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HBM4EU from the Coordinator's perspective: lessons learnt from managing a large-scale EU project

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ABSTRACT

We discuss some important management issues of the Human Biomonitoring Initiative (HBM4EU) from the perspective of the Coordinator that may be valuable for the design and management of similar projects. As a large-scale international collaborative project, HBM4EU comprised 118 institutions from 30 countries and the European Environment Agency and had a budget of about €74 million. It has set up an innovative cooperative network of national and EU authorities and scientific institutions at the science-policy interface. A project of this scale raises major management challenges and requires transparent, efficient, and well-organized administrative and scientific steering structures. We present four major points: *First*, prior to the beginning of the project, the Consortium Agreement needs to be well elaborated to prevent conflicts during the project lifetime. *Second*, a strong role for national and EU policy-making authorities in the administrative governance structure enhances the interest of recipients of project results. *Third*, large-scale international collaborative projects need an elaborate and well-financed scientific governance structure. *Fourth*, a differentiation of funding rates among project activities threatens to create conflicts. HBM4EU provides a prototype for EU funded large-scale projects targeting future policies for realizing the Green Deal and Zero Pollution Ambition in the field of chemicals, health, and environment.

1. Introduction

The European Human Biomonitoring Initiative (HBM4EU) started in 2017 and ended mid-2022. As a large-scale multi-national project, it focused on science-to-policy cooperation, broad data sharing and the systematic establishment of networks in the field of Human Biomonitoring (HBM) at national, European, and international levels (Ganzleben et al., 2017). Over a period of five and a half years, HBM4EU has produced new methods and findings that provide a scientific basis for policy making in the sector of environmental health and chemical policy. HBM4EU is unique in its form. It was the first HBM project located directly at the science-policy interface and had developed an ambitious research programme targeted to answer open policy relevant questions concerning prioritised chemicals, which had been identified by EU institutions and partner countries. The project was organized as a co-funded European Joint Programme (European Commission, 2022), designed to support coordinated national research and innovation projects and allowing for the implementation of joint activities, e.g. research and innovation, networking and training. HBM4EU provides a

blueprint for the even larger Partnership for the Assessment of Risk from Chemicals (PARC) and other EU funded large-scale projects targeting future policies for realizing the Green Deal and Zero Pollution Ambition in the field of chemicals, health, and environment.

A project of this scale raises major management challenges. HBM4EU had an overall budget of nearly €74 million, of which roughly €50 million were funded by the European Union's research and innovation funding programme Horizon 2020. EU funding was complemented by roughly €24 million matching funds from participating countries. The project started in 2017 with 106 partners from 26 countries and the European Environment Agency (EEA). By the end of its lifetime, it had grown to 116 partners from 30 countries plus the EEA. It included more than 600 collaborators, mostly scientists from public authorities, research institutions and universities. The German Environment Agency was appointed as Coordinator of HBM4EU.

In this article, we discuss some management issues of this large-scale, international collaborative project from the perspective of the Coordinator that may be valuable for the design and management of similar projects. While numerous substantial insights produced by HBM4EU and

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other projects are reported elsewhere, there is sparse information concerning experience made in the management of such large-scale co-funded EU initiatives. The project has produced many valuable lessons that may be useful for future initiatives. In the field of HBM, literature on previous projects mostly describes scientific results or the management of data and work content (Den Hond et al., 2015; Fiddicke et al., 2015). Thus, this paper differs from many reports of EU projects. It discusses some “lessons learnt” from the management of HBM4EU from the Coordinator’s perspective. It focuses on four management issues, which might be of particular interest for future initiatives, namely the preparatory phase, the administrative governance structure, the scientific governance structure, and financial matters.

We develop four major points: *First*, prior to the beginning of the project, the Consortium Agreement needs to be well elaborated to prevent conflicts during the project lifetime. *Second*, a strong role for national and EU policy-making authorities in the administrative governance structure enhances the interest of recipients of project results. *Third*, large-scale international collaborative projects need an elaborate and well-financed scientific governance structure. *Fourth*, differentiation of funding rates among project activities threatens to create conflicts among project partners.

2. Preparatory phase: negotiating the Grant Agreement and the Consortium Agreement

Transparent and fair decision-making was essential for joint work in HBM4EU, even before the project started in 2017. Based on the Horizon 2020 guidelines, HBM4EU was contractually anchored in two agreements, namely the Grant Agreement, signed by the EU and the project Coordinator, and the Consortium Agreement signed in 2017 by then 38 Grant Signatories. The number of Grant Signatories increased over time to 41, to which another 77 organizations were associated as Linked Third Parties.

Both the European Commission and the Coordinator encouraged the participating countries to name only one agency each as Grant Signatory, while other national institutes could be included as Linked Third Parties. This organizational structure was intended, on the one hand, to promote cooperation among different agencies and research institutions within a country, rather than advocating their own organizational needs in the consortium. On the other hand, it reduced management complexity by limiting direct interaction between the Coordinator and the Management Board on the one hand and the Grant Signatories on the other hand. The Grant Signatories would assume responsibility as lead agencies for all Linked Third Parties of their country involved in HBM4EU. This three-tier organizational structure (see Fig. 1) proved to be successful and did not create any specific problems.

The content of the Grant Agreement was largely pre-determined by, or negotiated with, the European Commission as the funding authority. The Grant Agreement defined the legal rights and obligations of the funding authority and the Grant Signatories. HBM4EU used a model Grant Agreement provided by the European Commission (European Commission, 2014). Options in the model contract itself were selected

according to the envisaged actions, which limited opportunities for proposing modifications. In its annexes, the Grant Agreement (HBM4EU, 2016b) outlined further structures (including budget and work package descriptions for the entire project runtime as well as descriptions of all partners, milestones and deliverables) for the work of the initiative.

In contrast, the Consortium Agreement (HBM4EU, 2016a), an agreement between the Coordinator and all Grant Signatories defining roles, rules and responsibilities, provided ample room for negotiations within the project. The Consortium Agreement relied on the DESCA Horizon 2020 Model Consortium Agreement (DESCA Core Group, 2016), which provided suggestions for numerous formal provisions that were mostly kept. However, the provisions of the template were considerably expanded to tailor the Agreement to the specifics and needs of the HBM4EU consortium. The set-up of the Consortium Agreement was an integral tool to establish basic conditions for the cooperation within the consortium, especially for preventing misunderstandings and conflicts that potentially could have arisen over time between the numerous partners in such a large-scale initiative.

From the Coordinator’s point of view, two aspects were essential when elaborating the Consortium Agreement: *First*, with the Consortium Agreement we endeavored to avoid postponing many issues that had to be addressed during the project’s lifetime and sought to regulate them already in advance. Hence, the Agreement became a lengthy document that regulated in some detail, inter alia, the responsibility of partners, liability and financial provisions, the administrative governance structure of the project, the scientific governance structure, governance bodies and their decision-making procedures (including agenda setting and deadlines for availability of documents), as well as issues of data protection and the exchange of (partly sensitive) HBM data, data dissemination and access rights, etc. We will discuss some of these topics below. The preparatory phase proved to be time-consuming, but the negotiation of project rules and obligations en bloc supported agreement, because all sides had to compromise. The detailed Agreement facilitated the day-to-day management of the project, and helped avoid conflicts and cumbersome debates at later stages of the project. Moreover, it provided the Grant Signatories with certainty on how the project would be conducted. The Consortium Agreement had to be signed by all Grant Signatories as a precondition for participation and also became binding for the Linked Third Parties. It did not have to be significantly amended during the lifetime of the project, thus reflecting the low level of conflict on project governance.

Second, negotiation of the Consortium Agreement was conducted in a highly transparent and fair manner. Agreement drafts were widely circulated and comments and proposals for revisions were communicated openly and accompanied by indicating the response action, i.e. whether the draft was amended or not, and in the latter case, the respective reasoning. In case of disagreement, meetings were held on short notice to facilitate finding solutions suitable for all involved parties.

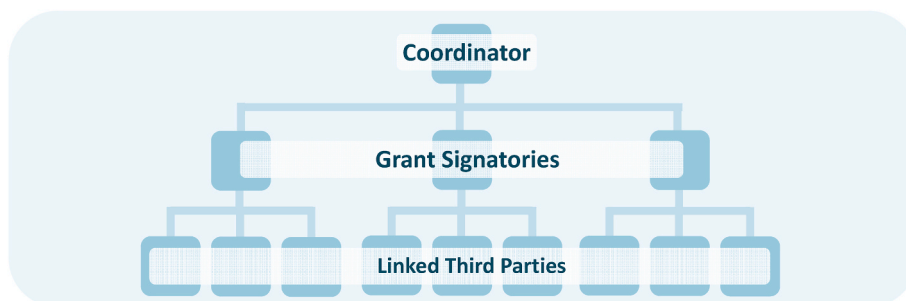


Fig. 1. HBM4EU organizational structure.

3. The administrative governance structure

The Consortium Agreement defined the administrative governance structure and established the following bodies for HBM4EU (see Fig. 2):

- The **Governing Board** as the ultimate decision-making body of HBM4EU;
- The **Management Board** as the operative body for the execution of HBM4EU, which reported and was accountable to the Governing Board;
- The **Stakeholder Forum** providing opportunities for stakeholders to feed in their knowledge and perspectives on priority setting and implementation of HBM4EU;
- The **Advisory Board** providing scientific and policy advice;
- The **Ethics Board** providing advice on the ethically correct conduct of HBM4EU.

The *Governing Board* was the project’s supreme decision-making body. It comprised the programme owners of the national programmes engaged in the HBM4EU Initiative as well as two EU agencies with particular interest in HBM, namely the European Chemicals Agency (ECHA) and the European Food Security Agency (EFSA) – but not the Grant Signatories. The national programme owners were superior public authorities (often national ministries) from the participating countries, which steer and finance national HBM studies and research programmes of their countries. Bringing in these programmes and respective data as background was a prerequisite for participation in HBM4EU. The Governing Board made the most important decisions on an annual basis, including adoption of the Annual Work Plan, project budget, intellectual property rights, and the evolution of the consortium. There were two main reasons for assigning these decisions to the Governing Board. *First*, this body comprised those member state authorities that were responsible for financing the matching funds of 30 percent of the whole project budget. *Second*, these national institutions and the two European Agencies were national and European regulators that would make use of HBM4EU results and data. The alternative had been to involve these actors in HBM4EU via an advisory body. By giving them the opportunity to decide on critical matters as member so of the Governing Board, they

gained more interest in the project and were directly involved in setting project priorities, as reflected in the Annual Work Plans and progress reports to the European Commission. This arrangement proved to strengthen the science-policy interface of HBM4EU tremendously, as indicated by the relatively high level of representatives.

To establish the Governing Board as the supreme decision-making body, some institutional arrangements had to be made.

The members of the Governing Board were not those agencies receiving research money and doing the actual project work, and they were not signatories of either of the two project agreements. The Grant Agreement was signed by the Coordinator (German Environment Agency) and the funding agency (European Commission), while the Consortium Agreement was signed by the Grant Signatories. This raised the question of how the Governing Board could be authorized to make major project decisions. As a solution, the Consortium Agreement stipulated to assign this authority to the Governing Board. By this arrangement, the Grant Signatories as the contracting parties to the Consortium Agreement delegated some decision-making authority to the Governing Board and accepted decisions of the Board as binding. To commit the Governing Board to the Grant Agreement and the Consortium Agreement, acceptance of Governing Board decisions as binding for the project was limited to decisions being made in accordance with the two founding agreements. In practice, this arrangement was successfully implemented and did not create any specific problems for the project.

Furthermore, five countries did not manage to designate a single national authority as national programme owner and member of the Governing Board. Three countries designated two authorities and two countries even three. The main reason was that several ministries, e.g. health, environment, and research, were involved in national activities related to HBM4EU and did not manage to agree on a lead authority. In these cases, countries were represented by more than one member, but did only have one joint vote and had to indicate, which of their members would cast that vote. It made voting procedures more complex, but did not pose any serious problems.

As a corollary of establishing the Governing Board as the supreme decision-making body, HBM4EU did not have a body comprising the Grant Signatories. Given that major decisions were made by the

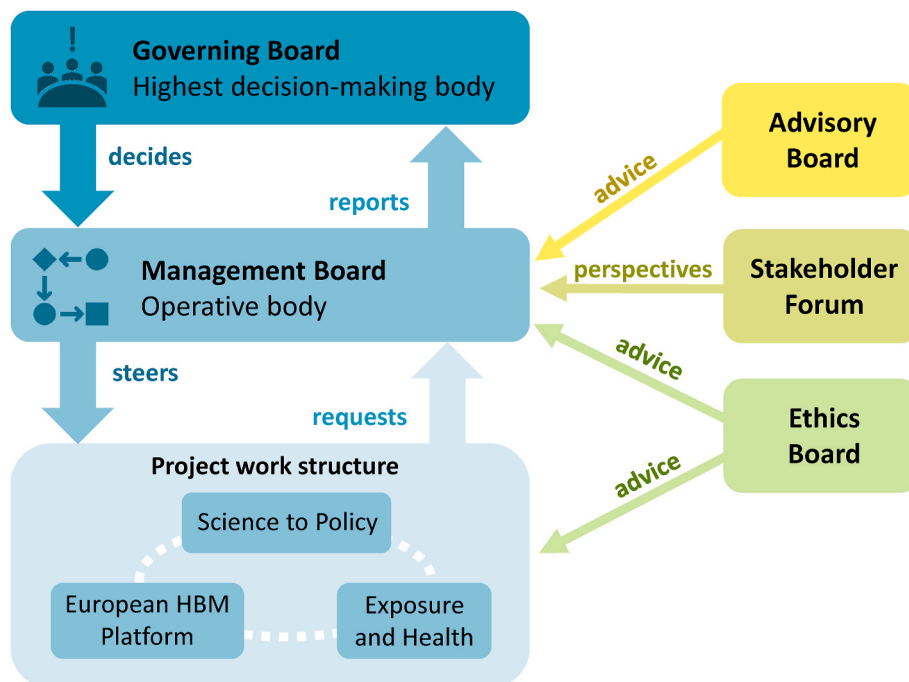


Fig. 2. HBM4EU governance structure.

Governing Board and day-to-day decisions by the Management Board, a body of Grant Signatories was deemed to have no function within the administrative structure of HBM4EU. However, the Grant Signatories played a major role in the scientific governance structure of the project. At some points, concerns were raised that Grant Signatories carried financial responsibility for their institutions and their Linked Third Parties without having a voice in administrative decision-making. Rather, they had to voice specific interests or needs through their country's members in the Governing Board. However, during the lifetime of the project, the lack of direct representation of Grant Signatories did not create any single problem brought to the attention of the Coordinator.

The *Management Board* was the main operational body of HBM4EU. It comprised the leaders of the fifteen work packages, as well as pillar leaders and the Coordinator and Co-coordinator, all of which were also Work Package Leaders. Since some persons led two work packages, the Management Board consisted of thirteen members and met roughly six times per year. Until the Covid-19 crisis forced a switch to virtual or hybrid meetings, these meetings were usually held in person. The main task of the Management Board was the preparation of the Annual Work Plan and the Annual Summary Progress reports as well as amendments to the Grant Agreement, all of which were submitted to the Governing Board for adoption. The Management Board also adopted decisions on many other issues, such as publications and the allocation of the reserve budget. It also discussed proposals for new activities and proposed the candidates for various boards, to be appointed by the Governing Board. Some of its decisions, especially those with implications for the use and allocation of resources, bore the potential for tension in the consortium. A transparent and structured decision process was therefore required.

To structure the decision process and enable the Management Board to take rapid and informed decisions, decision proposals submitted by the Coordinator or any other board member were prepared by standardized "Decision Memos", which provided a simple description of the decision asked for by the petitioner (see Table 1). Decision Memos were primarily used to facilitate proposals to decide on changes of the five and a half year work plan (Description of the Action) and the Annual Work Plans, which had implications for project activities and resources, as well on project publication initiatives. They required petitioners to justify changes to proposed activities and related resources, thus making the implications transparent. The use of Decision Memos available in time before a meeting as a preparatory tool for Management Board decision-making proved to be highly successful, as it ensured well-prepared and transparent decisions. Thus, it allowed participants to review proposals in advance and coordinate with partner institutions; and it precluded ill-prepared ad hoc decisions. The preparatory tool of Decision Memos was adopted later by the Governing Board. It is highly

recommendable, especially for larger-scale projects with multi-player boards in charge of decision-making. To avoid repeated discussion on its usefulness, Decision Memos should be provided for in the Consortium Agreement.

The *Advisory Board* played an important role in the project. It comprised members from international organizations and EU agencies, key players of international HBM studies from the US, Canada and Japan, and experts from various research areas related to HBM4EU. The Advisory Board was actively used to obtain input in and feedback on project activities. Repeatedly, Pillar Leaders asked the board for advice on the appraisal of progress achieved, remaining gaps, and perspectives for subsequent activities. The advice given has been implemented in HBM4EU activities and responses were reported back to the Advisory Board with requests to discuss their appropriateness. The interdisciplinary input of the Advisory Board has considerably improved HBM4EU activities. Moreover, the board supported the international outreach of the project to numerous institutions involved in related activities.

The *Ethics Board* consisted of several ethics experts and was consulted when advice was needed. It supported the task lead in making all partners aware of national ethics requirements and the EU General Data Protection Regulation (GDPR), which entered into force during the project's lifetime. It had an advisory and oversight role, while national contributions for studies still had to obtain separate ethical agreements prior to the respective activity.

The *Stakeholder Forum* was used to inform various stakeholders about, and enable them to comment, on HBM4EU activities. The forum comprised a broad range of members of different backgrounds, such as non-governmental organizations and industry associations. It enabled the HBM4EU project to realize the perspectives and needs of the represented stakeholder groups and design communication and dissemination strategies accordingly.

An important component of communication within HBM4EU was the so called "meeting week". All project bodies, with the exception of the Management Board, met generally once a year back-to-back during the same week. One important part of this meeting week was the meeting of the Consortium, in which all project partners discussed content-related issues and held work package meetings. The format of a meeting week was highly successful because it provided the prime opportunity for project partners and members of administrative bodies to meet and interact. Scheduling meetings in a single week also saved travel time and expenses.

4. The scientific governance structure

A science-to-policy project of this size and complexity cannot be effectively steered by a single person; it needs a scientific governance structure in addition to the administrative governance structure. HBM4EU included a wide range of scientific activities and required expertise from various disciplines. Many activities were based on highly specialized knowledge, such as conduction and interpretation of epidemiological studies, targeted and non-targeted chemical analysis of exposure in human blood and urine, computational modelling of exposure and intake of chemicals by human beings, investigation of effects by systematic derivation of effect markers and adverse outcome pathways, assessment of mixtures of chemicals and their adverse effects, science-to-policy transfer of results, and communication with policy makers and stakeholders. Guidance and supervision of these activities, as well as the control of the quality of products were key scientific tasks with a strong relevance for reaching the overall project goals. They determined the extent to which project results would be useful for policy-making and regulation.

HBM4EU had a pyramidal scientific governance structure (see Fig. 3). It was organized in the form of three pillars, which dealt with science-to-policy issues, HBM studies, and exposure and health studies. Every pillar comprised four to six work packages, and every work

Table 1

Structure of a Decision Memo as used in HBM4EU Management Board and Governing Board.

Section No.	Section	Question to be answered in this section
1	Cause and purpose	<ul style="list-style-type: none"> Why does this decision need to be taken by the board? What exactly is the issue the board is asked to decide upon?
2	Current status and background information	<ul style="list-style-type: none"> What is important background knowledge required for the board's informed decision? What is the current status of the issue?
3	Proposal for solutions	<ul style="list-style-type: none"> Which solutions can be proposed for the aforementioned issue?
4	Consequences	<ul style="list-style-type: none"> What are the consequences of the proposed solutions (e.g. financial impact)?
5	Vote/recommendation	<ul style="list-style-type: none"> What is recommended for the board to agree upon?

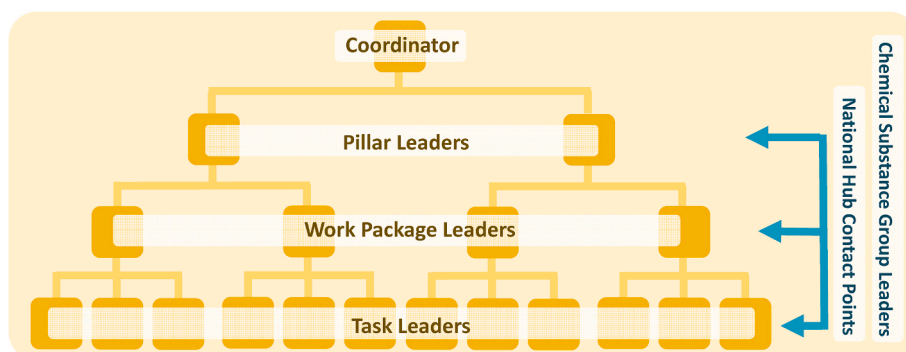


Fig. 3. HBM4EU scientific governance structure (schematic).

package was composed of several tasks. This structure reflected the idea of a clear hierarchical responsibilities. Pillar Leaders were responsible for all activities within their respective pillar. Under their authority, Work Package Leaders were responsible for the sub-set of activities within their work package. Under their authority, Task Leaders in turn were responsible for the subset of activities within their respective tasks. Hence, Task Leaders reported to their respective Work Package Leaders, which reported to their respective Pillar Leaders, which reported to the Coordinator. This applied also to quality control and approval of products and deliverables, as a precondition for the release of funding.

Outside of this hierarchical structure, Chemical Substance Group Leaders were responsible for integrating diverse insights on specific groups of chemicals elaborated in different pillars, work packages, and tasks. HBM4EU focused on answering open questions on priority substances relevant for policy-making and regulation identified by EU institutions and HBM4EU partner countries. These questions did not fall into a single task or work package. The task of the Chemical Substance Group Leaders was to encourage interaction across all work packages and to integrate results. It was highly important for the project as a whole and relied heavily on the output of relevant tasks and work packages.

Likewise, outside the hierarchical structure, National Hubs contributed to building a long-term HBM European Programme and infrastructure by bringing together national HBM activities. They were coordinated by a National Hub Coordinator and fed their domestic needs into the European process. Thus, they contributed to the objectives of HBM4EU and learned from the work carried out in the project. This approach enhanced coordination in countries, in which no systematic coordination for activities in the field of HBM had existed before.

Altogether, this scientific governance structure worked quite well. Most Pillar Leaders, Work Package Leaders and Task Leaders, as well as Chemical Substance Group Leaders took their responsibility serious. They coordinated and integrated the activities in their respective areas actively and supervised the timely submission and quality of deliverables effectively, with a view to realizing the overall goals of the project. They heavily contributed to the success of the project. As a result, HBM4EU delivered quality assured HBM data from across Europe, which establishes the baseline for the assessment of the EU chemical policy strategy and its success. HBM4EU also established a broad dialogue with policy-makers, stakeholders, and the wider public, including dissemination of project results through a broad variety of communication channels. However, the activities of the Pillar Leaders, Work Package Leaders and Task Leaders relied heavily of the commitments of individuals to the overall goals of HBM4EU and to fulfilling their steering responsibilities within the project.

In retrospect, HBM4EU had allocated far too few resources to scientific steering activities. This was an unfortunate result of the widely shared endeavour to limit the administration and coordination costs of the project to a minimum. However, the scientific governance of an international and interdisciplinary project of the size of HBM4EU is in

itself a scientific, not an administrative task, and it influences the overall project success heavily. After all, its pillars and work packages in themselves are comparable in size to many other EU projects as a whole. Well-structured scientific governance helps to use allocated resources effectively and in accordance with the project objectives. In practice, Pillar Leaders and Work Package Leaders were funded in an amount of few person months per year. This meant that they could not invest all or most of their work time in project steering activities, which then proved to be insufficient. Chemical Substance Group Leaders were also under-financed, which proved to be particularly difficult for those responsible for big substance groups comprising numerous substances, such as pesticides or plasticisers.

To strengthen the scientific leadership tasks structurally, incentives for individuals to fulfil their responsibilities properly should be reinforced. This might be realized in a number of ways. *First*, Pillar Leaders and Work Package Leaders could be assigned separate tasks of producing deliverables that integrate findings from more detailed activities within their areas of responsibility. For HBM4EU, it could have meant producing deliverables that compare findings across national studies or compare HBM data with results of exposure modelling. Integrated tasks should be carefully defined in the Description of Action and in Annual Work Plans. This would create a scientific interest, rather than mainly an administrative one, in steering and integrating activities. *Second*, a larger amount of funding should be allocated to the expanded scientific leadership functions (in contrast to purely administrative coordination). Pillar Leaders, and possibly Work Package Leaders, should invest most of their working time in the project, rather than in activities beyond the project. Depending on the extent of their integrative tasks, this might imply funding of senior scientists as assistants or small working groups, depending on the extent of the task. *Third*, scientific leadership tasks should be carefully defined in the Consortium Agreement to avoid conflicts about roles and responsibilities later on.

5. Financial matters

Budgetary issues are always of utmost concern for all project participants and bear high potential for conflicts within a consortium, unless clearly regulated from the beginning. The general allocation of funding for the project was defined in the Description of Action as part of the Grant Agreement, agreed upon with the European Commission. It was further specified in the respective Annual Work Plans. However, the need for resources could not always be exactly pinpointed in advance. Moreover, some tasks were not realized for different reasons and others were added later on, so that some resources were reallocated through the Annual Work Plans. Accordingly, many budgetary details remained open and needed to be decided on during the project lifetime. Detailed procedures and criteria for preparing and deciding on such changes to resource allocations can facilitate agreement and at the same time avoid conflicts and competition over these resources. Such procedures should be defined in the Consortium Agreement and comprise detailed

guidance for the continuous and transparent monitoring of budgetary issues and regular budget reviews provided by the Coordinator.

Two specific issues should be mentioned. First, the HBM4EU budget was determined as a total sum in Euros, while the allocation of funding of project staff to participating institutions occurred in the so called "Person Months" as predetermined by the European Commission. Of course, there are good reasons for this system. Person Months provide a simplified solution when planning activities in order to reach project objectives, because they are directly related to the work done by a given person in a month. Moreover, Person Months account for the differences in salary-levels of the participating countries. However, we did not translate the amount of Person Months assigned to a given institution for their project activities into a fixed amount of funding in Euros. This meant that any amount of costs per Person Month could potentially be eligible as long as the respective partner could provide proof of the actual costs. In some cases, this created claims beyond estimated costs. In other cases, actual cost claims were lower the approximated sum allocated to them at the beginning of the project, but project partners expected that the whole sum would be available for them during the entire runtime of HBM4EU. Even more important, the final budget per partner could only be estimated at the end of each reporting period when costs had been claimed. To avoid these budgetary issues, consortiums should find ways for translating calculations made in terms of Person Months into fixed budgets in Euros, which will remain set for the participating institutions throughout the project runtime.

Second, project internal funding rates assigned to different activities were a particular source of budgetary conflict. HBM4EU had an overall funding rate of 70% from the EU research programme Horizon 2020 and 30% matching funds from the member states. However, there was agreement that some coordinating activities should have a funding rate of 100%. To compensate for a selective 100% funding rate and still stay within the overall project budget, all other activities had to receive somewhat less than 70% of EU funding. Therefore, the consortium agreed to and defined in the Consortium Agreement several categories of differing internal funding rates. For example, concept development was funded at 70%, while the conduct of HBM studies received only 50 percent of EU funding, as these studies were typically also for the benefit of the respective member states. However, the boundaries of categories were subject to interpretation and, accordingly, led to some conflict. To prevent such conflict, categorization of activities with different internal funding rates to compensate for 100% funding of coordination should be avoided. A single funding rate for all other activities would have precluded these conflicts.

6. Conclusions

HBM4EU has created an innovative type of project focusing on the science-to-policy interface. It was conducted to support policy-makers and regulators with targeted research results and the data needed at EU and national levels for setting priorities and regulation for the management of chemicals. As a major innovation, it heavily involved policy-makers in all project phases, starting early on with the preparation phase and involving them until the project closure. It aimed to identify open policy-relevant questions and to develop a demanding research plan to answer these questions. This process was accompanied by a continuous dialogue between scientists, regulators and policy makers which established and strengthened cooperation among these groups. Another innovative step was the creation of an EU-wide network of national and EU agencies, research institutions, universities, and stakeholders. This network was interlinked with national networks coordinated via the National Hubs and resulted in a new level of shared agreement on the meaning and interpretation of data and results as well as on the health relevance of the exposure of the European population to chemical substances.

As the first initiative of its size and nature in the field of exposure and health, HBM4EU generated new challenges for project coordination. Its

size in terms of funding, its number of collaborating partners, and its ambitious scientific goals exceeded preceding projects in this area by far. As the spectrum of activities was enormously broad, steering required new ways of administrative and scientific governance. The effort invested in the elaboration of the extremely detailed Consortium Agreement ensured procedural transparency and clear expectations for all actors involved and thus precluded many conflicts during the lifetime of the project. Another major innovative element was the specific construction of the Governing Board, which bound policy-makers as addressees of results exceptionally tightly to the project. Altogether, the carefully prepared governance arrangements worked well. However, one major conclusion with a view to future projects is that in large-scale projects of this nature, scientific governance would benefit from further development of structure, tasks, and incentives for leaders. This would lead to safeguarding the most effective use of resources to realize overall project goals. Moreover, differentiation of funding rates among project activities threatens to create conflicts.

Major innovative elements of HBM4EU were taken up by the subsequent Partnership for the Assessment of Risk from Chemicals (PARC), which receives funding from the EU's Horizon Europe research and innovation programme under Grant Agreement No 101057014. These elements include the established network of national and EU authorities and scientific institutions at the science-policy interface, the National Hub structure, the inclusion of EU agencies as partners and Governing Board members, and the interlinkage of national and EU agencies. HBM4EU provides a blueprint for EU funded large-scale projects targeting future policies for realizing the Green Deal and Zero Pollution Ambition in the field of chemicals, health, and environment. It offers a best practice example. Therefore, its experiences should be considered for similar, future endeavours and may contribute to the success of large-scale EU projects in other sectors.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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