Regions4PerMed

# Interregional Coordination for a fast and deep uptake of Personalised Health

# Regions4PerMed

**Final Action Plan**

# Report

HORIZON 2020

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## DESCRIPTION

The Action Plan formulates and proposes a list of actions that need to be adopted at regional and national level in order to accelerate the creation healthcare systems that are able to prioritize Personalised Medicine implementation.

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# Table of Content

Rationale ..... 5

KA1: Big Data, electronic health records and health governance ..... 7

KA2: Health Technology and Connected and Integrated Care ..... 9

KA3: Personalising Health Industry ..... 11

KA4: Innovation Flow in the Healthcare ..... 13

KA5: Ethical and socio-economic aspects ..... 15

Actions to be undertaken at EU level ..... 17

CLUSTER OF ACTION 1:
Trigger the implementation process starting from the local authorities ..... 18

CLUSTER OF ACTION 2:
Foster Interregional cooperation ..... 19

CLUSTER OF ACTION 3:
Maintain Interdisciplinarity. ..... 20

CLUSTER OF ACTION 4:
Meet the daily growing need for technological advancement. ..... 21

CLUSTER OF ACTION 5:
Invest in socioeconomics and Ethics policy programmes. ..... 22

CLUSTER OF ACTION 6:
Encouraging in-situ visits for networking between regions. ..... 23

# Abbreviations

| | |
|---|---|
| EHDS | European Health Data Space |
| EHRs | Electronic Health Records |
| EP PerMed | European Partnership of Personalised Medicine |
| ICPerMed | International Consortium of Personalised Medicine |
| ICT | Information and Communication Technology |
| KA | Key Thematic Area |
| PH | Personalised Health |
| PM | Personalised Medicine |
| PPI | Public Procurement of Innovation |
| Regions4PerMed | Interregional coordination for a fast and deep uptake of personalised health |
| S3 | Smart Specialisation Strategy |
| TLS | Fondazione Toscana Life Sciences |

# Rationale

As defined in 2014 by the Horizon 2020 Advisory Group, Personalised Medicine (PM) is a medical model using characterization of individuals' phenotypes and genotypes, such as molecular profiling, medical imaging and lifestyle data, to tailor the right therapeutic strategy to the right person at the right time, determine the predisposition to disease and deliver timely and targeted prevention. This definition has also been adopted by the European Council Conclusion on PM for patients, which specified that "Personalised medicine relates to the broader concept of patient-centered care, which takes into account that, in general, healthcare systems need to better respond to patient needs" (2015/C 421/03). From both national and regional level, the main challenge facing healthcare systems are facing is the transition from a reactive standardised health model to a personalised, preventive, and predictive health model who ensures the highest quality of the treatments whilst ensuring financial sustainability. However, the high fragmentation of this sector at different levels generates the bottleneck holding back the implementation of PM and Personalised Health (PH), with the need of alignment and coordination between the different stakeholders involved, ranging from policy makers, industry, academia, and citizens. Although high-level concepts are becoming clear, many barriers remain in terms of information, integration, translation, logistics and acceptance across Europe and they need to be addressed. This constitutes a serious obstacle to PM and PH development and implementation, hampering the placement of investments. Thus, it is crucial to direct more efforts towards coordinated investments and policies and alignment among all the stakeholders in PM actions across Europe and beyond.

Regions4PerMed project supports the coordination of regional policies and innovation programmes in PM and PH to accelerate their deployment for the benefit of citizens and patients. The project strengthens cooperation between H2020, Horizon Europe and the Structural Funds on this topic, reinforces areas of industrial specialisation in Europe and enables PH to flourish as an emerging industry, enables joint interregional investments on PM.

In the last 4 years, the Project has organised 6 International conferences, 5 thematic workshops and 2 high level policy events with the scope to evaluate the current challenges to the implementation of PM, brainstorm with key opinion leaders and experts about potential solution and formulate policy

recommendations which have been gathered in reports publicly available here: ***https://www.regions4permed.eu/download/***

based on the previous work, this final action plan aims to formulate and propose a list of actions that need to be adopted/ taken at regional and national level for the implementation of a healthcare system that prioritizes personalized care and PM. The following document covers all the 5 pillar thematic Areas [KA1: Big Data, electronic health records and health governance, KA2: Health Technology and Connected and Integrated Care, KA3: Personalising health industry, KA4: Innovation flow in healthcare; KA5: Tackling ethical, economical, legal, and social aspects of personalised medicine] and calls upon academy, industry and policy makers to spread adopt these actions in order to achieve the desired outcomes.

# KA1: Big Data, electronic health records and health governance


## Overview

The relentless pace of technology, fuelled by the advancement in genome sequencing techniques and the digitalisation process within health systems has led to a significant increase in data production. The quality of data itself is changing, with "big data" now offering multiple possibility for using and sharing information. Big data in healthcare refers to health data sets whose management is not possible with traditional software and/or hardware or data tool, especially because, besides their volume, they present a high level of variety and differences. However, it is on their volume and in their multiple use that a Personalised Medicine (PM) approach can rely, since a huge amount of information is needed for every single patient. This raises several challenges that need to be overcome. On the one hand, new ways and standards to collect, store and manage big data need to be efficiently used to retrieve useful information, bearing in mind privacy and security concerns. Furthermore, especially for health-related data, new actors have gained a role in the process of its governance: not only patients, carers and medical staff, but also healthcare and public health authorities which, through the data, can shape more effective policies and reorganise services, and can provide support to industry and innovation stakeholders, for whom data can bring information

necessary to drive new advancements. The role of regions has therefore become pivotal in the health governance system. In this Key thematic Area (KA1) Regions4PerMed shed light on the most important issues of big data in health, presenting an overview of the current state of art of big data and suggestions, coming from all experts involved in the work, that can support research, regional policies and innovation programmes in PH and PM in order to accelerate the deployment of PM for citizens and patients.

## Main outcomes

Data that can drive research and enable healthcare transformation, but regulations must be drafted and interpreted to guarantee a secure and safe use of data in the best interest of patients, citizens, and their communities.

The deluge of data is changing how clinical decisions are taken. As most of the health-related data collected can carry errors, to guarantee a safe application of data analysis and machine learning further studies need to be carried out (understanding governance, model validation, explicability of data) and more fundings should be invested in these studies.

Data will not replace clinicians, and therefore conditions must be established to not loosen the doctor-patient relation, to maintain human control over machines and to develop training and education programmes for the actors involved.

To foster the transition towards data driven health and care, a governance system is key. Regions, as the administrative entities closer to the needs of a territory, shall involve all relevant actors to shape new digital health policies, which balance the benefits of new technologies, mitigate the risks (trust, privacy, security to mention a few) and maximise the impact (through accessibility and open science approach) for patients and healthcare systems.

Regions and intermediate institutions are also critical in addressing potential risk and streamline governance as they oversee translating general regulations in operational and day-to-day activities.

New training programs should be created, in order to train new professionals that will soon be needed: a mix of clinicians, doctors, biologists, nurses, managers, sociologists. Investments in education and training should be made now, or there will be a delay in dealing with relevant technological, organisational, and ethical issues.

Initiatives like "100.000 Genomes" carried out in UK, which is already leading to new medical discoveries, can be replicated at regional and interregional level. The use of non-genomic health data (clinical, administrative and socio-economic) are at the basis of healthcare reforms and help local authorities to face the economic sustainability of healthcare.

# KA2: Health Technology and Connected and Integrated Care


## Overview

Electronic Health Records (EHRs) are real-time and patient-centered records of health information and clinical care, generated and maintained by healthcare providers. They are designed to systematically collect patient information and share it across healthcare providers and settings to help deliver more comprehensive and accurate clinical care. Substantial investment and increased financial incentives to implement EHRs over the last decade have resulted in widespread EHR adoption in high-income countries. Many pilot projects in this area are being implemented worldwide and areas of opportunity are being identified to have a potentially global impact. Despite the potential of mHealth applications, many initiatives fail in the pilot stage. Barriers to large-scale adoption such as standards, security, and interoperability are also being identified. This Key Thematic Area 2 (KA2) was devised to tackle the main challenges of digital healthcare fostering PM, encompassing technological, regulatory, research aspects and translating the alters into effective and policies to be adopted at local and national level.

# Main outcomes

PM requires cross-border and interdisciplinary collaboration and the involvement of stakeholders along the healthcare continuum. The European Framework Programme for Research and Innovation **Horizon Europe** is providing funds to validate innovation in clinical setting through interregional and interdisciplinary collaboration.

New methods to gather the patients' voice (Patient Reported Outcomes - PROs and Patient Reported experiences - PREs) should be used to validate new organizational healthcare settings. The introduction of this new type of service is based on telemedicine and telehealth diagnostic, while strengthening the patients to manage their own health.

As Prevention is key if we want to achieve sustainable healthcare systems, data use and new technologies should be adopted. Standards, processes, and platforms to facilitate broad use of digital tools, big data, and advanced analytics across our neuroscience portfolio should be encouraged.

Technology can help in detecting emergencies and supporting healthcare professionals by giving them early access to health information and recommendations. Public-Private Partnerships should be encouraged in this field.

The institution of multidisciplinary teams is fundamental. Precision medicine especially in this pioneering phase requires competences which only a highly specialized and synergistic approach of different people may provide these competencies.

Artificial Intelligence is becoming part of our daily life as well as healthcare professionals' lives and is already applicable in image and signal processing, symptoms, and diagnosis support.

# KA3: Personalising Health Industry


## Overview

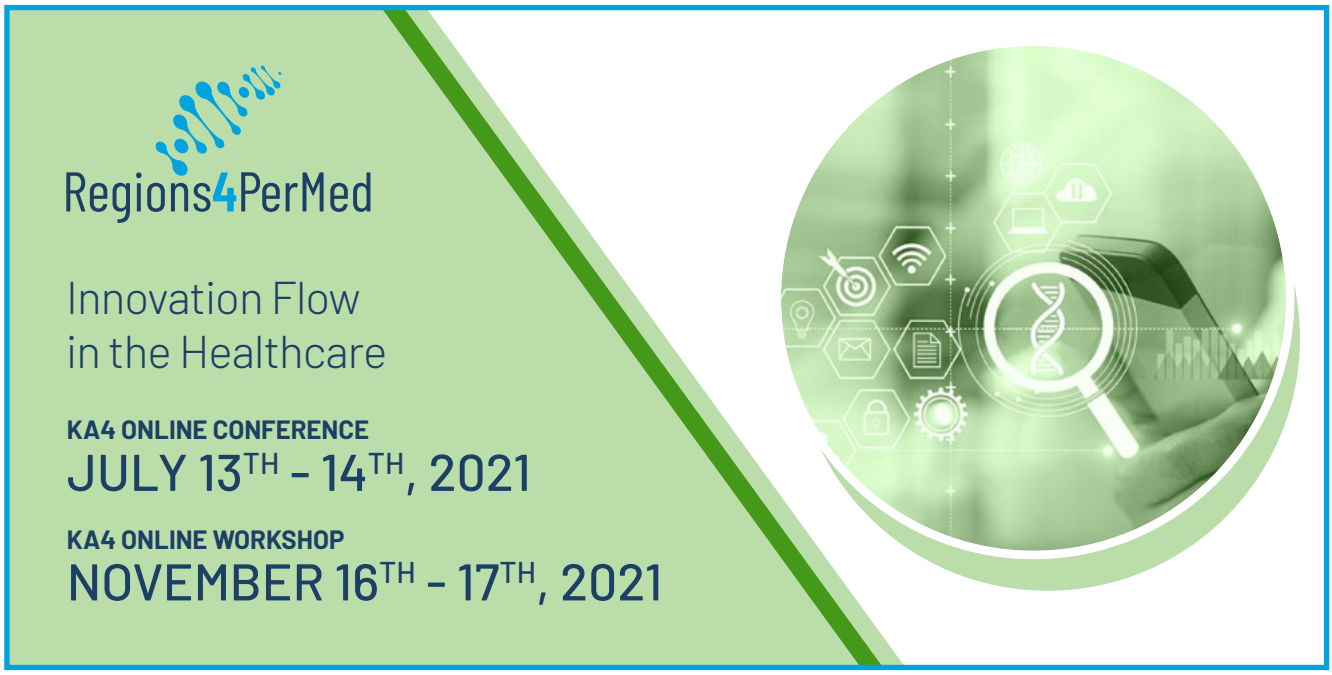
An increasing availability of health-data and enhanced processing capabilities make the foundation of significantly improved health interventions in a progressively digitalizing health economy that will have a tremendous impact on citizen health while transforming health industry. This growing potential for an increasingly PM and PH oriented economy represents a great development option for health industry while at the same time exposing it to big new challenges. The World Economic Forum sees an "urgency for stakeholders across the industry to transform their business models to remain relevant and financially viable in the long term" (World Economic Forum 2019). Ongoing medical innovation will include far-reaching business innovations when leading to a truly PM and PH. Market-entry of non-traditional competitors can be observed by IT and tech companies, but also start-ups offering innovative personal health data tools and products. But though it may be comparatively straightforward to enter the personal health market with novel direct-to-consumer products and services, the introduction of personalisation in the regulated health system is far more complex. Thus, the uptake of PM in the public health systems of Europe has been perceived to be rather slow so far. In this key thematic area on Personalising Health Industry, Regions4PerMed took a deeper look at what opportu-

nities and challenges health industry is facing in Europe when aiming to embrace PM and PH, and how they can contribute to the vision of the International Consortium of PM (ICPerMed) for "integrating an individual's characteristics for early disease diagnosis, prognosis, optimal choice of treatment, accurate disease risk estimation, and targeted prevention". Implementation of PM and PH shall be the basis of a healthcare for Europe with improved and optimised health promotion, disease prevention and management accessible to all citizens. For health industry this transition may also present a true shift of paradigm – changing its value chain and traditional therapeutic blockbuster-approaches. The ongoing medical and scientific innovation will entail novel research and development (R&D) approaches, product and production concepts, and consequently, also business strategies and models. These changes are not happening in isolation, as industry is always embedded in an ecosystem of other actors and stakeholders, closely interrelated, and interacting at all stages of the value chain. This ecosystem also has an important geographical dimension that needs to be considered. Whereas the global perspective may define the overall potential and innovation space of an industry, continental, national, regional, and even local settings may be crucial for specific innovation opportunities and the success of individual industry participants and local or regional clusters. In the context of healthcare, in Europe, the regional dimension warrants special consideration as healthcare here is not only regulated at the European and the national levels but, in many Members States to a significant degree also at the regional level, creating a complex market environment for health industry. Thus, innovation systems as well as health industry markets need to be considered in these regionally defined spatial (and cultural) settings. This regional perspective is the specific aim and objective of Regions4PerMed and sets the frame for this review and analysis of personalising health industry within this key thematic area.

## Main outcomes

Local and regional authorities can support the implementation of PM and PH, driving investments in infrastructures and technologies, and expanding regional specialisation. A regionally aligned strategy can result in economic benefits, improved health, and scientific excellence. Collaboration and alignment of policies are critical for achieving high-impact results. Participation in European Partnerships, such as EP PerMed, can increase visibility and access to the international R&D community. Precision and personalized medicine can improve quality of life and support economic growth, but public awareness and equitable access are crucial.

# KA4: Innovation Flow in the Healthcare




## Overview

Research is the cornerstone of the development of new medical approaches leading to more knowledge and innovation advances thanks to "-omics" technologies among others. The advances of genomics and other "-omics" in recent years, have paved the way to a new medicine, tailored to the patient and which is known as PM. PM is not only based on adapted-patient diagnosis and treatments, but also envisages the prevention of diseases before their outset. Research and Innovation (R+I) are at the basis of personalised healthcare services, therapeutics, diagnostics for citizens and patients. Institutional awareness and the commitment of policy and decision makers in all member States and regions across Europe are crucial to facilitate the R+I flow into European healthcare systems, contributing to personalised and patient-centred healthcare and medicine. R+I should be supported by relevant policy strategies, including the creation of solid R+I infrastructure exploitation models, deployment of suitable financial instruments and the correct screening and assessment of the outcomes obtained with R+I initiatives. The application of the supportive strategy leads to the desired outcomes and products from R+I projects. European Local and Regional Authorities are a driving force of Health Research, Innovation and Healthcare modernization and need to be engaged in joint and coordinated policies in Europe

to avoid fragmentation, ensure successful development of strategic initiatives and multiply benefits for citizen, industry academia and policy makers. The main aim of the Key Thematic Area 4 (KA4), titled Innovation Flow in the Healthcare, was to address and tackle the main barriers that are holding back the adoption, at regional level, of health innovation for Personalised Medicine into healthcare systems, encompassing different stages, ranging financial tools to invest in R+I, regional infrastructures for development and clinical validation on new Personalised Medicine solutions and approaches.

## Main outcomes

Research and innovation are crucial for the integration of new clinical prevention and diagnosis techniques, technologies, and services into healthcare. This requires research infrastructures that manage human data, including genomics, in compliance with ethical and proprietary standards to gain patient and partner trust. Public and private investments are needed to sustain the development and deployment of innovative prototypes, solutions, and technologies in PM with the support of innovative public procurement tools. In this regards, unmet needs should be clearly identified and defined before performing any R+I procurement, and different procurement tools should be used depending on the identified unmet needs. All solutions obtained should be implemented and exploited for their expected duration in research or clinical settings. Collaboration among regional research institutes, academia, industry, and public institutions is necessary to create an environment for accelerating and sharing new knowledge and advances. Harmonisation is necessary for labelling and certification procedures for Living Labs. The construction of a federated sustainable infrastructure for human genomics and translational data in Europe enables discoverability, access, sharing, and analysis of genomics data. Regional innovation programmes should provide the adequate investment and policy scheme to ensure capillarity in all the areas of Europe.

# KA5: Ethical and socio-economic aspects


## Overview

There is no doubt about the importance of implementing PM in clinical practice to create a healthcare ecosystem that is truly able to focus on the individual. The benefits for the individual are indeed reflected in society as prevention or patient-friendly strategies reduce costs both in terms of money and time. However, while different countries are introducing whole genome sequencing and PM approaches into clinical care (i.e., the United Kingdom's National Health Service plan to sequence 5 million genomes in 5 years and France and Canada which, at various stages, are kicking off publicly funded genomic healthcare services), the awareness about the ethical, economic, legal and social implication of PM are becoming central in the public discourse.

The Key Thematic Area 5 (KA5) was then conceived to tackle the socio-economic and ethical aspects linked to the development and implementation of PM in the healthcare system, with a focus on the regional level. In particular, the thematic Area addressed Ethics, Public trust, the Economic value of PM, Diversity and inclusion in PM and the issue of Sex and gender in PM.

# Main outcomes

To implement PM in a way that do not generate inequalities for patients and citizens, it is important to address ethical policies that balance research and clinical practice while protecting the safety and privacy of study participants. Transparency throughout the PM process is also crucial for building public trust. Health economic research is needed to validate new PM approaches, and authorities should consider new reimbursement systems for therapies based on, i.e., "payment for performance." Regional bodies have an important role to play in promoting the integration of PM in healthcare systems, which requires addressing complex socio-economic factors such as funding, access to healthcare, public trust, and patient education. Collaboration between stakeholders, including politicians, healthcare professionals, patients, and experts, is essential to creating a sustainable and equitable approach to PM in the EU. Therefore, investing in initiatives that facilitate the development and integration of PM in regional health systems and promoting collaboration among stakeholders is critical for achieving a comprehensive and inclusive approach to PH.

# Actions to be undertaken at EU level

During the Project lifetime it has been clear how local authorities often function as triggers for the implementation of projects on a wider up to national and in some cases, international level.

Through the various activities carried out, from the collection of good practices to the various examples of European excellence in infrastructure and academia as well as the discussion with the various experts involved in the various events that have taken place over these years, a number of actions that need to be taken have been highlighted. These can be grouped into clusters which represent the main guidelines needed to maintain the right path towards the concretisation of the project objectives.

# CLUSTER OF ACTION 1:
# Trigger the implementation process starting from the local authorities.

- Work towards increasing trust and perception of effectiveness of local governance among citizens.
- Use Local and Regional Authorities knowledge of the territory to inform and guide decision-making related to healthcare and technology.
- Develop and implement a interregional coordinated strategy, starting form smart Specialisation Strategy, in which PM and PH are correctly defined encompassed.
- Conduct regional pilot studies to support the implementation of PM and PH but ensure that they are aligned with the overall regional strategy.
- Ensure that regional instruments and policies are complementary to higher-level policies to maximize their impact and effectiveness.
- Leverage the knowledge of local and regional authorities to identify and drive investments in infrastructures, enabling technologies, and supportive structures necessary for expanding regional specialization in PM and PH.
- Encourage diverse strategies to make Research and Innovation infrastructures profitable and integrate new approaches in regional or national systems.
- Support the construction of real-life settings for testing new methodologies, techniques, prototypes, and services to create a comfortable real medical environment for patients and health personnel. This can be achieved through a combination of public procurement tools deployment and the expertise of research and innovation institutes.

# CLUSTER OF ACTION 2: Foster Interregional cooperation.

- Participate in European partnerships and other Public-Private Partnerships, especially the upcoming EP PerMed, to facilitate policy implementation on PM, establish a truly international R&D community, and participate in policy guiding activities within Europe.
- Prioritize interregional cooperation among diverse European jurisdictions to create a network for exchanging interoperable and accessible human and health related data, complying with privacy regulation and ethical aspects.
- Incentivize deeper inter-regional learning for the development of accessible tools to all PM community to include innovation strategies such as public procurement of innovation (PPI) or innovation partnership in PM.

# CLUSTER OF ACTION 3: Maintain Interdisciplinarity.

- Foster collaboration among different areas of policy implementation and across different stakeholders to achieve high impact results.
- Facilitate and promote dialogue among the different actors involved in Big Data in health to ensure effective coordination.
- Establish continuous patient engagement and empowerment programs, which can be monitored, reviewed, and updated, and design flexible organization to promote interdisciplinary teams needed to integrate specialized knowledge and competences.
- Involve all relevant actors, including industry, academia, healthcare providers, patients, and citizens, in shaping policies that are supportive of PM and PH and aligned with higher-level legislation.
- Encourage and invest in translational research, improving knowledge exchange between applied research institutes, academy and industry.

# CLUSTER OF ACTION 4: Meet the daily growing need for technological advancement.

- Implement information and communication technology (ICT) to deliver desired results in personalized and patient-centered health systems.
- Invest in and develop data-driven technologies, with a particular focus on big data in health and other sectors, to drive scientific, social, and economic advancements and boost industrial competitiveness.
- Construct research and clinical centers to respond to the demand for novel products or technologies in different healthcare systems.
- Invest in developing centralized, qualitative, and interoperable health data infrastructures, and endorse federated data mechanisms, while promoting benefit-sharing policies between public and private entities.

# CLUSTER OF ACTION 5: Invest in socioeconomics and Ethics policy programmes.

- Support economic growth and improved healthcare for citizens by promoting prediction and prevention of disease, equitable access, and increasing the population health benefits that enhance the quality of life within the regions.
- Develop strict and articulated definitions on the role of ethical committees and Health Data Access bodies in the upcoming European data regulation (European Health Data Space -EHDS), while ensuring patients and citizen representatives are included in ethic boards.
- Implement training and education programs for clinician-to-person dialogue and develop more lay communication to explain the benefits of personalized medicine.
- Promote transparency and disseminate information on the concrete clinical outcomes of personalized medicine and conduct more research on the health economics of PM that also factor in costs of tests and sharing best practices and examples among regions and countries.
- Adopt a new reimbursement system based on "payment for performance (outcome)" and introduce a new accounting system for treatments that, in general, have a high unit cost and reduction of cost for future years.
- Establish lifelong learning programs to change the patients' approach by professionals and raise awareness in Ethical Committee and Clinical trial office on how to assess clinical protocols, including the Sex and gender perspective.
- Promote diversity and inclusivity within the organizational changes and their gender equality plans and use policy platforms like Interreg Europe and Vanguard to promote policy in this sense.

# CLUSTER OF ACTION 6: Encouraging in-situ visits for networking between regions.

The Covid-19 pandemic imposed the change of the trim for most of the Regions4PerMed events such as the planned local visits to regional participants facilities. Nevertheless, the in-situ visits in Milan and in Wroclaw (the other were suspended or carried out virtually due to the pandemic mitigation measures) represented a valuable demonstration of the importance of organising exchanging competences and views through in-situ visits. These have proven to be an important activity that should be promoted as this is an immediate and effective strategy to allow visitors to appreciate the potential of scientific infrastructures and ecosystems. The exchange of experiences and the direct interaction are irreplaceable to fully appreciate the work carried out by research facilities and startups and to allow networking with different involved stakeholders. In this respect, it is strongly recommended to invest in the organisation of this type of events.


Regions4PerMed