, the stakeholder engagement was a fundamental approach toward validation of the desktop mapping exercise and enabled a dialogue to uncover the real context to understand the gaps and needs to develop the PM context.

3.1.2 Strengths, Weaknesses, Opportunities and Barriers to Develop PM in East Africa

EAST AFRICAN REGIONAL STRENGTHS

- *Have health research institutes with established research production, in mainly pathogen genomics with limited human genomics.*
- *Sequencing/NGS facilities are available for use in research and some human genomics sequencing capacity in Kenya, Ethiopia, Uganda, and Rwanda.*
- *Presence of genomic research focusing on different diseases, mainly infectious diseases.*
- *Training programmes especially at postgraduate level in bioinformatics and genetics scientific stream.*
- *All countries reported to have national research funding mechanisms; with access to national funding varying between countries, Uganda seemly has better access and control on government funding Grand Challenges Africa and Grand Challenges Ethiopia as well as Science for Africa and the African Academy of Science are positioned in Kenya.*
- *Health research policies available; in all countries with a supporting policy framework.*
- *Rwanda highlighted their advanced digitalisation and strategy for cross boarder data sharing – RISA (information system agency).*
- *Electronic health records exists but very limited for access to research etc.*
- *Active patient associations exist.*
- *All countries reported the supportive policy environment to develop more knowledge-based activities towards health innovation and introduction in health system. Some countries are also in the process to include such policies (e.g. Ethiopia has a Draft Health Act law).*
- *Most of the countries in the region have personal data protection laws. East African Committee (EAC) strategy is being implemented and there is a dedicated platform for data sharing.*
- *Apart from Ethiopia, the other countries are members of the East Africa Economic Community, with supportive regional commissions (East Africa Health Research Commission and East Africa Science and Technology Commission) with membership drawn from the member states. This provides a centralised mechanisms for support of the STI agenda in the region.*
- *Well established regulatory frameworks within each country for quality assurance of research activities including ethics regulatory system is well established within each country, e.g.: local ethics committee, national level with a regulatory committee, this is in place for both Clinical Trials and General Biomedical Research, as well as supporting intellectual property rights legislative frameworks.*
- *Ethiopia and Rwanda have research portfolio's in pharmacogenomics and genetics.*

The strengths depicted could enable the components of the East African PM ecosystem within the East African region. Envisaged development of the PM ecosystem may be viewed as leveraging strengths to overcome the Weaknesses to give rise to GAPS and NEEDS for PM in East Africa. Therefore, development is not classical with

D3.3 Report on gaps-and-needs assessment

regard to building a full PM system of health. Overall in some countries such as Rwanda the research community is small and hence it is easier to influence and develop pockets of research, in contrast bigger countries may have other impediments to influence resource allocation policy changes toward developing PM in the region.

EAST AFRICAN REGIONAL WEAKNESSES

- *Low level of PM knowledge, at a political level they have not prioritised a PM research agenda.*
- *The compliment of OMICS R&I are not yet established within the region, the capability exists for pathogen genomics surveillance mainly with very scarce resources in genomics, pharmacogenomics, metabolomics, proteomics and regulomics. Limited capacity mainly in pathogen bioinformatics.*
- *Low level of activity in clinical genomics and clinical scientific research as training facilities have low level of clinical research capacity within training hospitals.*
- *A high focus of outside funding for grants that are not led within the country. Therefore, no national /regional prioritisation of research is being addressed.*
- *Relatively weak health research system from poor implementation of relevant policies; or few current policies in draft format.*
- *Inadequate critical mass with right skill sets, across the PM value chain.*
- *Weak data driven systems: local electronic health records management; except for Uganda and Rwanda.*
- *Limited national data storage infrastructure.*
- *Localised biobanking practices at a very limited institutional or lab research level, no Biobanking co-ordination etc.*
- *Limited national research funding (smaller budgets), especially in non-communicable disease research.*
- *Some countries have a subjective approach to funding R&I from the national budget; this may not necessarily address prioritised areas.*
- *Lack of locally validated genetic interventions to motivate genetic testing.*
- *Sustainability in PM R&I will be an issue as the skills set is very limited.*
- *Genetic testing is not routine. Some private lab services send samples outside the country; however, even those run locally are expensive because of lack of demand.*
- *Lack of centralised Biobanking, localised biobanking practices at a very limited institutional or lab research level no biobanking co-ordination et*

These inherent ecosystem weaknesses convey an understanding of the development gaps and needs. This has led to discussions on what opportunities lie herein and what barriers exist for political will and enablement of the PM ecosystem within the region.

OPPORTUNITIES WITHIN THE EAST AFRICAN REGION

- *Capacity building programmes*
- *Building/strengthening collaborations especially with the glowing global interest in strengthening health systems*
- *Demographic youth bulge and broad access to mobile technology and digitisation as an opportunity for health solutions*
- *Precision diagnostics followed by mHealth applications may bring relevant solutions to remote areas for both infectious and NCD's*
- *Increased focus in NCD R&I agenda to address a burgeoning disease area with focused funding*
- *Developing transformative policy to drive the development of the innovation PM system of health may stimulate research and private funding to flow in*
- *OMICS for all -> including agricultural Biotech and OMIC for health could enable the capacity development aligned to the National Gross Domestic Product (GDP)*

BARRIERS AFFECTING PM DEVELOPMENT WITHIN THE EAST AFRICA REGION

- *Inadequate job opportunities for skilled people/brain drain*
- *Research agenda driven by external partners not addressing national health priorities*
- *Implementation of data protection legislature for genomic data sharing; limited national research data infrastructure and harmonisation in the region*

Regional conclusion for East Africa region

There are initiatives in each of the East African Country represented relating to PM. However, the efforts are segregated and far apart, thus they are not adequately felt by the society. Therefore, in this workshop, the needs and areas of interest for each country were discussed which is key in understanding the position of each country and in charting the way forward. Similarly, participants identified gaps and undertook needs assessment of the East Africa ecosystem by determining the Strengths, Weaknesses, Opportunities and Barriers (SWOB) for PM development in the region. This exercise was significant as it determined the SWOB regarding PM in each country. This information will help especially when forming collaborations, networks and understanding how best to push the agenda forward. There were important messages that came from the workshop discussions that are relevant for the development of PM in Africa. Among these are: developing consortiums in each country, involving policy makers, developing SMART objectives, creating awareness, having focal persons, advocacy, having health economics onboard and developing manuscripts for publishing.

Finally, it is important for the region to understand why they need to collaborate, what they will need to collaborate in, and how they will collaborate (at the regional or at the national level), to move the PM agenda in the East African Region.

Recommendations

1. Increase funding for PM in Africa: Governments and policy makers need to shift priorities and embrace PM as an answer to disease prevention and control by allocating more resources to this area.
2. Awareness creation: There is need for advocacy, preparation for manuscripts for publishing in this area, sensitization of policy makers, patients and the general public.
3. Increase data: data on African genome is inadequate. There is need to commission multicounty studies vs country specific studies as they carry a larger political and acceptance clout. The need to establish biobanks.
4. Capacity building: There is limited capacity among the health care workers in this area, and infrastructure is also limited.
5. Policy and regulatory frameworks: The policies governing PM need to be installed or strengthened and the regulatory frameworks need to be well established.



3.2 THE SOUTHERN AFRICAN REGIONAL ANALYSIS

3.2.1 The Southern African Scientific and Policy Landscape

The analysis on the Southern African region provides valuable insights into the state of health research in Southern African countries. The illustration in figure 5 highlights the scientific productivity of Southern African countries in the PM field and table 2 represents the outcome of policy mapping in Southern Africa (D2.1) with regard to various aspects of health research: Governance; financing resources to conduct health research; current outputs, international collaboration and the level of PM or genomics research within Southern African countries are categorised as low, medium or high. The variations across different aspects within Southern African countries are apparent:

1. There are levels in the governance of health research, within the region. South Africa and Zambia have excellent governance policies and followed closely by countries like Botswana, Lesotho, Malawi, and Mozambique which ranked slightly lower yet they still exhibit high governance, indicating that they have well-established frameworks and institutions to support and regulate health research. On the other hand, countries like Angola, Eswatini (Swaziland), Madagascar, Namibia, Seychelles, and Zimbabwe have lower levels of governance, suggesting a need for further development and strengthening of research governance structures.
2. Countries investing/financing their R&I are South Africa, Botswana, Malawi, Zimbabwe, ranking very high and followed closely by Mozambique ranked 'high', whilst other countries were ranked medium to low. Namibia have significant investment in R&I and ranked medium despite their very small population and high health research outputs, hence they were included in the stakeholder engagement process.
3. Health Research Resources: South Africa was seen to have excellent resources and followed by Botswana, and Mauritius who ranked high whilst other countries such as Malawi, Zambia, Zimbabwe and Namibia ranked medium.
4. Health Research Outputs, generated by South Africa, Botswana, Mauritius, Seychelles, and Eswatini, and Namibia correlates to the number of publications shown per country in the figure 5 below. This tangibility indicates the level of productivity and research experience within the countries.
5. International Collaborations in Health Research starkly contrasts countries such as Zambia and Zimbabwe who have significant international collaborations and were hence included in the stakeholder engagement.
6. PM/Genomic Research, Policy mapping related to PM and genomic research, showed that South Africa is ranked very high and leading with a national PM program. This is followed by Zimbabwe whilst the majority of the countries ranked medium to low in this category.

Countries in Southern Africa exhibit variations in the governance of research, financing of health research, health research outputs, health research resources, PM/Genomic Research, and international collaborations. These variations highlight the diverse landscape of health research policies and capacities across the region, with some countries showing strong performance and others presenting areas for improvement and further investment. Therefore, these results obtained from WP2 (D2.1) as shown in figure 5 and table 2 indicate that the following countries showed promise to develop PM within the region: South Africa, Zambia, Zimbabwe, Botswana, Malawi and Namibia.

D3.3 Report on gaps-and-needs assessment



COUNTRY	Number of publications 2010-2020	First author publications	Percentage of first author publications
Angola	6	5	83%
Botswana	29	25	86%
Mozambique	33	0	0%
Namibia	50	0	0%
South Africa	1176	632	54%
Swaziland	5	2	40%
Zambia	46	45	98%
Zimbabwe	42	3	7%

Figure 5: A regional view of the Southern African countries showing the PM specific publication output from 2010 to 2020 and first authorship in various countries

Table 2: Showing the outcome of the policy mapping in Southern Africa (D2.1)

COUNTRY	GOVERNANCE OF HEALTH RESEARCH	FINANCING HEALTH RESEARCH	RESOURCES FOR HEALTH RESEARCH	HEALTH RESEARCH OUTPUTS	INTERNATIONAL COLLABORATIONS IN HEALTH RESEARCH	PM/GENOMIC RESEARCH
Angola	low	very low	low	low	low	Low
Botswana	high	very high	High	very high	medium	medium
Eswatini (Swaziland)	low	medium	low	very high	medium	low
Lesotho	high	very low	low	low	low	very low
Madagascar	low	low	medium	low	low	low
Malawi	high	very high	medium	medium	medium	medium
Mauritius	medium	medium	high	very high	low	low
Mozambique	high	high	medium	low	medium	medium
Namibia	low	medium	medium	high	low	low
Seychelles	low	low	low	very high	low	very low
South Africa	very high	very high	very high	very high	very high	very high
Zambia	very high	medium	medium	medium	high	medium
Zimbabwe	high	very high	medium	medium	high	high

The regional engagement in Southern Africa with 50 participants from the Southern African health innovation

D3.3 Report on gaps-and-needs assessment

environment conveyed a robust analysis. Stakeholders included key decision makers such as policymakers, R&I funding agencies and councils, healthcare providers, researchers, scientific societies, industry, regional, technology developers and international organisations. The stakeholders were drawn from Southern African countries namely South Africa, Namibia, and Zambia. It should be noted that stakeholders from Botswana were invited, unfortunately, they were unable to participate due to resource constraints. (Annex 3- Southern African Regional Report). Limitations with stakeholder contacts may have also contributed to exclusion of countries such as Mozambique and Malawi.

3.2.2 The STRENGTHS, WEAKNESSES, OPPORTUNITIES & BARRIERS to Develop PM in Southern Africa

The context in South Africa contributes to a very uneven perspective for the region, as the developmental gaps vary from South Africa which has an advanced R&I and genomics ecosystem to grass root development required for neighbouring countries. Therefore, this is factored in the consolidated view of the region hereto conveyed:

SOUTHERN AFRICAN REGIONAL STRENGTHS

Skills:

- Excellent scientists in all areas of R&I, all ranked within the top 20 on the continent.
- Leaders in Pathogen Genomics Surveillance Initiative (PGI), H3Africa, AWI-Gen, APCC/SAHPRIN, DS-I Africa as well as newly proposed programmes such as GENCoE, African Population Cohort Consortium led and expanded through AHRI and the SAHPRIN programme and other large programmes on the continent. South African programmes such as DIPLOMICS and NGS-SA.
- Scientists are involved in all major programmes related to PM on the continent, either as leading or co-investigators. Cross-disciplinary skills in Big Data Science, host to large Square Kilometre Array (SKA) Programme

Infrastructure:

- Strong pathogen genomics sequencing capacity and both private and public funded high throughput human genome sequencing capacity with all the latest in NGS and long read sequencing capacity for human genomic sequencing. State of the Art labs, High-Performance computing facilities with dedicated bioinformatics cloud and storage capacity available. Infrastructure programmes like the SKA and DS-I Africa are closing the gaps on big data science, DIRESA, DIPLOMICS, ILIFU cloud, ELWAZI
- Well-equipped tertiary institutions, laboratories, private sector hospitals and labs, biobanks within all institutions as well as accredited private sector biobanks exist
- Centres of excellence. Public/private sector partnerships exist for laboratory equipment and supply on service agreements as well as patient databases. South Africa, Zimbabwe and Botswana also have specialised labs and technology platforms programmes
- Infrastructure support programmes run by the South African government ensure upkeep and upgrades to research equipment, DIPLOMICS
- AiBST in Zimbabwe and Botswana Hub are two high end infrastructure facilities

Funding:

- Public Health funding is available **and a good political will to fund health**. Attract private donor funding to enable scaled infrastructure programmes such as local vaccines to manufacture etc. **COVID-19 pandemic has renewed interest in genomics, data science, and bioinformatics. There is funding from international cooperating partners with international funders, industry partners and government.**
- **Government funded PM programme with focused funding for PM, in South Africa as well as research institutions have invested in data management infrastructure.**

Health System:

- Health systems are well organised and more movement to smart health systems, digital health. Research active, public and now private health systems are looking at adopting PM approaches.
- A lot has been done in terms of **universal health coverage**. A **national social insurance scheme** has been set up through the National Health Insurance Management Authority (NHIMA) in Zambia and South Africa is piloting and moving toward this.
- Robust **clinical trials are run in this region and well-regulated. There are programmes positioned to develop harmonised databases of clinical cohorts and expand toward Africa, e.g. SAHPRIN-APCC**

SOUTHERN AFRICAN REGIONAL STRENGTHS CONTINUED.....

Biobanks:

- There are biobanks in both public and private health facilities and health research institutions. There are programmes in place to develop the public-funded biobanks to become accredited. There are a few accredited facilities. Storage capacity for the H3A programme, and a few accredited stem cell banks exist in South Africa

Ethics and Regulations:

- There are well-established, functioning ethics and regulatory system regulating all research and researchers: research ethics committees and research institutions, regulating all clinical trials involving medicines, allied substances, and medical devices. Strong regulation around Genetically Modified Organisms. There are collaborations in place with neighbouring countries i.e. to set up harmonised regulatory frameworks
- Regulation on personal protection a very active and independent regulation authorities exist and recently launch of the African Medicines Agency framework, led by the SADC region to drive harmonisation of medicines regulation on the continent
- National health innovation policy and strategic plans with the inclusion of aspects of genomics/proteomics/PM aspects are included with South Africa having PM in their 10-year innovation plan. Active innovation agenda to transform toward a knowledge-based economy with key driving strategies to develop the biotech industry and R&I economy
- Regulation on personal protection & IP exist within the constitution in South Africa and are being mobilised in neighbouring countries. Well established and functioning ethics and regulatory system (for both research and clinical trials). Regulation of biobanking
- National health strategic plan and the bioeconomy strategy and new “Decadal Innovation Plan” in South Africa

Genomics:

- There are numerous genomic studies/activities in oncology, hypertension, cardiovascular disease, diabetes, neurogenetics, HIV, ARV, malaria, COVID-19 and TB.
- Research facilities are available and genomics activities across the PM value chain are taking place. Public sector omics platforms co-ordinated by DIPLOMICS programme and private sector NGS diagnostics companies that hold significant market share for genomic & pathology testing in Africa
- Countries with focused PM programmes include already developed portfolios of research (in genomics, precise diagnostics, neuro genetics and pharmacogenomics in NCD’s and NTD’s)

Collaborations: National, Regional and International collaboration

- There are **multiple collaborations that exist at a national level, inter-regional, continental, and international levels**
- International funding and leveraged partnerships for the development of PM in this region
- Working on a policy to increase % of research funding to 1% GDP with some countries already funding actively through their national budget
- South Africa supports African researchers through the national budget by participation as co-investigators on national projects, e.g. AiBST funded. Also, many experts from neighbouring countries hold academic posts or honorary posts at South Africa tertiary institutions
- Part of many treaties which help to guide/shift national policies, help in prioritisation and domestication, e.g. Universal health coverage, WHO and Africa-CDC
- Funding partnerships in place with the main health innovation funders e.g. BMGF, NIH, UKMRC, ANRS, EU-Programmes, e.g. EDCTP and ERA-PerMed/ICPerMed, Wellcome, GLoPIDR, GACD, CHI, AFRICA-CDC, WHO, USAID Newton Fund, GSK, NOVARTIS, Johnson& Johnson, ELMA Foundation, GARDP, BRICS -Newton Fund etc.
- Bilateral agreements and active research programmes in place with several leading countries: USA, China, Brazil, Russia, India, United Kingdom, Switzerland, including countries in the EU, e.g. France and Germany, and the Sudan.

SOUTHERN AFRICAN REGIONAL WEAKNESSES

Most strengths are attributed to South Africa and indicative of the WIDE gap between South Africa and the remaining countries. Therefore, there are contrasting weaknesses that arise in this region which indicate the level of development required:

Skills:

- **Career path** in the PM field is not clear.
- A limited number of clinical genetics and bioinformatics
- **Lack of job opportunities** for skilled people in PM. Lack of workforce, limited training and interest in PM field due to lack of scaled implementation.
- **Ongoing training** is taking place but skills are lost to other industries or outside the country
- **Limited number of specialists:** Bioinformaticians on human genomics analysis
- **Private healthcare** which wants to transform to PM is unable to train doctors, strong reliance on ailing public healthcare to train all doctors across the medical field. There are very few clinical genetics training programmes that exist
- **Limited cross disciplinary skills programmes**, e.g. big data scientists for genomics analysis, machine learning specialists for health data analytics etc.

Infrastructure:

- Scaled human genome sequencing capacity is not present in all countries except South Africa
- **There is low demand for the use of infrastructures, need for large scale projects and sustainability issues**
- Bioinformatics infrastructure are low, except for South Africa
- **Lack of a central data repository nationally;** though regulation and set up a Central Data repository at NHRA has commenced.
- **Other countries except South Africa noted:** The government have limited funds to meet the service agreements to maintain the laboratory and related ICT infrastructure
- **Underutilised high-throughput omics infrastructure** in South Africa due to the low number of scaled genomics projects and cost factors to perform sequencing within the country.
- **Data systems** exist in institutions but are not coordinated and there are limited resources to build a data repository for capturing “all data”
- **No central repository** that captures both public and private sector population genomics data and sample collections to create a national data bank.
- **National biobanking** is taking too long to develop despite the multiple biobanks available.

Funding:

- **Research funding** is limited, which inevitably impacts on PM funding.
- **Limited genetic testing** and care in the health system.
- **Most PM approaches, especially precision diagnostics, are funded out of pocket as opposed to reimbursement through medical insurance**
- Few studies are led in countries on NCD's except South Africa
- **Government has limited funds to fund scaled genomics studies at the level required**
- The cost of PM is perceived as costly.

Ethics and Regulations:

- **Specific guidelines on genomic/proteomic research are lacking and the current regulatory framework does not directly mention genomics/proteomics/PM** and may need amendments to fully address issues related to this emerging field of medicine.
- The sharing of genomic data aligned to legislature on protection of personal information act (POPIA Act)

Biobanks:

- **Accreditation for biobanking** through a central repository or federated system is asking very long to onboard.

Health Systems:

- Poor management and infrastructure upgrades required in public sector
- Private healthcare systems are unable to train doctors/ PM workforce.

SOUTHERN AFRICAN REGIONAL WEAKNESSES CONTINUED.....

Genomics:

- *Research studies in genomics/proteomics – very few NCD projects.*
- **Genomics research available but limited in scope and scale.**
- *Digital Health and Data Science*
- **South Africa has a small workforce in the digital health and data science areas**
- **Level of training and skills, lack of access to bioinformatics and data scientists.**
- **No formal programme on data science and PM in other countries except South Africa and Zimbabwe**
- *The global north has generated population genomic databases and specific biomarkers whereas Africa has yet to develop this type of baseline data and hence PM development is very limited*

Collaboration:

- *Equity in collaboration is an issue in most countries except South Africa due to its established funding across the innovation value chain*
- *Robust national funding programmes within each country is missing and partnership models with international funding partners. co-development of the scope of funding calls to meet the current contextual requirements is very limited*

OPPORTUNITIES WITHIN THE SOUTHERN AFRICAN REGION

The inherent weaknesses identified in this region have given rise to opportunities that maybe leveraged:

- *Foster industry partnerships to create efficiencies and redundancy for the flow of skills toward structured career paths*
- *Develop the PM agenda on the private healthcare system which accounts for about 80% of the total healthcare spent in South Africa and maybe quantified similar in neighbouring countries needs to be quantified in other countries within the region*
- *Leverage localised infrastructure and developed scaled population genomics programmes of research will have a greater demand and research output can increase within these countries*
- *Develop a basic research pipeline for targeted drugs for African cancers, and other prevalent NCD's*
- *Develop a database for logging African cancer variants on an OPEN science agenda*
- *Create a scaled genomics program to foster the workforce*
- *Develop use case scenarios to convince governments to prove cost-benefit analysis and health technology assessments*

BARRIERS AFFECTING PM DEVELOPMENT WITHIN THE SOUTHERN AFRICAN REGION

Unfortunately, external factors that may affect the potential to collaborate at a macro level given the political landscape and loss of talent or issues in being able to access resources and governance that are beyond the control of the public are seen as barriers to developing the PM system of health.

- *High level of government support for research in South Africa but neighbouring countries still require focused funding for PM research*
- *Convincing governments to place PM on their healthcare agenda and demystifying preconceived notions are an issue*
- *Development of data sharing policy and buy in across borders is challenging or rather the lack of a framework to foster cross border collaboration in genomics studies is a challenge*

Southern African Regional Conclusion

South Africa is seen to be a strong country to lead and develop PM within the Southern African region. It has significant ties with neighbouring countries as the regional collaboration within Southern African countries has been fostered in sharing resources, especially skilled personnel, and cross border proximity allows for shared infrastructure and skills transfer. The Southern African Development Community fosters science and innovation programmes as well as South African national funding which enables co-investigator support on national research grants, with mutual benefit to developing the regional PM system of health. Key regional academics have affiliate positions at some of the continent's top universities and have also established PM diagnostic companies and platforms within South Africa. The Southern African regional consortium model is rather fluid and the enabling political landscape will foster a mutual regional network. Strong country partners are certainly South Africa, Zimbabwe and Zambia, with an interest to further develop PM initiatives with Malawi, Botswana and Namibia. The core focus in regional development will aim to develop:

- A Southern African Population Genomic program.
- A strong affinity to develop cross sectional population studies to stimulate the knowledge on the African genome.
- Cancer, diabetes, cardiovascular disease, hypertension, nephrotic diseases, rare diseases and mental health as well as host genomics in TB, HIV and COVID- 19 were seen as key disease areas to further develop programmes for PM R&I.
- Expansion on the existing pharmacogenomics programme addressing fatal adverse drug reactions were also seen as pertinent.
- Big Data Infrastructure toward national genomic archive.
- Harmonised ethical and legal frameworks to enable genomic data sharing and technology development.

3.3 NORTHERN AFRICAN REGIONAL ANALYSIS

3.3.1 The Northern African Scientific and Policy Landscape

North Africa, or Northern Africa, is geographically the northern portion of the African continent. It may be defined as stretching from the Atlantic shores of Mauritania in the west, to Egypt's Suez Canal in the east. The African Union's definition for the region's boundaries includes Morocco, Algeria, Tunisia, Libya, Egypt, and Western Sahara, the territory disputed between Morocco and the partially recognised Sahrawi Republic (<https://web.archive.org/web/20181129014804/https://au.int/en/organs/assembly>). The Sahel, south of the Sahara Desert, can be considered as the southern boundary of North Africa.

The regional engagement in Northern Africa with participants from the Northern African health environment conveyed a robust analysis.

- 18 participants from Northern African French speaking countries gathered. Stakeholders included healthcare providers, researchers, and members from scientific societies. The stakeholders were drawn from Algeria, Morocco and Tunisia.
- 12 participants from Egypt were engaged in a separate workshop. The stakeholders represented healthcare providers, researchers, members of scientific committees and societies.

During the scientific and policy mapping exercise carried out by the project (outcomes from D2.1), these countries were found to have the capacity for PM development with R&I governance structures in place. The illustration of the context within the Northern African Region is shown in Table 3.

Table 3: Showing the policy mapping for North African Countries (D2.1)

COUNTRY	GOVERNANCE OF HEALTH RESEARCH	FINANCING HEALTH RESEARCH	RESOURCES FOR HEALTH RESEARCH	HEALTH RESEARCH OUTPUTS	INTERNATIONAL COLLABORATIONS IN HEALTH RESEARCH	PM/GENOMIC RESEARCH
Algeria	high	very high	high	medium	high	high
Egypt	high	very high	very high	very high	high	very high
Morocco	very high	medium	very high	high	high	high
Tunisia	very high	high	very high	very high	high	high

The results from Table 3 were used to compare these 4 countries within the region. Egypt and Tunisia seem to have similarities across multiple metrics, including high governance, very high financing and resources, as well as very high health research outputs, high international collaborations, and high PM/genomic research. Morocco stands out with its very high governance and high health research outputs but has a lower financing level compared to Egypt and Tunisia. Algeria also has high governance and financing, but its health research outputs are slightly lower than the others.

NORTHERN AFRICAN REGIONAL STRENGTHS

Education:

- *Highly skilled human resources in molecular biology and genomics (PhD & Post-doc programs); Medical Genetics*
- *Specialised programs and degrees MSc/PhDs of medical genetics in Egypt. Career advancement schemes available in Egypt focusing on skillsets of bioinformatics, big data, data mining and the use of AI tools*
- *Continuous education and access to educational resources supported by Egyptian Knowledge Bank on clinical decision support tools, clinical trials and research management, molecular diagnostic techniques, genomic sequencing techniques, data analysis and interpretation.*
- *skills in molecular biology, computer science, AI*

Infrastructure:

- *Genomics and High-Performance Computing*
- *Local biobanking capacities*
- *Establishment of the Egyptian Centre for Research and Regenerative Medicine (ECRIM) and Development of national structures in Egypt capitalising on large initiatives such as “100 Million Healthy Lives” initiative which is a massive screening program and including network of datacentres and biobanks*

Research (Genomics):

- *In Morocco and Tunisia: WGS, Exome, panel of genes, individual gene or fragment of gene leading to genetic data linked to clinical data*
- *In Algeria: research carried out alongside clinicians, geneticists, biochemists, immunologists, microbiologists, bioinformaticians, etc.*
- *In Tunisia, the Tunisian Genome Programme is starting with the support of the government*
- *All 3 Maghreb countries place oncology and rare genetic disorders as priorities for PM implementation*
- *Egyptian genome project including significant upgrade in infrastructure, studying 100k samples in addition to studying the genome of ancient Egyptian: Genetic services being integrated in Egyptian healthcare system, networks of data centres and biobanks, and the establishment of the Egyptian Centre for Research and Regenerative Medicine (ECRIM)*

Medical Scientific Organisations: Learned Society Organisations

- *Several scientific associations and societies are helpful to have an awareness role in Morocco and Tunisia*
- *Active role of scientific societies and NGOs in Egypt in PM fields such as National Society of Human Genetics and Egyptian Personalised Medicine Society*

Healthcare system:

- *New reform of the national health system in Morocco*
- *Good regulatory environment with legislative reform measures implemented in Egypt and the establishment of the Egyptian Drug Authority which achieved maturity level 3 for vaccine regulation in WHO classification of regulatory authorities that meet international standards with current efforts to reach maturity level 4 in 2024.*
- *Egypt: Building large data and research infrastructure: 100 Million Healthy Lives national initiative (massive screening of HCV, NCD, women health), biobanks, data centres and availability of national data on congenital and genetic disorders*
- *Egypt has introduced legislative measures in past few years including the clinical trials law, bioethics and supported the UNESCO Arab Charter of bioethics.*

NORTHERN AFRICAN REGIONAL WEAKNESSES

Infrastructure:

- *Reduced number of qualified platforms for clinical genetic testing and absence of proteomic analysis dedicated for PM.*
- *In Algeria, the number of research structures in PM remains insufficient in the face of future challenges and low impact of equipment dedicated to PM on citizens' health*

Education:

- *Lack of training on data analysis and interpretation*
- *Develop practitioners' training to guide them on appropriate tests to be used for genetic diagnostics*
- *In Maghreb countries, courses dedicated to PM are lacking or sparsely integrated in health science curricula*
- *Brain drain is a challenge in all countries and it is significant in Egypt*

Research: *Gaps between research and applied genomic medicine*

Biobanking and Databases:

- *No centralised biobanking facility at national level in the 3 Maghreb countries*
- *Lacking at the national level in each participating country: there is no accreditation of reference labs performing genetic testing*
- *Tunisia is the only Maghreb country with a National Human Genome project at this stage*

Funding:

- *Apart from PERMEDINA (financed by France) and Egyptian genome project (financed by Egyptian Government), there is no significant funding for PM-related projects*

Ethics, Policy & Regulation:

- *Lack of national strategies for PM implementation in the 3 French speaking countries*
- *Health systems and policies are not harmonised between the 3 French-speaking countries*

Health Systems:

- *Label structures and procedures to avoid outsourcing*
- *Algeria: project to build expensive biobanks, therefore slow process to set them up*
- *National pharmaceutical industry is not yet implicated in PM.*
- *In Tunisia, reduced number of platforms for clinical testing and absence of proteomic facilities*
- *Little research in digital health and data science in Morocco. In Algeria, the constraints of patient management is a limiting factor for research in digital health and data science*

OPPORTUNITIES WITHIN THE NORTHERN AFRICAN REGION

Policy & Regulation:

- Possibility to set up a national ethical committee where absent.
- Implementation of PM specific guidelines and harmonisation inside the region
- In Tunisia, national authorities are established (CNEM: National Committee of Medical Ethic; INPDP: National Authority for Protection of Personal Data; INEAS: National Authority for Evaluation and Accreditation in Health; CT-CRO: for clinical trials)
- Advocacy: at country level, national platforms could be established building upon health, research and higher education systems to support policy makers to tackle PM topics
- National committees are present in Egypt supported by Ethics Research Council and Medical Research Council, Academy of Scientific Research and Technology in Egypt. Egypt has introduced legislative measures in past few years including the clinical trials law, bioethics and supported the UNESCO Arab Charter of bioethics

Various Research Projects related to PM including clinicians, geneticists, biochemists, immunologists, microbiologists and bioinformaticians.

- Foster transdisciplinary collaborations in research involving policy makers, societies and pharmaceutical companies
- Tunisia:
 - Interest in developing federative research projects to allow for national networking
 - foster public/private partnerships

Training and Collaboration:

- Continuous training for health practitioners
- Integrate PM related fields such as AI, bioinformatics and genomics into existing health and life sciences curricula
- Foster collaboration with onco-genetic societies from other countries

Biobanking:

- In all 3 Maghreb countries: interest in setting up a biobank for different purposes (oncology is seen as most promising alongside rare diseases) that could be attached to hospitals or research structures
- Reflect on the most appropriate ways to invest in datasets
- Algeria: Projects are underway to install digital databases in health information processing and others focusing on human and animal health

Health Systems:

- Possible interventions for improvement toward patient centred health systems
- Digitisation of medical records in Morocco and Tunisia should facilitate future initiatives
- Morocco:
 - Generalisation of medical protection for all citizen in the country
- Algeria:
 - OMICS equipment and several centres dedicated to PM.

Databases: Sharing Genomic data for large cohorts (EU-AF inter-regional collaboration)

BARRIERS AFFECTING PM DEVELOPMENT WITHIN THE NORTHERN AFRICAN REGION

Research: *Cost of PM R&I*

- *Expensive cost of laboratory supplies used and in genomics compared to EU countries*
- *Poor communication between clinicians and scientist researchers*

Biobanking and Databases: *Lacking at the national level in each participating country*

Funding: *Lack of PM dedicated funding*

Ethics, Policy & Regulation:

- *Ethical laws lacking for genomic investigation*
- *Tunisia and Morocco are lacking supportive policy toward health innovation*

Health Systems:

- *Cost of PM research and implementation is an obstacle: the absence of financial support for genetic testing and targeted medication by health insurance schemes causes a financial burden for patients*
- *Tunisia:*
 - *Lack of clinical centre for investigation (participation in clinical trials)*
 - *Skilled genomics professionals are not well paid by public organisations*
- *Algeria:*
 - *lack of knowledge among physicians prescribing genetic analysis tests and weak involvement of the private sector*
- *Inadequacy between the objectives of the PM and those of the public authorities in terms of health expenditure.*

Regional Conclusion for Northern Africa

At present, there certainly are opportunities in Maghreb countries to simultaneously establish genomic studies and to adapt healthcare systems; however, these undertakings are not carried out as part of comprehensive strategies and frameworks in the hands of decision and policy-makers of Algeria, Tunisia and Morocco. In contrast, Egypt is advancing their PM system of health approaches having significant research outputs and developing the Egyptian Genome programme. This also represents a good opportunity and good potential in Egypt to stimulate local development of PM practices.

At this stage, the regional approach has led to a strong stimulation of stakeholders and triggered interest as well as fostering both scientific relations and public policy. Therefore, a regional consortium is being mobilised between Algeria, Tunisia and Morocco appears as a promising tool to foster (not-yet existing) interactions and to outline shared needs. Moving forward with consortium formatting shall help national and inter-country structuration, which could be supported by science or medicine academies in each State.

Relying on a “case study”, e.g. mutation of pathogens or cancer, could facilitate the integration of genomics into national healthcare systems and foster regional collaboration, as it could serve as a proper illustration of possible collective action.

3.4. THE WEST & CENTRAL AFRICAN REGIONAL ANALYSIS

3.4.1 The West & Central African Scientific and Policy Landscape

Western and Central Africa is a vast region with diverse cultures, beliefs, languages, and lifestyles. Stretching from the westernmost point of Africa, across the equator, and partly along the Atlantic Ocean till the Republic of Congo in the South, it encompasses 23 countries that spread across semi-arid areas in the Sahel, large coastal areas on the Atlantic Ocean and along the Gulf of Guinea and tropical forest covering:

- 14 Francophone countries (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo – Brazzaville, Côte d’Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, and Togo).
- 5 Anglophone countries (The Gambia, Ghana, Liberia Nigeria and Sierra Leone);
- 3 Lusophone countries (Cabo Verde, Guinea-Bissau, and Sao Tome & Principe).
- 1 Spanish country namely Equatorial Guinea.

There are several observations in the scientific and policy mapping landscape in Central Africa and West Africa. The governance of health research; financing mechanisms; resources; research outputs and international collaboration of health research within these regions were outlined and hereto summarised from Deliverable report 2.1. Figures 6a-b and table 4 convey key highlights to understand the diversity and levels of development:

1. Governance of Health Research:

- The governance of health research in Central African countries varies from very high (Cameroon) to low (Central African Republic, Democratic Republic of the Congo, Chad). This indicates differences in the level of emphasis and support for research governance in the region.
- In West Africa, the governance of health research is generally high, with countries like Senegal, Benin, Gambia, Ghana, Guinea, Guinea Bissau, Mali, Niger, and Senegal having high governance ratings. This suggests a relatively stronger focus on research governance in the West African countries compared to Central Africa.

2. Financing Health Research:

- Central African countries have varying levels of financing for health research, ranging from low (Cameroon, Chad) to high (Democratic Republic of the Congo). This indicates differences in financial investments and support for health research in the region.
- West African countries generally have medium to high levels of financing for health research. Countries like Benin, Gambia, Ghana, Guinea, Guinea Bissau, Nigeria, and Senegal have medium to high financing ratings. This suggests a relatively stronger financial investment in health research in West Africa compared to Central Africa.

3. Resources for Health Research:

- Data on resources for health research is limited for Central African countries, with "No data" entries for most countries in the region. This indicates a lack of available information on the resources allocated specifically for health research in Central Africa.
- The availability of resources for health research in West Africa varies, with countries like Burkina Faso, Nigeria and Senegal having high resources, while others have low or medium resources. This suggests differences in the availability and allocation of resources for health research among West African countries.

4. Health Research Outputs:

D3.3 Report on gaps-and-needs assessment

As previously reported, the bibliometric analysis using PubMed evidenced that West and Central African countries had the lowest PM publication rate between 2011 and 2020 (Figure 6b). However, if one quantifies this and considers the policy landscape the regional analysis shows:

- Central African countries generally have medium to low health research outputs. Countries like Gabon and Cameroon have relatively higher outputs compared to others in the region. This indicates variations in the productivity and output of health research in Central Africa.
- West African countries, particularly Nigeria, Ghana and Gambia, exhibit relatively high health research outputs in PM. These countries have a larger number of publications and research activities compared to other West African countries, indicating a relatively higher research productivity in the region.

5. International Collaborations in Health Research:

- Central African countries generally have low to medium levels of international collaborations in health research. Cameroon and Gabon stand out with higher levels of international collaborations. This suggests variations in the extent of collaboration between Central African countries and international research partners.
- West African countries exhibit medium to high levels of international collaborations in health research. Countries like Gambia, Ghana, and Nigeria have strong international research collaborations, indicating active engagement with international partners in research endeavours.

These differences highlight variations in the research and innovation landscapes between Central Africa and West Africa, including differences in research governance, financing, resources, outputs, and international collaborations. It suggests that West Africa generally demonstrates stronger research capacity and productivity compared to Central Africa, although there are variations within each region.



Figure 6a: West and Central African countries

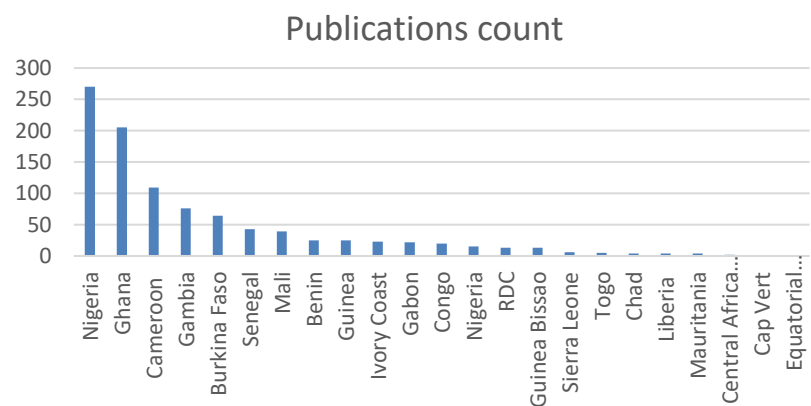


Figure 6b: Number of PM publications per country in West and Central Africa

Table 4: Showing the outcome of the policy mapping in West and Central Africa

COUNTRY	REGION	GOVERNANCE OF HEALTH RESEARCH	FINANCING HEALTH RESEARCH	RESOURCES FOR HEALTH RESEARCH	HEALTH RESEARCH OUTPUTS	INTERNATIONAL COLLABORATIONS IN HEALTH RESEARCH	PM/ GENOMIC RESEARCH OUTPUT	NUMBER of PUBLICATIONS
Cameroon	Central	very high	low	No data	high	high	High	109
Central African R.	Central	low	no data	No data	low	low	Low	2
Congo	Central	medium	no data	medium	medium	low	Low	20
Democratic Rep. Congo	Central	low	high	low	very low	medium	low	13
Equatorial Guinea	Central	no data	no data	No data	low	No data	very low	1
Gabon	Central	medium	high	No data	very high	medium	low	22
Sao Tome & Principe	Central	very low	no data	No data	medium	very low	very low	0
Chad	Central	low	high	low	low	low	very low	4
Benin	West	high	no data	low	medium	medium	Medium	25
Burkina F.	West	very high	very high	High	medium	high	Medium	64
Cabo Verde	West	low	no data	low	medium	low	Very low	1
Cote. d'Ivoire	West	medium	medium	medium	low	medium	low	23
Gambia	West	high	medium	medium	very high	medium	high	76
Ghana	West	high	medium	medium	high	high	high	201
Guinea	West	high	no data	No data	medium	low	low	25
Guinea Bissau	West	high	no data	No data	medium	low	very low	13
Liberia	West	very high	no data	No data	low	low	very low	4
Mali	West	very high	low	medium	low	medium	Medium	39
Niger	West	high	no data	very low	low	low	low	15
Nigeria	West	medium	medium	high	medium	medium	high	270
Senegal	West	high	high	High	medium	medium	medium	43
Sierra Leona	West	no data	no data	No data	low	low	low	6
Togo	West	low	medium	medium	medium	low	very low	5

The regional workshop for PM engagement was co-hosted by IRESSEF on 23 January 2023, with contribution from the EU-Africa PerMed consortium members. Over 33 participants (21 attendees from West Africa and 12 from Central Africa) including researchers, ethics stakeholders, health research institutions met online and discussed specific regional strength, needs, opportunities, barriers and weakness around the area of PM for potential collaboration between other African Sub-Regions and Europe. Participants of the following countries, Senegal, Mali, the Gambia, Nigeria, Democratic Republic of Congo, Cameroon, Ghana, Gabon, Guinea Bissau, Ivory Coast, Togo, Sierra Leone, Congo and Niger, joined the workshop and provided information about their countries.

3.4.2 The STRENGTHS, WEAKNESSES, OPPORTUNITIES & BARRIERS to Develop PM in West & Central African Regional Analysis

WEST & CENTRAL AFRICAN REGIONAL STRENGTHS

The level of skilled people:

- High skilled human resources including molecular biologists, human geneticist, bioinformaticians, computer scientists.
- Several training programs (Master and doctoral degrees) ongoing in human genetics or bioinformatics at the regional level (Senegal, Benin, Mali, Gambia, Cameroon, Nigeria, etc.). As a result, a critical mass of promising young scientists is being reached.
- Ethics and regulatory training from EDTCP program has enabled better training committee members.

Infrastructure:

- Existence of well-equipped genomic research centres in the region (Nigeria, Senegal, Ghana, Burkina Faso) Mainly pathogen genomics infrastructure with Nigeria equipped with human genome sequencing capacity
- Existence of high-performance computing servers for data storage and analysis (Nigeria, Senegal, Mali)
- Local biobanking facilities (Nigeria, Senegal, Mali, Ivory Coast, Ghana)
- Private diagnostics companies specialising in personalised medicine exists in Nigeria

Research in Genomics:

- Strong research institutions in Ghana, Senegal, Mali, The Gambia, and Nigeria
- Research programs are ongoing in human genetics (National Genome Programmes in Nigeria and Senegal), bioinformatics (software development in biostatistics, familial association studies, AI)
- Research programmes in microbial genomics (infectious diseases: malaria, microbiology, HIV, hepatitis...)
- Research programmes on cancer genetics (breast cancer: Senegal, Congo, Ivory Coast), Colorectal cancer (Nigeria, Senegal)

Funding

- Multiplication of financing opportunities accessible to countries in the sub-region
- Countries with higher research outputs and financing show some level of national support as well as strong international funding support (Ghana, Nigeria, Gabon, Burkina Faso)

Ethics, policy & regulation

- Multiplication of ethics committees (national, regional, and institutional), mainly with EDCTP sites and universities

Biobanking

- Sub-regional collaboration (south south); in the virtual biobanking in particular

Level of international collaboration

- Collaboration at country level with Europe and the EU (mapping of PM's scientific & policy landscape, policy briefs, etc.) especially with EDCTP sites

WEST & CENTRAL AFRICAN REGIONAL WEAKNESSES
The level of skilled people

- Lack of skilled human resources in many countries (bio informatics +++) with those who are trained are taken abroad for job opportunities
- Lack of regional collaboration for the development of training programs in genomics

Funding:

- Lack of PM dedicated funding in Africa
- Low levels of national funding and dependency on international funding partnerships to develop PM research

Ethics, Policy & Regulation:

- Lack of governance structures in most countries
- Lack of ethical and regulation laws and procedures across health innovation and in PM
- Lack of accredited labs in most of West and Central Africa

Infrastructure (including omics, high performance computing, data storage/handling etc.)

- Lack of well-equipped high throughput human genomic research centres in several countries
- Existing labs struggling to perform at international standards
- Lack of computing capacities for data storage and analysis
- Lack of biobanking facilities in many countries

Health Systems:

- Insufficient awareness/communication on the full potential of PM – for patients' care in particular
- Lack of skilled human resources in many countries (bio-informaticians, medical geneticist, human geneticists...)
- Lack of public clinical centres for genetic investigation and clinical trials
- Clinical genetics training and practice is lacking. Concept of PM poorly introduced and known by West & Central African healthcare practitioners.
- Poor management of existing infrastructures and upgrades are required
- Private healthcare systems are unable to train doctors, are not linked to public care, are also dwindling due to lack of resources, are very profit driven and performance is lacking
- Cancer registries lacking
- Electronic health records are also not in place

OPPORTUNITIES WITHIN THE WEST & CENTRAL AFRICAN REGION

- *Strong momentum for a single consortium putting together 18 West Africa and 8 Central Africa countries.*
- *Promotion of intra-regional collaboration between researchers in training and research and application to funding opportunities*
- *Developing training programs (e.g. regional hubs) with MSc, PhDs and post-doctoral fellows on PM building and harmonising the research agenda in West & Central Africa*
- *Fostering wider use of genomic data from the population*
- *Bringing back home well-trained African scientists established in the diaspora (in Europe and in the United States)*
- *Networking (e.g. building capacity, virtual biobanking)*
- *New generation of scientists that are open to modern medicine*
- *Build capacity on ethics policy and regulation*
- *Promotion of public and private partnership for research development*
- *Increase the number of public genomic research centres*
- *Develop research programmes for targeted disease of interest like cancers, infectious diseases and other prevalent NCD's*

BARRIERS AFFECTING PM DEVELOPMENT WITHIN THE WEST & CENTRAL AFRICAN REGION

- *Access to funding still difficult.*
- *Government level investment required to stimulate research and innovation within each region. Develop policy dialogue to promote and increase national investment on PM research and innovation.*
- *Inadequate/unprepared national health systems.*
- *Dependence to northern's institutions, expertise, and fundings.*
- *The concept of PM still unknown or misunderstood in West and Central Africa; even at central (ministries of health).*
- *Ineffective and limited platforms and infrastructures.*
- *Lack of intra national collaboration (national competition) leading to team isolation.*
- *Still difficult to convince governments to place PM on their healthcare agenda.*
- *Need to increase the level of government support for research.*
- *Harmonise PM capacities and practices in West and Central African countries. Deficient resources management systems.*
- *Language barriers (French, English, Spanish and Portuguese as 1st language in the 23 countries).*
- *Still unprepared ethics committees & regulatory agencies with regards to PM.*

4. THE AFRICAN CONTINENTAL GAPS & NEEDS

This regional analysis gave rise to an understanding of the Gaps and specific Needs to be addressed in order to build PM R&I agendas in the five regions of the African continent. It furthermore shows the diverse implementation levels of PM in the different African countries and the 5 regions. This emphasising that it is not possible to propose the same approach for PM research, development and innovation as well as implementation for the entire African continent although the basic elements to establish a PM system of health are similar.

Looking at the country level SWOB analysis, it was possible to derive concrete GAPS and Needs shown per African Region and subsequently validate these findings through the 2nd EU-Africa PerMed stakeholder workshop.

The results for each region are presented in the following tables:

Table 5: Summary of the PM gaps and needs from East Africa

PM Gaps	PM Needs	Kenya	Uganda	Tanzania	Rwanda	Ethiopia
Funding	There is a need for sustainable large-scale funding	✓	✓	✓	✓	✓
Stakeholder Engagement	Better communication to the right stakeholders such as insurance companies and patients for inclusion	✓	✓	✓	✓	✓
Ethics & Regulation	Data: Sharing data policy required for the different populations	✓	✓	✓	✓	✓
	Reliance on only WHO to set policy frameworks for implementation and mandates.	✓				
	Awareness and Advocacy for PM at all levels – EU, AU, regions and countries >>Inclusion of policy makers, researchers, clinicians and citizens >> create demand (Tanzania, Rwanda)	✓	✓	✓	✓	✓
	Regulatory frameworks and Ethical knowledge linked to PM (Ethical committees)	✓	✓	✓	✓	✓
Research	Bridging the gap between bench to clinical research	✓	✓	✓	✓	✓
	Networking to scale research- Fragmentation in research/Lack of data from African Population	✓	✓	✓	✓	✓
	National platforms and infrastructure	✓	✓	✓	✓	

D3.3 Report on gaps-and-needs assessment

	for PM research.					
Skills development	Capacity in PM development – Capacity building for healthcare providers, the need to have support (mentorship/ Critical mass of skilled workers) and working as a network and integrating into all health and related fields in PM>>Genetic and bioinformatics formation as degrees and post graduate qualifications.	✓	✓	✓	✓	✓



Table 6: Summary of the PM gaps and needs from Southern Africa

PM Gaps	PM Needs	South Africa	Zambia	Namibia	Zimbabwe
Funding & Research Landscape	Long-term funding (5-10-year commitment of funds) instead of small independent projects with 3-year funding cycle.	✓			
	National genomic project involving all stakeholders and active players in PM (Dpt. Health), should not be research project	✓	✓	✓	
	Inclusion of all 'omics in the strategy (have in mind at the sampling stage)	✓			
	Good political will to fund health research		✓	✓	
	Need for focused national funding		✓	✓	✓
	Access to external funding - Donor funding internationally for PM	✓	✓	✓	✓
	Availability of funding in health research.		✓	✓	✓
Infrastructure	Lack of in country PM infrastructure (Sequencing Platforms)		✓	✓	✓
	No access and availability of PM infrastructure - Genomic sequencing laboratories		✓	✓	
	Lack availability of biobanks / Accredited biobanks.		✓	✓	✓
	Clinical sequencing needs a different quality control, standards in clinical genomics testing	✓			
	A facility to coordinated all the sequencing		✓		
	PM data, homogenised the data collected, standard protocols for all projects	✓			
	Require the implementation of PM research approaches in public and private clinical setting	✓			
	Require the availability of well-established Data Management Facilities	✓	✓	✓	✓
	Central database - Health records	✓	✓	✓	✓
	Create opportunities for the private sector and link to the public sector (Public Private Partnerships, PPP)	✓	✓	✓	
Clinical trials	Lack of clinical trials and regulations		✓		✓
	Localisation of clinical trials - Demand the industry to carry out more clinical trials locally especially in oncology, this can push to have more skilled people.	✓	✓	✓	
	Limitations to training programmes, i.e. medical genetics, bioinformatic (from network admin to molecular tool developers to data analysis). Need for formal education and training in PM associated skills (data science, genomics/proteomics, clinical genetics etc.)	✓	✓	✓	✓
Capacity and Skills - Medical genetics	Capacity building in public and private healthcare in PM - Skills development.	✓	✓	✓	✓
	PM awareness and education - Among policy makers, clinicians, public and private health workers and citizens.	✓	✓	✓	✓
	Issue of brain drain relating to PM in the respective country	✓			✓
	Defined career paths in PM, i.e. for trained medical genetics, data analysts are needed	✓	✓	✓	✓

Table 7: Summary of the PM gaps and needs from North Africa

PM Gaps	PM Need	Algeria	Tunisia	Morocco	Egypt
Funding	Long-term national funding	✓	✓	✓	✓
	National genomic project involving all stakeholders	✓		✓	
	National strategies for PM implementation	✓	✓	✓	✓
Infrastructure	Nation-wide centralised biobanking facilities / accredited biobanks	✓	✓	✓	✓
	Strengthening of structures and procedures to avoid outsourcing to handle samples	✓	✓	✓	✓
	Harmonisation of health systems	✓	✓	✓	✓
	Implementation of PM research approaches	✓	✓	✓	✓
	Central database - digitalisation of health records	✓	✓	✓	✓
Capacity and Skills - Medical genetics	Thorough integration of courses dedicated to PM in health science curricula	✓	✓	✓	✓
	Practitioners' capacity building to guide on the use of appropriate tests to be used for genetic diagnostics	✓	✓	✓	✓
	Training on data analysis and interpretation	✓	✓	✓	✓
	Issue of brain drain relating to PM in the respective country	✓	✓	✓	✓
Policy	Ethical laws for genomic investigation	✓	✓	✓	✓
	Supportive policy towards health innovation		✓	✓	
	Integration of genetic testing costs to social insurance schemes	✓	✓	✓	✓

Table 8: Summary of the PM gaps and needs from West and Central Africa

PM Gaps	PM Needs	Senegal	Mali	The Gambia	Nigeria	Cameroon	Congo	Gabon
Funding	Facilitate access to finance in health research at large	✓	✓	✓	✓	✓	✓	✓
	Facilitate access to finance in PM	✓	✓	✓	✓	✓	✓	✓
	The need to include “omics” in the health system	✓	✓	✓	✓	✓	✓	✓
	National political and financial commitment	✓	✓	✓	✓	✓	✓	✓
	Map and attract key strategic stakeholders	✓	✓	✓	✓	✓	✓	✓
Infrastructure	Gap in Human Genomics sequencing facilities. High throughput labs in public and private sector	✓	✓	✓	✓	✓	✓	✓
	Data capacity -infrastructure	✓	✓	✓	✓	✓	✓	✓
	Improve the research environment	✓	✓		✓	✓	✓	✓
Health system	Encourage research and innovation for impact and development from public and private sectors	✓	✓	✓	✓	✓	✓	✓
	Develop biobanking at national level and in public institution	✓	✓	✓	✓	✓	✓	✓
	Foster electronic health records	✓	✓	✓	✓	✓	✓	✓
	Create cancer registries	✓	✓					
Clinical trials	Create clinical trials sites and or health and demographic surveillance systems with skilled teams	✓			✓	✓		
	Foster collaboration with pharmaceutical industry	✓	✓	✓	✓	✓	✓	✓
	Bioinformatics training for sustainable workforce development	✓	✓			✓	✓	✓

D3.3 Report on gaps-and-needs assessment

Capacity and Skills - Medical genetics	Reshape the role of research and training institutions	✓	✓	✓	✓	✓	✓	✓
	Harmonise and reformat trainings in “Omics”	✓	✓	✓	✓	✓	✓	✓
	More training opportunities in “Omics” for public and private sectors	✓	✓	✓	✓	✓	✓	✓
	Accelerate training in bioinformatics, Omics, data sciences	✓	✓	✓	✓	✓	✓	✓
	A need for a coordinated regional consortium for genomics capacity development consortium	✓	✓	✓	✓	✓	✓	✓
Scientific Networks	Improve projects’ management standards	✓	✓		✓	✓	✓	
	Existing PM research governance structure in all 23 countries	✓	✓	✓	✓	✓	✓	✓
Biobanks	More biobanks/accredited biobanks in private and or public sectors						✓	

5. Gaps-and-needs in the African personalised medicine system of health

The inclusion of African countries in the global PM research agenda can help reduce existing health disparities between developed and developing countries, as well as facilitate African countries' access to new tools and technologies that can make healthcare more efficient and equitable. The EU-Africa PerMed first Policy Brief-call of action indicates that African leaders are encouraged to prioritise investing resources in collaborations, partnerships, and networks to enhance capacity building, genetic testing, health electronic record systems, and health economic research at continental, regional, country, and institutional levels. Furthermore, leaders are also encouraged to strengthen the relationship with the EU to learn and identify opportunities to advance research and policy that facilitates progress in the advancement of PM in Africa.

Developing PM in Africa faces several challenges and gaps that need to be addressed. Some of the key gaps are described below together with proposed solutions on how to address the needs:

1. **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 strong need to enable population genomics projects to close the gaps in scientific knowledge on the African genome
2. **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 strong need to leveraging stronger well-resourced partners within each region e.g. through regional consortia to close the gaps on access to infrastructure and the need to develop infrastructure programmes e.g. comparable to the South Africa's federated "Distribution of Platforms in OMICS" (DIPLOMICS) programme to coordinate and support any infrastructure developments within each region and foster regional collaborations to develop the PM system of health. Other programs trying to address this issue is the recent Pathogen Genomics Initiative in Africa through Africa CDC and world bank who drive the pandemic preparedness fund.
3. **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 e.g. genomic and other novel technologies, limited availability of specialised equipment, and a shortage of trained personnel and bioinformatics pose barriers to PM implementation. This vast gap may only be addressed with addressing the need to develop scaled projects and centres of excellence to disseminate the skills and know-how through developing programmes of R&I that can foster the development of the skills and reverse the brain drain in Africa.
4. **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 hinder the development of robust data repositories necessary for PM.

There is a need to plug this gap by including centralised data infrastructure at least at a regional level as the political landscape may be too vast to address this need at a continental level. There are several programmes initiated to understand what databases exist in Africa such a Project Gradient and Data Science for Innovation in Africa (DS-I Africa), other initiatives such Square Kilometer Array programme has laid infrastructure across the African Continent. H3Africa has also developed Nodes and the ELWAZI

D3.3 Report on gaps-and-needs assessment

programme to enable data sharing is also a continental initiative.

5. **Healthcare Infrastructure and Awareness:** Healthcare systems in Africa face numerous challenges, including inadequate healthcare facilities, 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 for raising awareness and educating healthcare professionals and the general public about the benefits and implications of PM.
6. **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.

EU-Africa PerMed has identified these gaps and proposed addressing specific needs to close the gaps. However, this requires a multi-faceted approach involving investment in research infrastructure, capacity building in genomics and data science, strengthening collaborations and partnerships, improving healthcare infrastructure, and prioritising ethical and legal considerations. International (e.g. African-European) collaborations for knowledge sharing and joint PM research, development and innovation, and support from global initiatives can also play a vital role in advancing PM in Africa.

In terms of time frame and priority, the African stakeholders underlined during the 1st stakeholder workshop that the identified needs cannot be tackled, fostered or implemented in a linear time scale one after the other but should receive support the very same time and in parallel (see also EU-Africa PerMed “D3.1 List of African personalised medicine needs”¹). As mentioned above, the implementation level of PM differs between the African countries and the 5 regions. It is not possible to propose the same approach for PM research, development and innovation as well as implementation for the entire African continent despite the fact that the basic elements and needs to establish a PM system of health are similar. Considering the listed needs, the requirement of leveraging the necessary resources, particularly funding measures, are important and could be seen as high priority to advance PM developments and implementation. Depending on the level of advancements, this requires development funding for countries that need to establish basic structures, often provided by external development funding organisation, or dedicated national funding in countries that established already a functioning healthcare and health research environment.

Within the African context, the development of regionally organised consortia to mobilise the PM agenda could be a tangible approach. The idea to empower regional consortia and drive initiatives that can address the gaps and needs of each region will be most feasible to build a collaborative network model, that can take up the current analysis to develop efforts in building the African PM system of health.

¹ <https://www.euafrica-permed.eu/wp-content/uploads/2022/06/D3.1-List-of-African-PM-needs.pdf>

6. References

- EAHRC (2018). "Policy Brief: Innovative Domestic Financing for Health Research in the East African Community: A baseline assessment and road map towards a sustainable health research and development". (Arusha, Tanzania: : East African Health Research Commission.
- Kamau, Lynette, Nyawira, Teresia, Njambi Musembi, Charity, Onsarigo, Mary, Mia, Rizwana, Kgomo, Karabo, & Sela, Erika. (2022). Opportunities to advance Personalised Medicine research in Africa. Zenodo. <https://doi.org/10.5281/zenodo.7786300>
- Sela Erika, Guinea, Joaquín, Radwan, Amr, Kamau, Lynette, Gitau, Evelyn, Nyawira Teresia, Onsaringo Mary, Njambi -Musembi , Charity, Mia , Rizwana, Mulima , Nomsa, & Moiloa, Nthabiseng. (2021). Mapping the Scientific and Policy Landscape of Personalized Medicine in Africa- EU-Africa PerMed report. Zenodo. <https://doi.org/10.5281/zenodo.7934221>



Annex 1: SWOB Analysis methodology and critical questions used for landscape analysis.

To determine the Strengths, Weaknesses, Opportunities and Barriers to the development of PM in African countries, participants in the stakeholder regional workshops were invited to split up the analysis into respective country groups.

The regional workshop participants were informed about: **What does it mean to determine the Strengths Weaknesses, Opportunities and Barriers to develop PM in African countries (used for the regional SWOB analysis)**

- Determine and analyse what the country possesses that could be leveraged to build capacity for growth in the region including 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 this is critical to developing the strategic direction and ultimately an implementation plan.
- Essentially it is to identify each country's competitive advantages—such as infrastructure, programs of research and innovation, activities and any unique stand points that make the country special or competitive in the national and the East African regional innovation ecosystem—juxtaposed against those internal or external factors that can keep a country from realising its potential.
- Why? So synergies may form for a stronger regional network. Countries within a region can assist each other, form stronger consortia in solving their barrier to developing PM in their regions and fostering international collaboration to fast track development of PM
- The ultimate aim is to identify gaps and needs for developing areas of interest within the African region.

The SWOB analysis was carried out per country or group of countries, depending on the regions: East and Southern Africa as initially described and North and West/Central all together.

How to differentiate each quadrant?

STRENGTHS	WEAKNESSES
<i>These are the positive indications for development or existence of PM research within the country- giving a perspective of all or even a few points to understand the level of skilled people, infrastructure, funding Ethics policy & regulation, Biobanking and status of health systems, and research in genomics/proteomics and digital health and data science.</i>	<i>These are the negative indications for development or existence of PM research within the country- giving a perspective of all or even a few points to understand the level of skilled people, infrastructure, funding Ethics policy & regulation, Biobanking and status of health systems, and research in genomics/proteomics and digital health and data science.</i>
OPPORTUNITIES	BARRIERS
<i>These are the opportunities for development or existence of PM research within the country- giving a perspective of all or even a few points to understand the level of capacity development, infrastructure, funding Ethics policy & regulation, Biobanking and possible interventions for improvement toward patient centered health systems, and research in genomics/proteomics and digital health and data science, that may exist in potential programs that exist or could be developed through collaboration with EU.</i>	<i>These are the external factors that may affect the potential to collaborate at a macro level – the political landscape and loss of talent or issues in being able to access local funding. Also aspects such as lack of core high end infrastructure, unskilled people and lack of supportive policy toward health innovation etc...</i>

CRITICAL QUESTIONS TO GUIDE THE ANALYSIS OF EACH COUNTRY

The following questions guided the discussions for each aspect and the session time allocation for discussing each aspect, i.e. the strengths, weaknesses, opportunities and barriers to development of PM.

Look at the cross-cutting factors and relate to the pillars of each discipline, where is the country placed in terms of the following: Genomics Science, Digital Health including big data science, health systems and patient sample biobanking – how they operate, must be understood, and should correlate to the bibliometric/scientific and policy mapping conducted.

The moderator needs to help determine if the answers are categorised in terms of the strengths, and opportunities that exist in the country for collaboration in PM research. Whilst looking at answers that may relate to inherent weaknesses and those with no mitigation steps to be categorised as barriers for that country. Cross cutting areas to interrogate, form the foundation of the ecosystem and must be understood, how are they organised? How do they operate, especially in the areas of focused funding, skilled people? infrastructure available, ethics and regulation structures in place.

1. Skilled People: a. Are there enough skilled people? At what level are they in terms of - geneticists, clinical geneticists, genetic counsellors, bioinformaticians, big data science, working at the translational level? b. what sort of access to education and training are there for innovative technology deployment? c. What tertiary level genomics, clinical geneticists in med school, bioinformatics, genomic science, and data science courses are available for development of cross disciplinary skills in the PM ecosystem enablement?

2. Infrastructure: a. Is there NGS capability in the country for human genome sequencing? b. Is there NGS capability in the country for pathogen genomics surveillance sequencing? What sort of omics-, genomics and proteomics infrastructure is available? c. Is there infrastructure available for translational research initiatives, incubators etc. d. Are there specialised labs with medical imaging equipment/ hospital infrastructure available? e. What level of fully accredited facilities for clinical diagnostics exist? f. What sort of data and big data infrastructure is available? g. What sort of biobanks exist? How is it organised? h. What kind of clinical infrastructure exists (Private vs. public healthcare facilities)? Are there High-Performance Computer Centres? Internet and Cloud Access available? j. Are there any big data storage systems available? k. Clinical genetic testing laboratory services? Is it private / public sector? l. public sector treatment clinics in disease control e.g., such as TB and HIV ARV (antiretroviral) treatment clinics?

3. Funding: a. What funding is available for genomic/proteomic science, digital health/ data science? b. Who is funding? c. Which NGO and other funding support are available? d. What sort of programmes of research and innovation are being funded? e. How does private funding feature in supporting research and innovation? f. Feasibility and costs for precise diagnostics and translational research in your country? g. How does international funding feature?

4. Health System: a. How is the health system organised in terms of digital health records, patient centric care, precise diagnosis, and access to targeted treatment? b. Where is the country at with respect to universal health coverage? c. Are there private healthcare facilities? d. Private Medical Insurance available? e. Who supports public healthcare? f. Reimbursement of newer diagnostic or targeted treatment with medical insurance? g. Is genetic/pathology testing offered in the healthcare system? h. Are public hospitals involved in clinical studies? What sort of large-scale public healthcare role out programs exist, HIV ARV care, TB, NCD Chronic care, COVID and other diseases? Think about the readiness of the healthcare system (Public & Private) for PM?

5. Ethics Policy and regulation: a. Are there research ethics committees and frameworks in place? b. Who are the medicines' regulatory authorities and what is the level of activity? c. Supportive government policies that exist that can include genomics and data science within their strategies? d. Is the policy environment supportive to develop more knowledge-based activities toward health innovation etc.? e. How amenable is the political environment with respect to GDP generated in the country to support health research and innovation? f. What sort of personal data protection and sharing policies exist?

6. In genomics and proteomics science: a. What sort of research interests exist? b. What disease areas are scientists working on? What disease areas are people working on in genomics and proteomics? Regional

D3.3 Report on gaps-and-needs assessment

Population Genetic diversity, needs to be considered or outlined? c. What sort of large scale/ longitudinal clinical studies exist? d. Are there any population genomics projects/programmes taking place? e. Are there any large-scale data intensive programmes that exist? f. Is there translation research of precise diagnostics, or targeted treatment interventions into the health system? g. What sort of precision diagnostics tools and services can be offered? h. What sort of precision treatments are being offered or can be offered? How does international collaboration feature?

7. In Data Science: a. What level of training and skills exist? b. What level of NGS support exists from a bioinformatics perspective, WGS and big data analytics perspective? c. What disease areas have pipelines and algorithms been developed? d. What sort of big data sets exist? e. Are there any digital health applications developed and utilised in the clinical setting? f. Access to experts Bioinformatics workforce. There are regional experts that exist? Square kilometer Array Program laying out Infrastructure for big data science, H3ABionet level of involvement? What other data intensive programs are available to leverage? g. How does international collaboration feature?

