

External Review of the World Health
Organization Initiative for Vaccine Research
2007/2008

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Abbreviations

| | |
|----------|---|
| AAVP | African AIDS Vaccine Programme |
| ADIP | Accelerated Development and Introduction Plan |
| BMGF | Bill & Melinda Gates Foundation |
| CDC | Centres for Disease Control and Prevention (Atlanta, USA) |
| DCVMN | Developing Country Vaccine Manufacturers Network |
| DOMI | Diseases of the Most Impoverished |
| EDCTP | European & Developing Countries Clinical Trial Partnership |
| GAVI | Global Alliance for Vaccines and Immunization |
| GCP | Good Clinical Practice |
| HPV | Human Papillomavirus Vaccine |
| HVI | WHO-UNAIDS HIV Vaccine Initiative |
| IAVI | International AIDS Vaccine Initiative |
| ICDDR, B | International Centre for Diarrhoeal Disease Research, Bangladesh |
| INDEPTH | International Network of field sites with continuous Demographic Evaluation of Populations and Their Health in developing countries |
| IVI | International Vaccine Institute |
| IPR | Intellectual Property Rights |
| IVAC | Advisory Committee of the Initiative for vaccine Research |
| IVR | Initiative for Vaccine Research |
| MVP | Malaria Vaccine Project |
| NVDS | New Vaccine Delivery Systems |
| PATH | Program for Appropriate Technology in Health: international, non-profit organization |
| PDP | Product development public-private partnership |
| PDVI | Paediatric Dengue Vaccine Initiative |
| R&D | Research & Development |
| SAGE | (WHO) Strategic Advisory Group of Experts |
| SARS | Severe Acute Respiratory Syndrome |
| SCIH | Swiss Centre for International Health |
| STI | Swiss Tropical Institute |
| UNAIDS | The Joint United Nations Program on HIV/AIDS |
| WHO | World Health Organisation |

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Executive Summary

In June 1999 WHO launched the Initiative for Vaccine Research (IVR) with the aim of streamlining the vaccine R&D endeavours scattered across the Organization. It was originally conceived by WHO and UNAIDS with the aim of reinforcing linkages between vaccine research and development and other components of immunization. The purpose of the review is to assess the relevance, efficiency, effectiveness and impact of the IVR in relation to its stated mission, functional structures, activities and operating budget.

Apart from a review of relevant documents, 159 stakeholders of IVR shared their views and opinions on the IVR, either in face-to-face interviews or through an online questionnaire.

Overall the IVR is doing very well. The leadership and performance of the IVR-team is widely appreciated. While the normative and facilitating function of the IVR/WHO is unanimously recognized, the product development role and to some extent even the leadership in vaccine R&D is less accepted and sometimes questioned as it is widely assumed that there are more competent actors in this field. Nevertheless the Meningitis Vaccine Project (MVP), the largest IVR's product development project, is widely recognized as the landmark achievement of the IVR in recent years. In general terms the IVR has promoted partnership and it has developed a very good reputation and credibility in the field of vaccine R&D. IVR has been successful in getting developing country health priorities on the global vaccine agenda but, in spite of acknowledged efforts of the IVR, there is an insufficient involvement of partners from developing countries. The funding situation is difficult for the IVR, being trapped between the possibilities to find easy funding for project work, but facing increasing difficulties to fund its core activities.

The recommendations are structured in four areas:

- a) Develop a long term strategic plan: despite the constraints and policies of WHO it is vital for the IVR to have such a plan, as vaccine R&D takes a long time.
- b) Developing countries should receive (even) more attention: Teaching and training should receive a more prominent position. Along the same line institutional capacity building is important, both in the area of clinical vaccine trials as well as in the area of implementation research. Vaccine producers from Developing Countries should receive more attention, for example by including them more in the emerging Product Development Public/Private Partnerships.
- c) Learn from the IVR success stories: IVR should rather go for "landmark" projects that aim for a public health impact.
- d) Re-focus of the IVR-portfolio: the IVR should build on its WHO-status and the power and influence which comes with it, rather than try to compete with players it will not be able to compete with. In the rapidly changing environment of global vaccine initiatives there is a need for a strong coordinating and normative body, which can act as a credible interface with developing countries. This should be an interesting opportunity for funding agencies, which want to make a difference in this field.

1 Introduction

In this chapter the Initiative for Vaccine Research and the objectives of the external review will be presented.

1.1 The Initiative for Vaccine Research

In June 1999 WHO launched the Initiative for Vaccine Research (IVR) with the aim of streamlining the vaccine R&D endeavours scattered across the Organization. It was originally conceived by WHO and UNAIDS with the aim of reinforcing linkages between vaccine research and development and other components of immunization.

*IVR vision:
A world in which all
people at risk are
protected against
vaccine-preventable
diseases*

The mission of the IVR is to "*accelerate innovation for the development and optimal use of safe and effective vaccines and technologies against infectious diseases of public health importance*", particularly in developing countries where WHO priority diseases are endemic. To this end, IVR needs to involve developing countries in research and decision-making, and in strong networks that include experts and institutions from these countries.

The IVR aim is to develop and promote a global and sustainable R&D pipeline delivering optimal and cost-effective vaccines for priority diseases. Yet, despite global agreement on the IVR vaccine research priorities, and the activities and achievements of the Initiative within a short space of time, its core funding has been dwindling dangerously low over the last years.

In 2005, the IVR decided that it needed to consolidate its core, normative functions if it were to meet the expectations of its clients, especially those in developing countries. Reflecting its comparative advantages, the IVR therefore established three areas:

- knowledge management, guidance and advocacy through partnerships
- research and product development (as a developer or facilitator)
- implementation research and tools to inform national policies and strategies

The IVR work plan and budget are oriented towards the achievement of the WHO Expected Result on vaccine R&D approved by the World Health Assembly. IVR's activities are guided by the IVR Strategic Plan 2006-2009.

The Initiative is administratively hosted by the WHO Department of Immunization, Vaccines and Biologicals (IVB) and works closely with a wide range of other departments and clusters within WHO. Its priority-setting and vaccine research agenda also draw on consultations with global public health research initiatives, donors, research institutions, policy-makers and countries. The Initiative is guided by the needs of WHO's Member States and responds to the vaccine research

priorities expressed by the World Health Assembly. An independent expert committee (IVAC) provides overall strategic and technical advice.

The IVR also acts as focal point within WHO for interaction on vaccine R&D with external partners and organizations including the Global Alliance for Vaccines and Immunization (GAVI), the Program for Appropriate Technology in Health (PATH), the International Vaccine Institute (IVI), the International AIDS Vaccine Initiative (IAVI) and the Global HIV Vaccine Enterprise.

The IVR has a multidisciplinary team of 30 individuals, with very broad expertise, and backgrounds from academia, industry and management.

The total IVR budget for 2008-2009 is US\$ 92.61 million, of which US\$ 60 million correspond to activities aimed at increasing pandemic influenza vaccine preparedness. At the end of 2007, there is a shortfall of US\$ 11 million (nearly 70%) over a US\$ 16 million budget planned for core IVR activities.

1.2 Objectives of the External Review

Although the IVR has monitored its own development and milestones, the IVR decided to commission an external, independent evaluation of its work since its inception in 2000.

The purpose of the evaluation was to assess the relevance, efficiency, effectiveness and impact of the IVR in relation to its stated mission, functional structures, activities and operating budget. The scope of the evaluation was to be broad and managerial in nature, focusing on the IVR vision, strategy and direction in the context of a growing number of other players in the field of vaccine research.

The evaluation was not expected to assess the IVR scientific programme of work.

The Terms of Reference can be found in Annexe 6.1.

2 Methods

The review of documents provided by the IVR and other sources (see Annex 6.2). On this basis an initial set of questions was elaborated. The team leader conducted 12 semi-structured interviews with Geneva based staff, mainly the IVR- and WHO-staff members. The names of the interview partners are given in Annex 6.3. These interviews and the analysis of information in the available documents provided the basis for elaborating an online questionnaire. For this purpose the FlexiForm-tool was used (<http://flexiform.unibas.ch>). An automatically generated e-mail with an invitation to participate in the survey was sent to 303 stakeholders of the IVR containing a personalized URL access.

The questionnaire (see Annex 6.4) consisted of 21 questions, mostly closed questions, but also, with options to add comments and recommendations for the future development of the IVR. A detailed overview of questionnaire responses is presented in table 3 in Annex 6.5. The questionnaire was anonymous and would not allow the identification of individuals. However, the software did recognize those who had not responded after two weeks and generated a corresponding reminder email. 12 addresses were not valid any more, and 10 persons contacted explicitly stated that they were not willing to participate. The most common reason mentioned was their insufficient familiarity with the IVR which would not allow them to provide a qualified opinion. The first round generated some 80 responses, the reminder email another 67. In total, 148 fully completed data sets were received. The rather high response rate of over 50% (excluding the non-valid addresses), highlights the interest of stakeholders in the IVR.

In total, information from 159 stakeholders was obtained either through direct interviews, or through the above mentioned online questionnaire.

Table 1 Composition of contacts/respondents

| Stakeholder Group | Number of contacts |
|--|--------------------|
| WHO Advisory Group members | 26 |
| IVR-collaborators | 5 |
| WHO collaborators (other than IVR) | 18 |
| Global Health Initiative collaborators | 8 |
| University/researchers from developing country | 21 |
| University/researchers from industrialized country | 21 |
| Industry collaborators from developing country | 8 |
| Industry collaborators from industrialized country | 16 |
| Collaborators from donor/funding agency | 10 |
| Other stakeholders (NGOs, like Médecins sans Frontières, PATH, combinations of the above etc.) | 26 |
| Total | 159 |

3 Findings

3.1 Role and comparative advantage of IVR

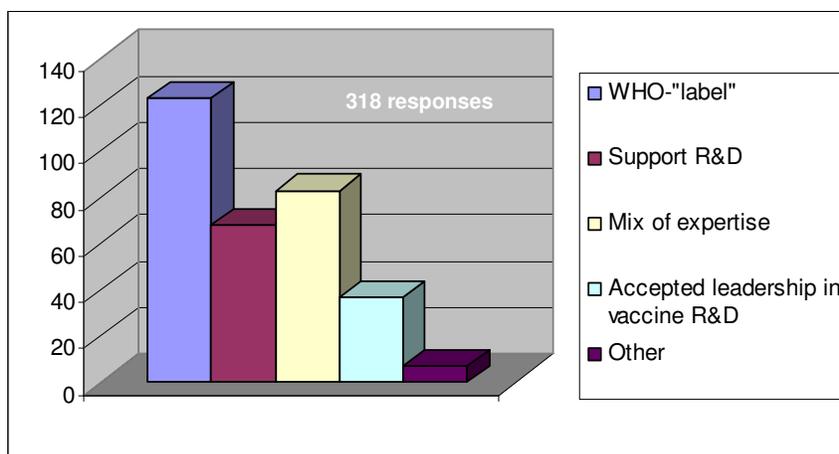
*“... It is the only truly independent initiative in the field of vaccine R&D”
IVR-stakeholder*

The IVR likes to see itself as a “facilitator” of vaccine research and a product “developer”, depending on which it considers to have the biggest impact.

From the outside, stakeholders rank first the facilitating role that is guiding the policy and the global vaccine R&D agenda (see Figure 1).

The convening role of the global vaccine R&D community comes second. This role is for obvious reasons closely linked to the WHO-label. Normative tasks, such as the development of guidelines are often mentioned in this context. In more general terms the IVR is also seen as a clearing house for information. Still on the positive side the bridging between vaccine R&D and product availability in countries is frequently mentioned.

Figure 1 Comparative Advantage of the IVR



There is some regret that the IVR is not really leading the vaccine community, and other players, like philanthropic agencies and global health initiatives – be it only because of their much higher financial resources - are getting more important and gaining influence.

The fact that the IVR is filling gaps left by others is considered as an advantage by IVR outsiders. Within the IVR, this aspect of its work is not much appreciated, as it does not really allow the development of an identity, which is commensurate with WHO.

There are also many critical remarks, pertaining mainly to the “developer” role of the IVR. Quite a number of stakeholders have doubts on whether IVR should really get engaged in the actual development of new vaccines, and some stakeholders go even as far as saying that “R&D will go on, with or without IVR...”

In short, while the normative and facilitating function of the IVR being an integral part of the WHO is unanimously accepted, there are fewer acceptances for the actual developer role and to some extent for the leadership in vaccine R&D.

3.2 Achievements and Non-achievements

“Rotavirus Vaccine is the first vaccine, which has been introduced in parallel in the North and in the South”

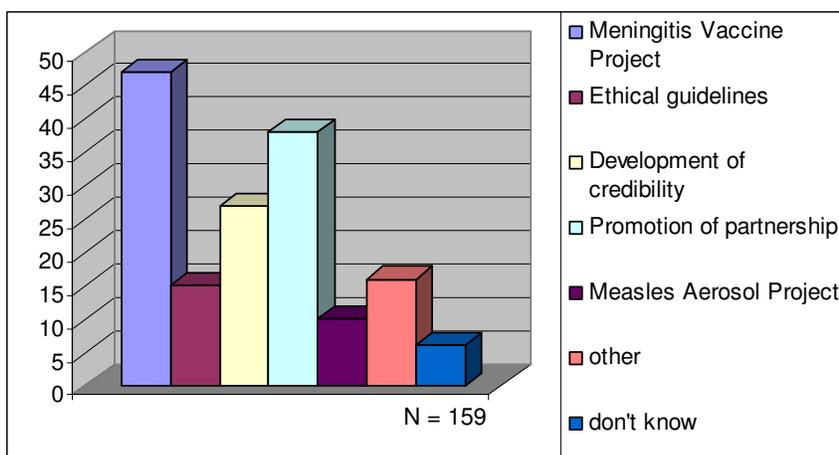
IVR-Stakeholder

The track record of the IVR’s achievements since its inception is good, as nearly 75% of respondents qualify IVR’s overall achievement since 2000 as high or very high. Since its creation seven years ago, the IVR continues to facilitate the development of vaccines, to improve existing immunization technology and to ensure that these advances are available to people who need them most. Recent key achievements of the IVR, include:

- a conjugate meningitis A vaccine tailored to eliminate epidemic meningitis in Africa, which should be licensed in 2008 (in collaboration with PATH). This project is the largest product development initiative in which IVR is involved;
- a new aerosol measles vaccine for mass vaccination against this disease, which could be available as early as 2010;
- support to 6 developing country manufacturers (Brazil, India, Indonesia, Mexico, Thailand, Viet Nam) to enable them to produce pandemic influenza vaccine domestically;
- a network of centres of Excellence in Africa (through the African AIDS Vaccine Programme) to enhance research and development of an AIDS vaccine for Africa by Africans;
- a key participation in the development of an international collaborative effort to accelerate the development of an effective malaria vaccine for African children (The Malaria Vaccine Technology Roadmap, in collaboration with PATH, the Wellcome Trust and the BMGF);
- an ambitious research agenda to optimize immunization schedules and increase cost-effectiveness of conjugate vaccines.

The majority of stakeholders interviewed refer to the Meningitis Vaccine Project (MVP) as the single most important achievement (see Figure 2).

Figure 2 Greatest achievement of the IVR



However, it is noteworthy that more than 50 % of respondents consider “non-product development” results, such as the development of ethical guidelines, or the promotion of partnership as the most outstanding achievements of the IVR.

The IVR’s prominent role in WHO’s overall health research policy and objectives and research-setting agenda is also widely acknowledged, and has certainly helped to develop a large credibility in the vaccine research arena.

The promotion of partnerships among the different stakeholder groups is also considered as a success of the IVR. In terms of concrete output the contribution to the development of ethical guidelines in the context of vaccine trials and the Measles Aerosol Project are cited. As for the ethical guidelines it needs to be said, that these guidelines have an interest which goes beyond vaccine trials, but has become a landmark document for clinical trials in general.

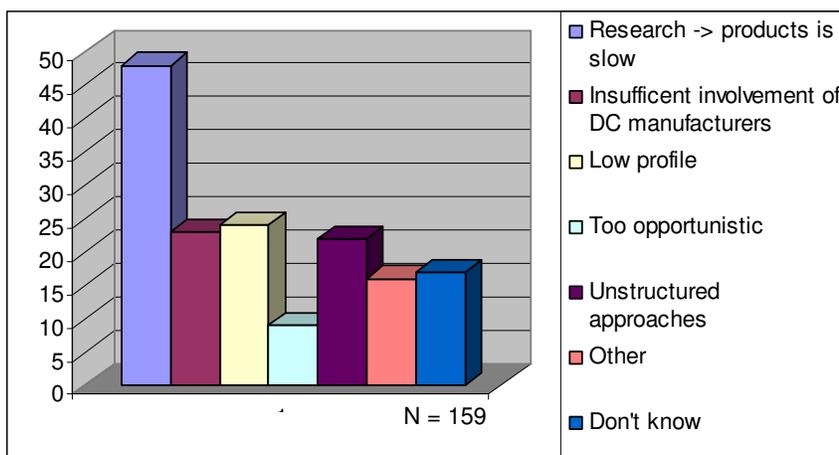
Advocacy and mobilisation of international commitment and resources is considered as being the most effective contribution of IVR, followed by the IVR’s knowledge management. In this context the Global Vaccine Forum (Salvador da Bahia 2005, Montreux 2004, and Seoul 2002) are quoted as a good example.

If there is light, there is also shadow. The non-achievements of the IVR mainly refer to the slowness in translating research into products (see Figure 3). Most respondents do not elaborate on this, but some rightly state that people are dying because vaccines are not available quickly enough. Apart from isolated remarks it is not clear to what extent the IVR is hold responsible for these delays.

“The progress from results to policy is too slow!”

IVR-Stakeholder

Figure 3 Failures/Non-achievements of the IVR



In spite of its success the IVR’s profile is too low, which is reflected in a comparatively low visibility, partly explained by the fact of being “hidden” in a WHO-department. Some stakeholders have the impression that the IVR undertakings are not very well structured. In particular the initial approach towards implementation research is mentioned, which was – in spite of its acknowledged importance – not a success. However, it is understood that the shortcomings are now being addressed.

In spite of quite some efforts of the IVR to support developing country manufacturers, a major point of criticism is the insufficient involvement of them. This point is mentioned by the parties concerned, but also numerous other stakeholders have identified this as a point of concern. Along similar lines it is not understood why the IVR is “the only WHO programme, where capacity building, teaching and training are not really visible”. It has to be mentioned though that the IVR is active to some extent in training in GCP/GLP and in bioethics, and that the main focus of the African AIDS Vaccine Programme is on capacity strengthening for HIV vaccine research in Africa.

In spite of the success of the MVP, frequently cited examples for ineffectiveness are product development and implementation research.

Although the documents reviewed, and in particular the biannual reports are clear and concise, there are perhaps some short-comings in the communication management of the IVR. It is noteworthy that quite a number of respondents were unable to quote either achievements or non-achievements. The IVR’s global visibility is not considered to be very high.

3.3 Management of IVR

The leadership of the IVR is widely appreciated and highly praised.

“IVR is one of the parts of WHO that seems to function well and continues to move forward”

IVR-Stakeholder

In general the IVR receives good marks considering that it belongs to the WHO. One stakeholder is impressed that IVR is one of the parts of the WHO that seems to function well and continues to move forward.

The professional profile of most of the IVR’s technical staff is also very much appreciated. In particular the mix of scientific, industry and management backgrounds and expertise gives the IVR a strong image for a majority of its stakeholders.

Perhaps typical for WHO’s reality for 2008 – the support staff level (G-level) is thinly spread. As a consequence many IVR technical staff are occupied with tasks, for which they are not really trained for, such as organizing conferences, responding to routine correspondence and archiving etc. There is also no middle-management (P1-P3-level), which could assist coordinators and senior staff members. For obvious reasons this is demoralizing, reduces the ability to concentrate more on the respective areas of expertise, and thus leads to a waste of scarce resources. On the other hand, this challenge has to be seen in the context of a large, possibly too large portfolio, which could be reduced to the comparative advantages of a WHO based IVR.

3.4 Funding

More than half (62%) of the respondents consider that investment in IVR is cost-effective or very cost-effective, and that therefore the initiative is good value for

*“IVR is a bargain”
“IVR is a crucial
initiative at WHO, but
its resources have
been too limited”*

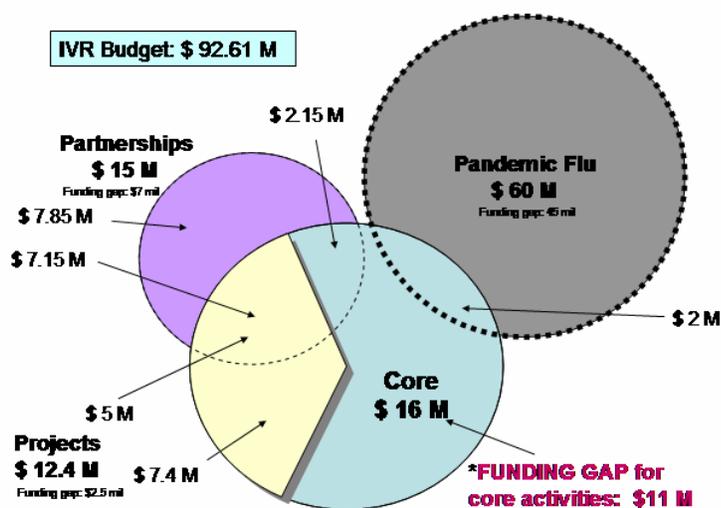
IVR-Stakeholders

money. The IVR budget for 2008-2009 is an impressive US\$ 92.61 million (see Figure 4), of which US\$ 60 million have been allowed exceptionally for activities related to pandemic influenza vaccine preparedness. Currently there is a total budget shortfall of US\$ 65.5 million, of which US\$ 11 million correspond to core IVR activities. This makes up for a striking 69% funding gap (US\$ 11/16 million) for what IVR considers as its core activities.

The core funding for the IVR has decreased, reflecting international donor priorities on one hand, and competition on the other hand, partly also linked to internal WHO pressure to decentralize resources to the regions.

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Figure 4 The IVR-Funding 2008 – 2009 (figure by courtesy of Guido Torelli/IVR)



The graph depicts the difficult situation of the IVR, which disposes of just over 30% of its core funding and is heavily dependent on external project funding. Funding mechanisms have clearly an impact on the functioning, as not necessarily long term strategies can be pursued, but activities follow funding, leading to an opportunistic approach, which is not necessarily in line with a long term development perspective.

The majority of stakeholders interviewed believe that the IVR is good value for money, but realizes at the same time that the financial resources to achieve its management are largely insufficient. One explanation provided for this difficulty is a lack of interest of major donors to fund particular core functions, and the well known budgetary constraints of WHO in general, which do not allow to allocate substantial resources to the IVR. The constant need to mobilize resources limits the capacity to focus on content and to develop visions. This has the risk to become a vicious cycle.

The general trend of big philanthropic funding sources and the influence coming with it becomes a possible threat to IVR. One stakeholder advises the IVR to make sure that such sources “do not usurp the leadership role” of the IVR.

3.5 Involvement of developing countries

The IVR has undertaken considerable efforts to involve researchers and decision makers from developing countries. All the IVR advisory committees show a significant participation of developing countries experts, and Global Vaccine Fora (Salvador da Bahia etc.) are well attended by participants from developing countries.

However, the view is widespread that it is not “*enough to bring a few people from developing countries*” to conferences. There is a mixed perception to what extent the IVR has succeeded to get developing country health priorities on the global vaccine research agenda (see Figure 5), although about half of the respondents think that the success of the IVR in this area has been considerable.

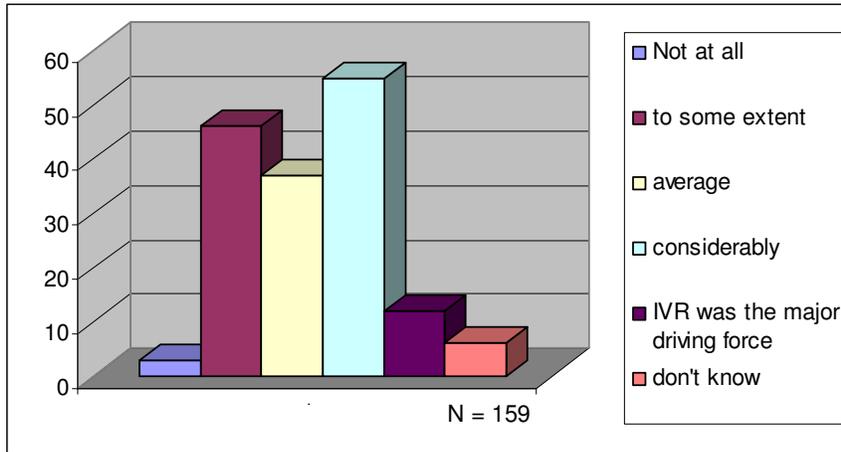
However, many stakeholders regret that teaching, training and capacity building are not more prominently mentioned in the IVR strategy. It is generally understood that GCP/GLP and bioethics training are among IVR activities, but more systematic capacity building seems to be lacking. Comments are also made that there is no specific reference in the Strategic plan towards empowering developing countries. A widespread perception that the IVR has not reduced much of the 10/90 gap is therefore not surprising. Of note is the fact that for some respondents there may be some confusion between the IVR and the Special Programme for Research and Training in Tropical Diseases (TDR), whose mandate specifically concentrates on Training and Strengthening besides Research and Development, which is not the case for the IVR.

In addition, manufacturers from developing countries have the impression that they are insufficiently involved in vaccine R&D. This is yet another aspect of the 10/90 gap between industrialized countries and developing countries with the added and complicated dimension of Intellectual Property Rights and patents. However, it has potentially far reaching consequences as manufacturing capacities in developing countries are in dire need.

...the list of IVR's collaborating partners reads as a "Who is Who" among Western or industrialised interests!"

IVR-Stakeholder

Figure 5 Success of the IVR in getting DC health priorities on the global vaccine agenda?



4 Discussion

The reputation of the IVR and its achievements is overall good in the vaccine R&D community.

The “slowness” of translating research into actual vaccines is a fact. IVR cannot really be blamed for this, as it is one side inherent in vaccine development, and looking at the IVR as a facilitator, it cannot do much to accelerate this time consuming process. The facilitator’s role also limits the leadership the IVR can impose on the complex group of stakeholders, which have partly very vested interests.

As with any agency the clarity of its mission is also critical for the IVR. It is generally better to focus on a few areas and excel, than try and cover too much ground and under perform. There is widespread concern that the IVR does not really know (or possibly does not communicate) how it sees the long term perspective of vaccine R&D. Although this can be explained by the constraints and policies of WHO, it is a serious handicap for the IVR which has to move in a field which by definition needs a long term perspective, as vaccines R&D takes a very long time from the bench to the field.

It is also quite obvious that the IVR has a too large portfolio related to the resources it has available. The funding future is not really bright, as interest of funding agencies in supporting the core function of the IVR has gone down in recent years or is linked to specific projects, and there is also quite some competition in the product development field. The IVR has not many options to align resources and mandates. Basically the IVR has the choice, either to increase income or to shrink its mandate to areas of work which it does really well. Increasing income has been possible in the past through opportunistic responses to opportunities and through addressing gaps. The filling gap function is considered as an advantage by the IVR outsiders, but is within the IVR-team not equally appreciated, as it is just a fill-in and not really commensurate with the visionary and leading role the IVR aims to play in vaccine R&D.

The most widely acknowledged comparative advantage of the IVR is the WHO-label. None of the other actors in vaccine R&D disputes or will be able to dispute this position. Also in terms of credibility and promotion of partnerships the IVR has built itself a very strong reputation. However, if it comes to product development, there are many players and initiatives, with whom the IVR has and will have, as a part of WHO, difficulties to compete both in terms of science as well as in terms of resources. Although WHO has a longstanding experience in product development, the option to develop a WHO-independent leg for product development does not seem very promising either, mainly because of the tough competition of global health initiatives, which are already in place and extremely well resourced.

Furthermore one has to ask the question what added value the IVR on its own would have for product development, apart in niche-projects. As for product development, the emerging Product Development Public-Private Partnerships (PDPs) are more promising to enhance existing R&D initiatives. Secondly and

more importantly the “independency” would come at the price of losing the WHO-credibility. This is particularly important if it comes to regulatory matters, where conflicts of interest must be avoided at all costs. The problem of being “referee and player” at the same time needs to be addressed, and one of the roles needs to be chosen. The referee seems to be the obvious role for a WHO-body. However, the player role, that is working as a “virtual” company is less obvious. Nevertheless, the IVR cannot completely pull out of product development, because it needs to maintain its expertise in this field.

It is acknowledged that teaching and training are at this point in time not explicitly part of the mandate of the IVR, but this might need to be reconsidered in the context of a WHO-initiative.

For obvious reasons there is sometimes a conflict of interest between accelerating the development of new vaccines, which probably involves working closely with existing mostly developed country manufacturers and strengthening DC manufacturers. Stimulating the development of new vaccines by developing country manufacturers directly will not produce tangible results as fast as when collaborating with top-notch manufacturers from highly industrialized countries.

The IVR leadership and the management of the IVR-team are good. The overall performance of the IVR is widely appreciated. However, it is obvious that staff of all levels works at their limits. The shortage of support staff has multiple explanations, last but not least due to the budgetary constraints the IVR is facing. The shortage of technical staff could possibly be addressed through visiting scientists/sabbaticals or exchange programmes with relevant stakeholders. However, adaptations of the human resources would have to be undertaken on the basis of the requirements of the scope of work the IVR will cover in the future.

The funding situation of the IVR is to some extent a “Catch-22” situation. Because of its ability to attract external (project) funding, the IVR has a difficult stand in obtaining internal WHO-core funding. On the other hand, the dominance of project funding has the inherent risk to divert the focus of the IVR and cut down on its core functions. With the massive influx of new funds for vaccine R&D this situation is unlikely to change, and the IVR will have to be careful not to be drawn too much into the relative attractiveness of project funding and taking the risk to lose sight of its core functions.

There should be “enlightened” funding bodies, which would be willing and able to recognise the need for supporting the vital core functions of the IVR.

5 Recommendations

As mentioned above achievements of the IVR since its inception are quite impressive.

It is therefore not surprising that almost a third of the persons interviewed stated, that the IVR would not need to change and should continue to function as it has done in the past seven years.

However, in spite of its success in the past there are problem areas which need to be addressed if the IVR wants to maintain and expand its role in the future.

In particular it is proposed to strengthen and to rethink the following areas:

- e) Develop a long term strategic plan
 - Because of the long R&D time it takes to develop vaccines and despite the constraints and policies of WHO it is necessary for the IVR to develop a long term strategic perspective, of what should be achieved in vaccine research, by when and by whom.
 - A long term strategic plan would also provide a basis to do more “upstream” work, such as target product profiles, liaisons with industry (from developing and industrialized countries) and promoting Product Development Public-Private Partnerships (PDPs).
 - Last but not least the IVR could thus improve its advocacy role for new vaccines that are not vital in industrialized countries, but are surely needed in developing countries and develop strategies for their development.

- f) Developing countries should receive (even) more attention:
 - Teaching and training should become a more explicit focus in the IVR work, and/or closer collaboration with other groups or organizational units within WHO which are more active in teaching & capacity building should be sought.
 - Strengthen institutional capacity building in developing countries. In particular the IVR could assist in increasing the capacity of national institutions to evaluate new vaccines. This would include capacity for carrying out all phases of clinical trials. Equally important, developing country institutions should be strengthened to be able to evaluate the capacity of health systems for vaccine delivery, that is the implementation aspects of vaccines. This would also be a contribution to bridge the 10/90 gap in an important area of medical research.
 - More involvement of the countries in setting PH and the research agenda is necessary; exploit the IVR unique position to have access to and the role of WHO regional and country offices.
 - Particular attention should be paid to the strengthening of developing country manufacturers, as currently undertaken by IVR for influenza vaccines, possibly through PDPs. Such partnerships could be useful to

producers from developing countries; facilitate the transfer of technologies. Also teaching and training in the context of intellectual property rights could be useful areas of activities.

g) Learn from the IVR success stories:

- Focus on landmark projects, like the Meningitis Vaccine Project. This project is a good example for a consortium approach, which brings different players together – while maintaining oversight and support of the IVR.
- Aim at public health impact.
- Make sure that there is a strong participation of developing countries concerned, without neglecting strong partners from industrialized countries.
- Try to refrain from small projects which fill gaps, which as commendable as they are, do neither strengthen the position of the IVR in the international arena nor do they make a difference, but instead absorb scarce resources. Exceptions should only be made, if such small projects are clearly linked to landmark/consortium projects mentioned above.

h) Re-focus of the IVR-portfolio

- The IVR would be well advised to focus rather on oversight, coordination, convening, facilitating exchange and its normative power than on product development. Today, most vaccine development projects/initiatives are "vertical" in nature.
- The IVR can help each of these projects/initiatives to build on the success (or failure) of others so that development of all products becomes overall more efficient. It could function as an interface/entry point to partner countries.
- The IVR should try to find a better interaction with donor agencies and should convince them that in the rapidly changing environment of new initiatives and heavy resources both from the philanthropic as well as from the commercial sector, the independent broker or in some cases referee role of WHO needs to be strengthened and is vital to achieve progress.

6 Annexes

6.1 Terms of Reference

Background, vision and mission

The Director-General of WHO launched the Initiative for Vaccine Research (IVR) in June 1999 with the aim of streamlining the vaccine R&D endeavours scattered across the Organization. Pointing to IVR's research agenda-setting and convening roles, and urging the newly-formed group to lead through advocacy, coordination and leverage, Dr Brundtland anticipated improved synergies and common goals with key partners such as UNAIDS.

The mission of IVR is to "accelerate innovation for the development and optimal use of safe and effective vaccines and technologies against infectious diseases of public health importance", particularly in developing countries where WHO priority diseases are endemic. To this end, IVR's mandate is to ensure the involvement of developing countries in research and decision-making, and in strong networks that include experts and institutions from these countries.

The Initiative is administratively hosted by the WHO Department of Immunization, Vaccines and Biologicals (IVB) and works closely with a wide range of other departments and clusters within the Organization. Its priority-setting and vaccine research agenda also draw on consultations with global public health research initiatives, public-private partnerships, donors, research institutions, policy-makers and countries. The Initiative is guided by the needs of WHO's Member States and responds to the vaccine research priorities expressed by the World Health Assembly. An independent expert committee provides overall strategic and technical advice.

IVR also acts as focal point within WHO for interaction on vaccine R&D with external partners including the Global Alliance for Vaccines and Immunization, the Program for Appropriate Technology in Health, the International Vaccine Institute, the International AIDS Vaccine Initiative and the Global HIV Vaccine Enterprise.

IVR structure and activities

IVR's aim is to develop and promote a global and sustainable R&D pipeline delivering optimal, cost-effective vaccines for priority diseases. The international research community acknowledges IVR's vaccine research priorities, and welcomes the activities carried out and achievements made within a short space of time. Yet, IVR core funding continues to dwindle precariously low, despite major new vaccine research funding sources arriving on the scene over the last years.

In 2005, after extensive consultation and an internal assessment, IVR decided that to consolidate its core, normative functions in order to meet the expectations of its clients, especially those in developing countries. Reflecting its comparative advantages, IVR established three, mutually reinforcing research areas, namely implementation research, product development and knowledge management. The IVR organigram retains a discrete team that focuses on HIV, TB and malaria, in line with the global priority given to these diseases. A list of major activities carried out in these areas can be found in the IVR Report 2004–2005, the IVR Strategic Plan 2006–2009 and the organigram of the Initiative.

Purpose and scope of the evaluation

Although it has monitored its own development and milestones set, IVR has decided to commission an external, independent evaluation of its work since its inception in 2000. The purpose of the evaluation is to assess the relevance, efficiency, effectiveness and impact of IVR in relation to its stated mission, functional structures, activities and operating budget. The scope of the evaluation will be broad and managerial in nature, focusing on IVR's vision, strategy and direction in the context of a growing number of other players in the field of vaccine research. The evaluation is not expected to assess IVR's scientific programme of work.

The evaluation will cover all programme areas and diseases under the auspices of IVR. Following current practice, a comprehensive set of documentation produced by, or relevant to the Initiative should provide a detailed understanding of the *raison-d'être*, goals, achievements and challenges of IVR. This phase should assist the evaluator(s) to develop a list of issues, questions and indicators that will enable an independent assessment and evaluation. Face-to-face, telephonic and/or electronic interviews with a list of strategic individuals will provide the input needed. While this list will be suggested by the IVR Secretariat, the evaluator(s) are at liberty to identify others.

It is estimated that the evaluation will require 30 working days over a period of four months.

Suggested issues to be covered by the evaluation (to be developed by the evaluator(s))

- Assess IVR's global achievements since 2000 including likely direct and indirect impact on WHO public health priorities (e.g. MDGs)
- Assess IVR's role in WHO's overall health research policy and objectives and research-setting agenda
- Assess the current relevance of these roles and comparative advantage(s)
- Is IVR cost-effective?
- Is its programme of work focused on its comparative advantages?
- Do its human resources match its financial resources?
- Are its funding sources the right ones?

Confidentiality and Conflict of Interest

The Contractual Partner shall treat the information provided to it under this Agreement as confidential and proprietary and agrees to take all reasonable measures to ensure that such information:

- is not used for any purpose other than the performance of the work; and
- is disclosed and provided only to persons who have a need to know for the purpose of performing the Work and are bound by like obligations of confidentiality and non-use as contained in this Agreement.

The Contractual Partner shall not be bound by any obligation of confidentiality or non-use, to the extent it is clearly able to demonstrate that the information:

- (a) was known to the Contractual Partner prior to any disclosure by or on behalf of WHO; or
- (b) was in the public domain at the time of disclosure by or on behalf of WHO; or

- (c) becomes part of the public domain through no fault of the Contractual Partner; or
- (d) becomes available to the Contractual Partner from a third party not in breach of any legal obligations of confidentiality.

In addition, the Contractual Partner undertakes to abide by similar obligations of confidentiality and non-use as provided above with regard to the work performed under this Agreement.

The Contractual Partner is also required to complete, sign and return the Declaration of Interests form in Annex 2 of these Terms of Reference.

Programme

It is envisaged that the evaluation will be conducted as follows.

Table 2 Time Frame

| Activity | Schedule |
|--|----------------------------|
| Initial meeting with IVR Secretariat to discuss terms of reference, indicators, outcomes and remuneration. Consultants to receive full background documentation | Early November 2007 |
| Review of documentation | November 2007 |
| Interviews in Geneva with staff of IVR and key collaborators (IVB, FCH, TDR, RPO, UNAIDS, PATH, GU... IVR Sec. to suggest a list and to facilitate). Update meeting with IVR Secretariat to identify unmet needs | Early to mid December 2007 |
| Communications with other players across the world (GFVR, GAVI, BMGF...IVR Sec. to suggest list) | During December 2007 |
| Discussion with IVR Sec. and sharing of draft recommendations | January 2008 |
| Submission of final report and recommendations | February 2008 |

6.2 Documents consulted

- WHO Medium-term strategic plan 2008 – 2013 and proposed programme budget 2008.2009
- IVR strategic plan 2006-2009
- State of the art of new vaccines: research and development REVISED 2005
- Current Status of Vaccines in Development, February 2006
- IVR Activities Report 2004 - 2005
- IVR Activities Report 2002-2003
- Assessing the global need for vaccine R&D, November 1999
- Report on the overview of vaccine R&D in WHO and UNAIDS, June 1999
- Today's challenges in vaccine R&D: WHO's perspective
- Report on WHO Consultation on Viral Vectors, December 2003
- Proceedings of the Sixth Global Vaccine Research Forum and Parallel Satellite Symposia, 12-15 June 2005, Salvador da Bahia, Brazil
- Proceedings of the Fifth Global Vaccine Research Forum, 7-10 June 2004, Montreux, Switzerland
- Proceedings of the Fourth Global Vaccine Research Forum, 30 June - 2 July 2003, Seoul, Republic of Korea
- Proceedings of the Third Global Vaccine Research Forum, Geneva, 9-11 June 2002
- Proceedings of the Second Global Vaccine Research Forum, Montreux, Switzerland, 10-12 June 2001
- Proceedings of the First Global Vaccine Research Forum, Montreux, Switzerland, 7-9 June 2000
- Ethical considerations arising from vaccine trials conducted in paediatric populations with high disease burden in developing countries WHO/IVR ethics meeting, 26 – 28 November 2002, Accra, Ghana

6.3 People met/Recipients of online questionnaire

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6.4 Online Questionnaire

853-External Review of the IVR

Basel, 21 December 2007

Dear Madam/Dear Sir,

The Director-General of WHO launched the Initiative for Vaccine Research (IVR) in June 1999 with the aim of streamlining the vaccine R&D endeavours scattered across the Organization. You may want to have a look at the IVR Report 2004-2005 (http://www.who.int/vaccine_research/documents/IVR_Report_0405.pdf) for a history of IVR's stated objectives or IVR's Strategic Plan 2006-2009 (http://www.who.int/vaccine_research/documents/Final_version.pdf).

The Swiss Centre for International Health (SCIH), a department of the Swiss Tropical Institute (<http://www.sti.ch>), has been contracted by WHO to undertake an external review of the Initiative.

IVR is committed to improving its collaboration in the global vaccine research and development arena in order to maximise its effectiveness, and impact. The results of the review will serve this purpose. A variety of stakeholders in the field of international health and research are being interviewed on their appreciation of the role and effectiveness of IVR, and the results they have produced.

The SCIH would highly appreciate it if you could spare a few minutes to fill in the questionnaire below before the 14th of January 2008. We will possibly send you a short reminder on 8th January.

We should inform you that all answers will be treated with absolute confidentiality and statements will not be linked to individual persons or institutions in the presentation of the results to IVR.

For details of the mandate given to the reviewer please contact Kay Bond (bondk@who.int).

For any enquiries concerning the questionnaire or if you would prefer to have a telephone conversation with the reviewer, please contact Nicolaus Lorenz (nicolaus.lorenz@unibas.ch; Tel. +41 61 284 81 25) or Svenja Weiss (svenja.weiss@unibas.ch; Tel. +41 61 284 81 92) of the SCIH.

We are most grateful for your collaboration and send you Season's Greetings and the best wishes for a happy and successful 2008.

Dr Nicolaus Lorenz
Head of the Swiss Centre for International Health
Swiss Tropical Institute

Questionnaire

Please tick the appropriate box(es) and comment freely. Where you will see a "!" you have to make a single choice. Where you do not see "!" you have multiple choices.

1. What is your relationship with IVR (please tick the most appropriate) !

- WHO advisory group member
- IVR-Team-member
- WHO-collaborator (including IVR constituency of TDR and UNAIDS)
- Global Health Initiative
- University/researcher from developing country
- University/researcher from industrialized country
- Industry collaborator from developing country
- Industry collaborator from industrialized country
- Donor
- Other stakeholder

2. In your opinion, what is IVR's role(s) in international vaccine R&D?

- to lead the global vaccine R&D community
- to convene the global vaccine R&D community
- to guide policy and the global vaccine R&D agenda
- to set R&D norms and standards
- to act as a clearinghouse of information
- to bridge vaccine R&D and product availability in countries
- Do not know/cannot comment

Other, please explain _____

3. What is/are for you the comparative advantage(s) of IVR?

- "WHO-label" (normative, convening power, independence etc.)
- Supporting key products that lack R&D investment and leadership
- Mix of expertise (academic, industry, countries)
- Accepted leadership in vaccine R&D
- Do not know/cannot comment
- Other, please explain _____

4. How would you assess IVR's overall achievements since 2000? ①

- Very high
- High
- Not so high
- Low
- Do not know/cannot comment

5. What is for you the biggest achievement of IVR?

- Meningitis Vaccine Project
- Contribution to development of ethical guidelines
- Development of Credibility
- Promotion of partnership (such as AAVP)
- Measles Aerosol Project
- Do not know/cannot comment
- Other, please explain _____

6. What is for you the biggest failure/non-achievement of IVR?

- Translation of research into products is slow
- Insufficient involvement of development country manufacturers
- Low profile
- Too opportunistic
- Unstructured approach to implementation research
- Do not know/cannot comment
- Other, please specify _____

7. Since 2000, in what area(s) has the contribution of IVR been most effective? ①

- Implementation research
- Product development
- Knowledge management
- Advocacy and mobilisation of international commitment and resources
- Do not know/cannot comment
- Other, please explain _____

8. Since 2000, in what area(s) has the contribution of IVR been least effective? ①

- Implementation research
- Product development
- Knowledge management
- Advocacy and mobilisation of international commitment and resources
- Do not know/cannot comment
- Other, please explain _____

9. Has IVR contributed to getting developing country health priorities on the global vaccine research agenda? ①

- not at all
- to some extent

- average
- considerably
- IVR was the major driving force
- Do not know/cannot comment

10. To what extent has IVR succeeded to involve developing countries in setting the global vaccine research agenda? ⓘ

- very small
- small
- average
- high
- very high
- Do not know/cannot comment

11. Do you think that IVR's output has an impact on public health outcomes? ⓘ

- none
- small
- some
- high
- very high
- Do not know/cannot comment

12. In your opinion is IVR good value for money? ⓘ

- somewhat a waste of scarce resources
- some value for money
- cost-effective
- very cost-effective
- Do not know/cannot comment

13. How appropriate are IVR's human resources to fulfil its mandate? ⓘ

- very insufficient
- insufficient
- average
- adequate
- perfectly adequate
- Do not know/cannot comment

14. How are IVR's financial resources to achieve its mandate? ⓘ

- very insufficient
- insufficient
- average
- adequate
- perfectly adequate
- Do not know/cannot comment

15. How is IVR's global visibility ? ⓘ

- not visible
- poor visibility
- average
- high profile
- very high profile
- Do not know/cannot comment

16. How much interest is there from major donors and agencies to invest in IVR work? ⓘ

- no interest

- some interest
- average interest
- high investment
- very high investment
- Do not know/cannot comment

17. Do you think that IVR faces WHO-in-house competition? ⓘ

- no competition
- some competition
- average competition
- tough competition
- very tough competition
- Do not know/cannot comment

18. How much competition does IVR face with other vaccine R&D initiatives? ⓘ

- no competition
- some competition
- average competition
- tough competition
- very tough competition
- Do not know/cannot comment

19. In your opinion what modifications should IVR consider to improve its performance in the future?

- No changes necessary
- Yes, changes are necessary

20. What changes/modifications would you propose?

21. Finally, do you have any other comment(s)?

Thank you very much for your time and the effort you have put into filling in this questionnaire!

Senden / Submit

6.5 Detailed Results of Online Questionnaire

Table 3 Overview questionnaire responses

| What is the role of the IVR?* | Responses | % |
|---|-----------|--------|
| Lead the global vaccine community | 40 | 8.60% |
| Convene the global vaccine community | 85 | 18.28% |
| Guide policy and the global R&D agenda | 105 | 22.58% |
| Set norms and standards | 68 | 14.62% |
| Act as a clearinghouse for information | 69 | 14.84% |
| Bridge vaccine R&D and vaccine availability | 79 | 16.99% |
| Don't know | 0 | 0.00% |
| Other | 19 | 4.09% |
| *multiple answers were possible | 465 | |
| How would you assess the IVR's overall achievement since 2000? | | |
| Very high | 19 | 11.95% |
| High | 100 | 62.89% |
| Not so high | 35 | 22.01% |
| low | 2 | 1.26% |
| don't know/cannot comment | 3 | 1.89% |
| | 159 | |
| Has the IVR involved developing countries? | | |
| Very small | 3 | 1.89% |
| small | 27 | 16.98% |
| average | 70 | 44.03% |
| high | 39 | 24.53% |
| very high | 8 | 5.03% |
| don't know/cannot comment | 12 | 7.55% |
| | 159 | |
| Do you think that the IVR has had a public health impact? | | |
| none | 2 | 1.26% |
| small | 20 | 12.58% |
| some | 70 | 44.03% |
| high | 42 | 26.42% |
| very high | 12 | 7.55% |
| don't know/cannot comment | 13 | 8.18% |
| | 159 | |
| Is the IVR good value for money? | | |
| a waste of resources | 4 | 2.52% |
| some value for money | 52 | 32.70% |
| cost-effective | 77 | 48.43% |
| very cost-effective | 22 | 13.84% |
| don't know/cannot comment | 4 | 2.52% |
| | 159 | |
| How appropriate are the IVR's human resources? | | |
| very insufficient | 10 | 6.29% |
| insufficient | 70 | 44.03% |
| average | 50 | 31.45% |
| adequate | 21 | 13.21% |
| perfectly adequate | 3 | 1.89% |
| don't know/cannot comment | 5 | 3.14% |
| | 159 | |
| How are the IVR's financial resources to achieve its mandate | | |
| very insufficient | 20 | 12.58% |
| insufficient | 81 | 50.94% |
| average | 44 | 27.67% |
| adequate | 7 | 4.40% |
| perfectly adequate | 2 | 1.26% |

| | | |
|--|-----|--------|
| don't know/cannot comment | 5 | 3.14% |
| | 159 | |
| How is the global visibility of IVR? | | |
| Not visible at all | 4 | 2.52% |
| Poor visibility | 33 | 20.75% |
| average | 83 | 52.20% |
| high profile | 34 | 21.38% |
| very high profile | 2 | 1.26% |
| don't know/cannot comment | 3 | 1.89% |
| | 159 | |
| Interest of major donors to invest in the IVR? | | |
| no interest | 4 | 2.52% |
| some interest | 70 | 44.03% |
| average interest | 55 | 34.59% |
| high investment interest | 18 | 11.32% |
| very high investment interest | 1 | 0.63% |
| don't know/cannot comment | 11 | 6.92% |
| | 159 | |
| Is there WHO-in-house competition for funding? | | |
| no competition | 16 | 10.06% |
| some competition | 56 | 35.22% |
| average competition | 53 | 33.33% |
| tough competition | 25 | 15.72% |
| very tough competition | 3 | 1.89% |
| don't know/cannot comment | 6 | 3.77% |
| | 159 | |
| How much competition is there with other Vaccine R&D initiatives? | | |
| no competition | 11 | 6.92% |
| some competition | 38 | 23.90% |
| average competition | 39 | 24.53% |
| tough competition | 50 | 31.45% |
| very tough competition | 14 | 8.81% |
| don't know/cannot comment | 7 | 4.40% |
| | 159 | |
| Does IVR have to adapt to improve its performance? | | |
| Yes changes are necessary | 111 | 69.81% |
| No changes are necessary | 48 | 30.19% |
| Don't know/cannot comment | 0 | 0.00% |
| | 159 | |
| In which area has the IVR's contribution been most effective? | | |
| Implementation research | 17 | 10.69% |
| Product development | 14 | 8.81% |
| Knowledge management | 39 | 24.53% |
| Advocacy and mobilization of commitment | 85 | 53.46% |
| Don't know cannot comment | 2 | 1.26% |
| Other | 2 | 1.26% |
| | 159 | |
| In which area has the IVR's contribution been least effective? | | |
| Implementation research | 40 | 25.16% |
| Product development | 68 | 42.77% |
| Knowledge management | 8 | 5.03% |
| Advocacy and mobilization of commitment | 28 | 17.61% |
| Don't know cannot comment | 5 | 3.14% |
| Other | 10 | 6.29% |
| | 159 | |