Beyond One Million Genomes

D1.1 - Document describing the operational organisation and processes for the Stakeholder Coordination Group (SCG)

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23/07/2020	0v2	Denis HORGAN (EAPM)]	Feedback received from WP1 team via conference call and recirculated
31/07/2020	0v3	WP1 Team	Presentation at the monthly Work Package meeting
04/08/2020	0v4	WP1 Team	[B1MG-OG comments addressed. Version circulated to B1MG-GB for feedback through google shared drive
05/09/2020	0v5	Denis Horgan (EAPM)]	Feedback incorporated
23/10/2020	0v6	WP team	Presented to stakeholders
12/11/2020	0v7	WP team provided additional feedback taking into account Stakeholder Coordination meeting as well as alignment with B1MG which D. Horgan incorporated	Comments addressed and integrated
20/11/2020	0v8	Denis Horgan (EAPM)	B1MG-OB and GB comment addressed.
24/11/2020	1v0	Juan Arenas (ELIXIR Hub)	Final version uploaded to the EC Portal

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Table of Contents

B1MG has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 951724

1. Executive Summary

B1MG WP1 organises the stakeholder engagement in the field of genomics-based health that have the expertise and capacities to play a role in the European 1+MG Initiative. Priority is to engage key stakeholders in the essential workstreams organised as part of the B1MG Work Packages (and their corresponding 1+MG Working Groups). Stakeholders are organisations of a variable nature and scope, and B1MG chooses to organise their involvement at multiple levels.

Stakeholders are here defined as European, national and regional organisations and individuals active in and/or interested in the development and implementation of genomics-based health in national and regional healthcare systems. In particular, B1MG addresses stakeholders active in and/or interested in realising the key goal of the 1+MG initiative: the ability to make genomics and related health data accessible across borders for trans-national use in research, diagnostics and/or innovation of healthcare.

The B1MG stakeholder organisation targets stakeholders at the follow level, and in the following manner:

1. **General public**: B1MG has opened a website to inform the general public on issues related to genomics-based health and data access.
2. **All stakeholders with an active role in 1+MG:** B1MG arranges for a **Stakeholder Forum and Stakeholder Portal** to inform and engage the broad range of key European, national and regional organisations that play an active role in implementation of genomics-based health and help create the conditions to facilitate cross-border data access.
3. **Selection of key European stakeholders to drive and help realise the 1+MG initiative:** B1MG arranges for a **Stakeholder Coordination Group** bringing together experts from a selected range of key organisations and projects crucial for the realisation of the 1+MG Roadmap until and beyond 2022.

Stakeholder Forum

The B1MG Stakeholder Forum (SF) acts as a key platform of interaction and consultation between all active stakeholders from B1MG, including stakeholders in signatory countries of the 1+MG initiative and at the European level. Collecting input and discussing viewpoints from patient organisations, clinicians, medical specialists, regulators, industry and HTA bodies and others will be crucial to shape the work of B1MG, especially in its thematic Work Packages WP2 (ELSI), WP3 (data standards and quality), WP4 (technical infrastructure) and WP5 (implementation in healthcare), alongside the implementation of the B1MG project. The role of the SF will be to provide methods to coordinate between stakeholders at the EU, country and regional level and to actively inform the stakeholders and involve them in the B1MG Work Packages.

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Stakeholder Coordination Group

The B1MG Stakeholder Coordination Group (SCG) acts as a strategic council to the 1+MG initiative, and includes a selection of experts of key European initiatives, umbrella-organisations and major projects derived from the Stakeholder Coordination Forum. Additionally, B1MG SCG members are selected to help advance the field and align agenda's along the thematic B1MG Work Packages WP2-5.

2. Contribution towards project objectives

With this deliverable, the project has reached or the deliverable has contributed to the following objectives/key results:

Objective/Key Result No & Description	Contributed
Objective 1: Engage local, regional, national and European stakeholders to define the requirements for cross-border access to genomics and personalised medicine data	
1: B1MG assembles key local, national, European and global actors in the field of Personalised Medicine within a B1MG Stakeholder Coordination Group (WP1) by M6.	Yes
2: B1MG drives broad engagement around European access to personalised medicine data via the B1MG Stakeholder Coordination Portal (WP1) following the B1MG Communication Strategy (WP6) by M12.	Yes
3: B1MG establishes awareness and dialogue with a broad set of societal actors via a continuously monitored and refined communications strategy (WP1, WP6) by M12, M18, M24 & M30.	Yes
4: The open B1MG Summit (M18) engages and ensures that the views of all relevant stakeholders are captured in B1MG requirements and guidelines (WP1, WP6).	Yes
Objective 2: Translate requirements for data quality, standards, technical infrastructure, and ELSI into technical specifications and implementation guidelines that captures European best practice	
Legal & Ethical Key Results	
1: Establish relevant best practice in ethics of cross-border access to genome and phenotypic data (WP2) by M36	No
2: Analysis of legal framework and development of common minimum standard (WP2) by M36.	No
3: Cross-border Data Access and Use Governance Toolkit Framework (WP2) by M36.	No

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Technical Key Results	
4: Quality metrics for sequencing (WP3) by M12.	No
5: Best practices for Next Generation Sequencing (WP3) by M24.	No
6: Phenotypic and clinical metadata framework (WP3) by M12, M24 & M36.	No
7: Best practices in sharing and linking phenotypic and genetic data (WP3) by M12 & M24.	No
8: Data analysis challenge (WP3) by M36.	No
Infrastructure Key Results	
9: Secure cross-border data access roadmap (WP4) by M12 & M36.	No
10: Secure cross-border data access demonstrator (WP4) by M24.	No
Objective 3: Drive adoption and support long-term operation by organisations at local, regional, national and European level by providing guidance on phased development (via the B1MG maturity level model), and a methodology for economic evaluation	
1: The B1MG maturity level model (WP5) by M24.	No
2: Roadmap and guidance tools for countries for effective implementation of Personalised Medicine (WP5) by M36.	No
3: Economic evaluation models for Personalised Medicine and case studies (WP5) by M30.	No
4: Guidance principles for national mirror groups and cross-border Personalised Medicine governance (WP6) by M30.	No
5: Long-term sustainability design and funding routes for cross-border Personalised Medicine delivery (WP6) by M34.	No

3. Methods

Both the Stakeholder Coordination Group and the Stakeholder Forum acts as a key platform of interaction and consultation between all stakeholder groups. Collecting input and discussing viewpoints from diverse stakeholder groups, such as patient organisations, clinicians, regulators, industry, infrastructure and HTA bodies at the European and Member State level will be crucial to shape the work of B1MG, especially in the framework of the thematic workstreams that are ongoing via the other B1MG Work Packages WP2, WP3, WP4 and WP5 and the corresponding Working Groups in the 1+MG Initiative.

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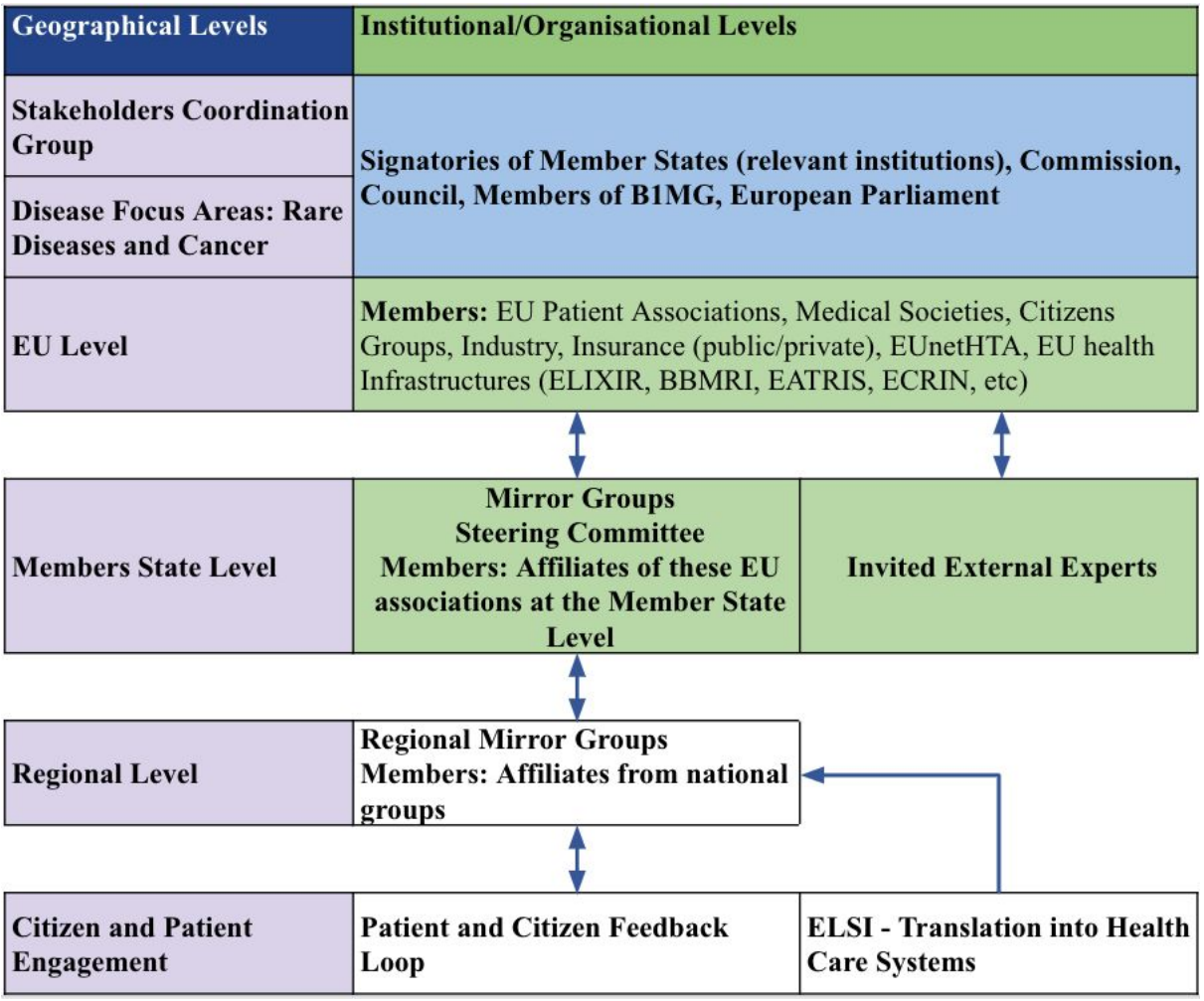

Figure 1. Overarching Overview of Stakeholders Engagement for the Stakeholders Coordination Group and Stakeholder Coordination Forum from the local to the European Level

The SF will discuss barriers, gaps, and needs potentially leading to a coordinated consensus on innovative solutions to support the aim of the B1MG. There will be four face2face meetings, after which a report will be written. The document will outline the following areas:

- Yearly report on recommendations to facilitate genome/clinical data integration to the EJR-RD and Cancer Mission, SCG Roundtable meeting and Thematic framework (M12)
- Yearly report on recommendations to facilitate genome/clinical data integration to the EJR-RD and Cancer Mission, SCG Roundtable meeting and Thematic framework (M24)
- Yearly report on recommendations to facilitate genome/clinical data integration to the EJR-RD and Cancer Mission, SCG Roundtable meeting and Thematic framework (M36)

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The recommendation will document enablers and barriers, opportunities and constraints as to improve coordination in above areas. Depending on the topics in consultation, the reports can provide the basis for coordination which will be disseminated in collaboration with WP6 and it will be shared with stakeholders in the portal.

The SF will be structured by the following stakeholder clusters as set out in the platform as represented by the following stakeholder clusters:

1. Citizens & Patient organisations
2. Clinicians, medical specialists
3. Academics
4. Medicines authorities (EU/EMA and national level)
5. HTA bodies
6. Payers
7. Industry (Diagnostic, Pharmaceutical, ICT)
8. National Policy/Decision Makers
9. Infrastructures
10. EU Joint Actions

The SF will liaise with these stakeholder clusters to understand viewpoints, concerns and requirements which support the work in B1MG.

The SF discussion and consultations with stakeholders will consider the outcomes needs to improve coordination with respect to the following Work Package:

- WP2 - Ethics, Legal, Societal Impact,
- WP3 - Standards & Quality Guidelines,
- WP4 - Federated Secure Cross-border Technical Infrastructure,
- WP5 - Delivering Personalised Medicine cross-borders: Implementation in Healthcare systems and Societal Impact,
- WP6 - Communication, Governance and Sustainability

Finally, SF will also be a place to engage with policy makers from all these stakeholders so as to ensure bottom up and top down alignment. An overview of the levels that the SF will engage with is outlined in the following description.

The clusters will meet in Stakeholder Coordination Forum portal plus four meetings over the whole 3-year project period which will take place virtually or physically.

The key to successful and effective stakeholder integration is the generation of relevant recommendations to address coordination and support decision-making in relation to data, regulatory approval, HTA, clinical, shared decision making and health literacy etc.

B1MG is in a privileged position to provide a coordinated forum between all relevant stakeholders developing or using high-quality data sets; discussions that will address

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uncertainties in decision- making regarding access to data, brainstorm around and set the path for development of guidelines and new clinical pathways, and likely provide a solid evidence base to inform increasingly Member States alignment

WP1 will develop a new model for multi-stakeholder dialogue by creating a Stakeholder Coordination Group, which will be a selection of key stakeholders derived from the Stakeholder Coordination Forum, involving the 1+MG member states Mirror Groups and B1MG partners, and external experts at the EU and Member State level. This will enable broad representation of the diverse models of genomics and healthcare systems in the EU, and include patients and clinicians, regulators, HTA bodies and payers, as well as stakeholders involved in evidence generation. This Stakeholder Coordination Group will be essential to provide input and advice for Member States to ensure the generalisability and applicability of the outputs from the B1MG within EU member states from a bottom up and top down perspective.

Regarding relationship with Policy Makers, given that their responsibilities are linked to legislations which are difficult to influence, this Stakeholder Coordination Group will develop in collaboration with WP6, with the idea to bring the representatives stakeholders information on the B1MG work streams and output, in particular about the objective of supporting the aims of B1MG and the 1+MGG.

4. Description of work accomplished

4.1. Stakeholder Clusters

The Stakeholder Coordination Group consists of 10 different clusters. Each cluster is chaired by a cluster lead selected from the stakeholders. The Cluster Lead will:

- propose a list of experts or organisations within that stakeholder cluster,
- get in touch with them to obtain their approval for participating into the SCG consultations,
- maintain the list of stakeholders and stakeholders' participation active (or replace them whenever necessary),
- check their availability prior to schedule any F2F or teleconference meeting,
- formally invite them to consultations,
- send them feedback about results of the consultation,
- and communicate with them about the progress of the B1MG project.

The coordination of the consultation of cluster members will be done by the WP lead, the European Alliance for Personalised Medicine and its sub-team; it means:

- organisation of the consultation (by email, phone or F2F meeting),
- setting a date for the consultation,

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- providing briefing book to experts,
- keeping track of feedback received,
- producing the summaries.

To avoid asynchronous point-to-point communication and a disconnect cluster, the coordination between cluster leads will be done by WP1 and keeping the WP Leads informed.

4.1.1. Patient organizations

The patient organisations cluster is organised by the disease areas which include at least the areas of oncology and rare diseases, preferably extended to cover also disease fields of common and complex diseases and infectious diseases, all use-cases in the 1+MG initiative.

Each disease area will have a named person as a disease area lead which will derive from the EU representative organisation. Each disease lead in this cluster is liaising with e.g. WP2 and WP5 on disease-specific questions, but also makes sure that it provides a report on that interaction to the WP1 coordinators, to keep discussions on the B1MG Operational Group level in sync.

4.1.2. Specialists, clinicians

The clinicians cluster consists of two subgroups from the oncology, rare disease area

Target members are the relevant medical societies at the EU level such as the European Society of Medical Oncology, European Society of Pathology and corresponding affiliates at the country level.

4.1.3. Academics

Academics and researchers involved in oncology, rare disease, common complex disorders such as in the neurology area and data science.

Target members are relevant academic centres from the relevant disease areas such as Cancer Centres as well as cross-cutting bodies that will deal with issues such as genomics, ethics, legal and medical universities.

4.1.4. Medicines authorities (EU/EMA and national level)

The medicines authority cluster will be coordinated by a representative from the European Medicine Agency and will collect input from regulatory authorities into B1MG activities both in terms of methodology and experience. Members of the medicines authorities cluster can include the following:

- Federal Institute for Drugs and Medical Devices (BfArM)

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- Spanish Agency of Medicines and Medical Products (AEMPS)
- European Medicines Agency (EMA)
- Swedish Medical Products Agency (MPA)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Italian Medicines Agency (AIFA)
- Swiss Agency for Therapeutic Products (SwissMedic)

4.1.5. HTA bodies and projects

The cluster lead of HTA experts will be a representative of EUnetHTA.

The HTA cluster of the Stakeholder Forum will aim to involve a representation of HTA bodies from across Europe, up to 7 HTA agencies in Europe, to be selected in alignment with WP5. The agencies will be chosen according to their willingness to participate in these consultations. The aim is to ensure that there is an understanding of processes and policies that affect the selection and definition of health outcomes and explore big data offers potential to reduce decision uncertainty in HTA assessment of innovative technologies. The cluster already has a good connection with EUnetHTA and will connect with relevant European projects as appropriate.

4.1.6. Payers

Payers have a very different profile across European healthcare systems and within countries as well.

Payers are defined as any decision-makers who are involved in setting therapies price and/or reimbursed price or in deciding about regional or hospital healthcare budget allocation.

However, it is important to pay attention to the fact that collaboration of these stakeholders can be difficult to set for projects done in a Private-Public partnership. Indeed, both at the national and local levels, it can be challenging sometimes to find ‘Payers’ willing to collaborate with the pharmaceutical industry. Additionally, for national ‘Payers’ the price negotiation is 1/ based on the HTA appraisal of the comparative clinical benefit of new therapies; 2/ highly driven by national law and regulations, and very little by research; therefore, it might not be a highly relevant stakeholders group for the B1MG project. The cluster lead will therefore assess first the willingness of these stakeholders to participate in the Stakeholder Coordination Group.

4.1.7. Pharmaceutical, Diagnostic and ICT industry

This will derive from the umbrella trade associations that are active in the sphere of the B1MG project and will work closely with 1+MG WG7, which is assessing industry involvement possibilities and challenges in the 1+MG initiative.

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Target members are those companies active in the Pharmaceutical, Diagnostic, Biotech and ICT industry.

Target groups include COCIR, EFPIA, MedTech Europe etc.

4.1.8 National Policy/Decision Makers

This cluster ensures a connection with key national policy/decision makers involved in the relevant B1MG policy area and involved in the assembly of country representatives of the 1+MG initiative.

Target members are officers and representatives working in national ministries and affiliated agencies. Members will be selected in alignment with WP6 (National Mirror Groups).

4.1.9 Infrastructure

Research Infrastructures are facilities that provide resources and services for research communities to conduct research and foster innovation. They can be used beyond research e.g. for education or public services and they may be single-sited, distributed, or virtual.

They include

- major scientific equipment or sets of instruments
- collections, archives of scientific data
- computing systems and communication networks
- any other research and innovation infrastructure of a unique nature which is open to external users

Target members include EU infrastructures such as the EATRIS ERIC - European Advanced Translational Research Infrastructure in Medicine, BBMRI ERIC - Biobanking and Biomolecular Resources Research Infrastructure, ECRIN ERIC - European Clinical Research Infrastructures Network and ELIXIR, European Distributed Infrastructure for Biological data.

4.1.10 EU Joint Actions

Joint Actions are a type of funding instrument under the third EU Health Programme. They encourage and support cooperation between Member States to improve the health policies that benefit their citizens. Examples include in the area of cancer and rare disease, in alignment with the prioritised use-cases within the 1+MG initiative.

Target members include the JA European Health Data Space, Joint Action on Cancer, Joint Action on Rare Disease, etc.

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4.1.11 International Consortium

International Consortia include networks such as the International Genome Consortium, International Cancer Genome Consortium etc, as well as global standard setting organisations such as GA4GH, that will allow the B1MG to engage with the international community.

4.2 The Stakeholder Coordination Group

The Stakeholder Coordination Group acting in the public interest shall assist the B1MG consortium in its effort to support the 1+MG initiative, which is based upon the commitment of 22 European Member States and Norway that have signed the Declaration 'Towards access to at least 1 million sequenced genomes in the EU by 2022'.

It shall foster exchanges of relevant experience, policies and practices between the Member States and the various parties involved.

To achieve the aims referred to in paragraph 1, the Stakeholder Coordination Group shall:

A. assist the 1+MG by acting as a body to engage stakeholders at the European and national level in the field as outlined in the Declaration 'Towards access to at least 1 million sequenced genomes in the EU by 2022'.
B. contribute to the implementation of 1+MG actions in the field, organised through workstreams of B1MG Work packages and their corresponding Working Groups in 1+MG, in particular by engaging stakeholders in these actions and suggesting improvements to the measures taken;
C. contribute to the preparation of reports on the implementation of the 1+MG programme
D. deliver opinions, recommendations or submit reports to the 1+MG assembly of country representatives, either at the request of the 1+MG initiative, or driven from the B1MG project;
E. assist the B1MG community in international alignment on matters relating to Declaration 'Towards access to at least 1 million sequenced genomes in the EU by 2022'.;
F. assist the B1MG Work Package teams in engaging stakeholders to their work streams, so as to recruit capacity and expertise, have guidance, recommendations and any other action that would provide support to the 1+MG;
G. provide an annual report of its activities.

4.2.1 Membership

The Stakeholder Coordination Group shall comprise of 67 stakeholders members (44 stakeholder representatives plus 23 National Mirror Group representatives) and the corresponding alternates, namely:

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A. one representative per mirror group from ministries or government agencies responsible for 1+MG; the representative shall be designated by the government of each Member State;
B. four representatives from patients' organisations;
C. four representatives from industry which includes: 1 from the pharmaceutical trade association, 1 from the diagnostic trade association and 1 from digital trade association.
D. four representatives from the scientific medical community
E. four representatives from research infrastructure
F. four representatives from universities/academics (excluding medical)
G. four representatives from Medicines authorities (EU/EMA and national level)
H. four representatives from HTA bodies
I. four representatives from payers
J. four representatives from National Policy/Decision Makers
K. four representatives from International Consortium
L. four Representatives of the EU Joint Actions

Members of the Stakeholder Coordination Group corresponding to groups (b) to (k) shall undertake to act in an independent manner. They are under no power of direction from their body of origin when carrying out their tasks as members.

4.2.2 Criteria for Membership

The following criteria should apply to all individuals accepted to be on the Stakeholder Coordination Group (SCG). A recognized expertise, to be demonstrated by one or more of the following:

1. A record of scientific publications on the relevant issues, preferably in peer-reviewed publications or a recognised expert from the respective stakeholder group i.e patient representative;
2. Experience at a high level in global, EU, national or regional activity relating to the issues relating to health, big dataenvironment and other relevant areas, including socioeconomic aspects that the Declaration ‘Towards access to at least 1 million sequenced genomes in the EU by 2022’ sets out;
3. Experience at a high level in the design and management of other major global, regional or national initiatives in health science, assessment, health protection, disease related, clinical, patient management, sequencing, data or other similar functions related to the health environment and other relevant areas, including socio-economic aspects;
4. Demonstrated effective participation in international processes relevant to the health environment or integrated assessment and other relevant areas, including socio- economic aspects; and

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5. The ability to serve in an independent, individual capacity.

4.2.3 Term Of Office

The term of office of members of the Stakeholder Coordination Group shall be for the duration of the B1MG project timeframe, and is expected to be embedded in the governance of the 1+MG initiative.

A member's term of office shall come to an end before the expiry of the three-year period in the event of her/his resignation, the termination of her/his membership of the organisation which she/he represents, permanent incapacity to attend the meetings, incapacity to contribute effectively to the committee's deliberations, or in case of subsequent non-compliance with the qualifications and conditions specified in the call for expression of interests. A member's terms of office may also be terminated if the organisation which nominated her/him requests her/his replacement.

Members whose term of office comes to an end before the expiry of the three-year period may be replaced for the remaining period of their mandate.

4.2.4 External Experts

The SCG may invite any person who is specially qualified in a particular subject on the agenda to take part in the work of the Committee as an external expert.

External experts shall only take part in the work on the particular subject for which their attendance is requested.

4.2.5 Expert Group

The SCG may set up temporary Expert Groups. These groups may notably be established when work of a temporary or ad-hoc nature is required such as preparation of proposals on a specific scientific topic, or preparation of responses to specific questions raised by the Committee in relation to specific scientific fields.

Expert groups consist of external experts selected according to their specific expertise.

The Committee shall adopt a mandate for each working group, indicating its objectives, composition, meeting frequency and the duration of its activity.

For the preparation of its opinions, the Stakeholder Coordination Group may entrust a rapporteur, who can be one of its members or an external expert, with the task of drawing up reports in accordance with its rules of procedure.

One or more members of the Committee may be nominated by the Committee to participate as observers in the activities of other expert groups of the Commission.

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4.2.6 Remuneration

No remuneration shall be attached to a member's duties; travelling and subsistence expenses for meetings of the BM1G and of the working groups set up under the B1MG shall be met in accordance with the administrative rules in force.

4.2.7 Frequency of Meetings

The Stakeholder Coordination Group shall be convened by the WP1 of the B1MG and shall meet on a regular basis. It shall meet at least twice per year virtually.

4.2.8 Quorum

1. The quorum required for the adoption of opinions, reports or recommendations by the Stakeholder Coordination Group shall be reached when two thirds of the total members of the Committee are present.
2. Whenever possible, scientific opinions, reports or recommendations of the Committee shall be taken by consensus. If such a consensus cannot be reached, the opinion shall be adopted by a majority of the Committee members who are present.
3. The Commission, when requesting the Committee's opinion or a recommendation, may set a deadline within which the opinion should be delivered.
4. The views expressed by the different categories represented in the Committee shall be recorded in the minutes, which shall be transmitted to the B1MG. Where the opinion requested has been agreed unanimously by the Committee, the Committee shall draft common conclusions which shall be annexed to the minutes.
5. Draft opinions and recommendations can, after approval of the Chairperson, be submitted by the Secretariat to the Committee for adoption by a written procedure to be laid down in the rules of procedure of the Committee. However, such written procedures should be, as much as possible, restricted to urgent measures required to be taken between scheduled meetings.

4.3 Discussion

4.3.1 Consultative Mechanism

4.3.1.1 Type of consultations

The Stakeholder Group has identified three mechanisms for eliciting stakeholder feedback through consultation and discussion within the clusters, or across multiple clusters at a time.

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4.3.1.2. Face2Face Meetings / Feedback in person

Four face2face meetings of the Stakeholder Group are foreseen within the duration of the B1MG project.

A written Stakeholder Group Feedback Report will be produced, providing summaries of the discussions, describing the consensus and disagreement on the topics discussed. The Stakeholder Group Feedback Report will be shared in the coordination stakeholder portal.

4.3.1.3. Feedback by electronic surveys and E-Mail

Survey monkey will be used to elicit feedback from the clusters on a specific topic. The survey will be distributed to stakeholders of each cluster by the cluster lead. A Stakeholder Group Feedback Report will be produced by task lead and subteam providing summaries of the qualitative and quantitative feedback received.

E-Mail may also be used for consultations, however is not seen as very efficient to collect and document feedback in a structured way.

4.3.1.4. Feedback and discussion by teleconference

A teleconference system will be used for group discussions. The system to be used for such consultation will be clarified later.

4.3.2 Process to set up a consultation

4.3.2.1. Requesting a consultation

Channel 1:
When a WP member (thereafter called the applicant) would like to activate a consultation of the SCG, an email request should be sent to WP 1 leaders (thereafter called WP1 LT) with the following information (with copy to the WP leads to which the applicant belongs to):

- Objectives of the consultation
- Clusters the applicant would like to consult and eventually number of stakeholders per cluster
- Involved partners in B1MG (other WP members, etc...)
- Type of consultation: individual TC or group TC with length of the TC, or electronic consultation or F2F meeting (please note that some restrictions apply to the F2F meetings)
- Expected date to consult them

Channel 2: Stakeholder Coordination Portal

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Through the Stakeholder Coordination Portal, this will act as the main forum for discussion with stakeholders on a regular basis. The task lead of the Portal is EATRIS which is led by Emanuela Oldoni.

4.3.2.2. Validation of the objectives of the consultation

For both channels, the WP1 LT will communicate the topic of the consultation to the B1MG Steering Committee to obtain their approval to go to the next step of the consultation process. Feedback is expected in a timeframe of a working week (5 days).

Once the Steering Committee has given positive feedback on the topic of the consultation, the Task lead and participants will distribute the objective of the consultation to the cluster leads. The WP 1nd cluster leads will:

- assess and validate which clusters are relevant to be consulted on the topic of the consultation,
- give recommendation regarding the type of the consultation
- assess feasibility of the timeline for consultation

The output of this step will be a written answer on these three points to the applicant, with copy to his/her WP leads.

Once the principle of making a consultation for the topic submitted by the applicant has been agreed by WP1, then the next steps are implemented to organize the consultation.

4.3.2.3. Preparing the consultation

The WP1 Leader and co-leads will set a TC with the APPLICANT and his/her team to get the supplementary details of the consultation: more detailed objective of the consultation, targeted stakeholders, type of consultation, length of consultation, and possible dates for the consultation; as well as information to send stakeholders ahead to maximize the consultation, type of feedback expected, format of feedback; any logistical resources needed.

The following steps are required to be done by the APPLICANT and his/her team to prepare the consultation

• Provide to the Task 1.1 leaders (thereafter, Task1.1 LT) an invitation letter which will be provided to the stakeholders. The letter should follow the B1MG format with related logo, present the objectives of the consultation, the type of consultation and include expected dates / timelines (depending on the type of consultation) of the consultation and output required to the stakeholders

- Set themselves the TC consultations with stakeholders, in case of TC with only one stakeholder at a time

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- Prepare a presentation or a briefing book and/or questionnaire to submit to the stakeholders
- Take minutes of the TC or F2F meeting with the stakeholders

The following steps will be set by the Task1.1 LT for organizing the consultation:

- Submit the stakeholders lists to the APPLICANT and pick up with him/her the names of the ones to be consulted
- Set up the venue of the consultation for F2F meeting and support for organizing the trips of the Stakeholders invited to the meeting; and manage the budget for the event
- Support for group TC (consultation of multiple stakeholders in one TC), to the extend it's no more than one TC per cluster
- Ask the Cluster Leads to:

o Contact the chosen stakeholders and send them the invitation letter

o Secure the consultation with a minimum of stakeholders from their clusters. Or find replacement whenever necessary

o Attend the meetings when appropriate from APPLICANT standpoint or wished by the Lead

4.3.2.4. Dissemination and Tracking of feedback by each cluster

The following steps are required to be done by the APPLICANT and his/her team to finalize the consultation:

- Prepare a summary report of the output of the consultation (following the B1MG internal review process)
- Send the summary report to each stakeholder consulted in a joint email with the Cluster Lead, plus the B1MG SCG representative.
- Collaborate with WP1 LT and WP6 for developing and implementing a dissemination plan of the findings of the consultation to other B1MG participants and externally whenever appropriate.

The following steps will be set by the WP1 Lead for ending the consultation:

- Ask the Cluster Leads to:
    - Send the summary report to each stakeholder consulted in a joint email with the applicant
    - Thank the stakeholders for their participation by an email or a letter with official template of B1MG project

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- Collaborate with the applicant, WP1 LT and WP6 LT for developing and implementing a dissemination plan of the findings of the consultation to other B1MG participants and externally whenever appropriate

The aforementioned reports about the feedback received will be provided to all cluster members as well as to the B1MG Steering Committee, consisting of the Work Package leads.

The WP leads are responsible to disseminate the feedback to the WP members concerned. They are also responsible for feedback to the Stakeholder Forum and the B1MG Steering Committee where the feedback has been incorporated in the work and implementation of the WP.

4.4. The Stakeholder Coordination Portal

The above methodology provides the state of play of how the Stakeholder Coordination Group operates. This will be complemented by the Stakeholder Portal implemented in close collaboration with WP6 . The stakeholder coordination portal aims to efficiently deliver timely analysis of challenges, opportunities and solutions resulting from the SCG to the operational WPs. It delivers tools and defines workflows to de-risk and improve the flow of data generation and integration towards patients. These tools will help reduce cross-border barriers, and facilitate the development of operational pipelines based on the integration of genomic and health data.

4.4.1 Main features of the stakeholder coordination portal

The stakeholder coordination portal has to meet the following requirements:

1. Facilitate community participation and engagement
2. Facilitate communication and collaboration
3. Facilitate documents sharing and management

4.4.2 Facilitate community participation and engagement

The stakeholder coordination portal allows the users to share contact information and develop a network within the B1MG project. This allows the creation of a vibrant community, organised and focused, that can collaborate in an effective and advantageous way. People can be organised in groups that reflect the stakeholder clusters with the possibility of users to create transversal sub-communities supported by specific communications channels that provide access to a set of additional functionalities including group VC .

4.4.3 Facilitate communication and collaboration

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In order to facilitate the communication and collaboration between users, the stakeholder coordination portal has been developed with the following features:

- discussion forum capability with secure access to allow information sharing;
- a space for surveys and for sharing survey results;
- tools that enable meetings, instant messaging, chat as space for dialogue;
- the ability of authorised users to create virtual workspaces that enable to share files and documents (Reports, TC minutes…);
- the possibility to integrate platform for video and audio conferencing for virtual meetings;
- full use of Outlook functions for emails, calendar and tasks for sharing relevant events for the project;
- a space for the consultation process

The stakeholder coordination portal is divided in different workspaces for specific purposes, called rooms. Rooms provide a shared view into the work being done. With access to the same information, everyone in the channel can work in lockstep, and new members have full context when they join. While working in channels, conversations and files become a searchable archive that gets more useful with time.

The stakeholder portal has been released with a limited set of the functionalities described above that will be extended as and when needed according to the utilisation and needs of the stakeholders. Details of the stakeholders portal can be found in D6.3 Communication strategy and in D6.2 Project Data Management Plan.

4.4.4 Facilitate documents sharing and management

The stakeholder coordination portal is provided with a space for documents storage. This allows authorised users to easily have access to relevant documents and contribute to them. This space can be used as a repository for different types of documents, such as meeting agendas and minutes, working documents and reports.

5. Conclusions

This document establishes the structure (SF, SCG) and the processes that are going to enable the involvement of Stakeholders in the validation, promotion and adoption of the recommendations that will be produced by the technical WPs in order to support the implementation of the 1+MG Roadmap.

6. Next steps

- Establishment of the Stakeholder Coordination Group

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- Engage the SCG through stakeholders meetings and the Stakeholder portal

7. Impact

This document describes the mechanisms for the ways that the:

- Stakeholders can interact with the B1MG
- WP can interact with stakeholders at the regional, national and EU level
- WP can focus on specific stakeholder to drive the aims of their WP
- Stakeholders and WP can reach consensus
- Stakeholders from different levels at the local, regional, national level and EU level can link to the B1MG as well as the 1+MG
- Provide a sustainable structure

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