ADVISORY REPORT 2/2013

Enhancing Research and Development in Health Sciences

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The Academy of Sciences Malaysia acknowledges the following for their contribution as Moderators and Rapporteurs at the two data-gathering sessions:

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Academy of Science Malaysia, 3 March 2012

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Foreword

I would like to convey my heartiest congratulations to Academy of Sciences Malaysia's Task Force on Enhancing R&D in Health Sciences chaired by Prof Jafri Malin Abdullah, FASc for this Advisory Report. This effort would not have been possible without the strong support and co-operation that ASM had received from the Ministry of Science, Technology and Innovation, Ministry of Health and its Institute of Health Management as well as many stakeholders who had gathered together in the workshop and round-table forum organized by ASM.

The Academy strongly believes that R&D in health sciences is of paramount importance to contributing and to enhancing Malaysia's economy; it extends from the provision of world class health-care to her citizens, enhancing treatment, but is also in revenue generating and boosting the medical reputation of a country. Notwithstanding the fact that R&D in health sciences is essential for Malaysia as a developing nation, but there are challenges that include minimal research activity in health sciences, the over-focus on the delivery of health care instead of a balance between practice and R&D, insufficient investments in health sciences R&D, lack of R&D participation by the private sector, weak innovation and incentive systems, lack of qualified personnel for R&D, increased workload for health practitioners and outdated or inadequate infrastructures, among the factors.

This Advisory Report is yet another important initiative of the Academy of Sciences Malaysia and we are confident that the findings contained therein would lead to the Government taking concrete step towards enhancing research and development in the Health Sciences areas. We are hopeful that the Government will consider implementing the recommendations proposed in the Report.

Tan Sri Ahmad Tajuddin Ali, FASc
President
Academy of Sciences Malaysia

Preface

The Malaysian health system has always been focusing on increasing the health status of the population, to improving the responsiveness of health services to the population, and to improving the financial fairness of funding for the health system.

The ASM Task Force on Enhancing R&D in Health Sciences organized two data-gathering sessions; the first, a *Workshop on Enhancing Research and Development in Health Sciences* and, the second, a *Round-table Forum on Enhancing Publications in Medical and Health Sciences*. Both data-gathering sessions were designed and organized to bring together clinical practitioners, academics, policy makers, researchers, industrialists, pharmacists, dentists, medical scientists, medical and health sciences journal editors. The *Workshop on Enhancing Research and Development in Health Sciences*, held on 14–15 February 2012 at the Institute of Health Management (IHM), grew from the urgent need to produce a roadmap on enhancing R&D in medical and health sciences while the *Round-table Forum on Enhancing Publications on Medical and Health Sciences*, held in the Academy Sciences Malaysia on 3 March 2012, was focused on developing the strategies to enhancing publications in medical and health sciences.

The ideas shared in both data-gathering sessions obtained through the feedback from the varied participants in further enhancing R&D in medical and health sciences in Malaysia in prioritised areas including natural products, pharmaceutical and traditional complementary medicine, medical devices, diagnostics and vaccine, omics, nanotechnology and stem cells, areas identified from the Report on the *ASM Mega Science Framework Study on Sustained National Development 2010–2050*.

Ideas generated were incorporated as input into the *ASM Advisory Report on Enhancing R&D in Health Sciences* will be forwarded to the Ministry of Science, Technology and Innovation (MOSTI), Ministry of Higher Education (MOHE), the Ministry of Health (MOH), other relevant ministries and agencies for their consideration. This will also be a template for future emerging medical and health sciences like Neurosciences in the near future.

We hope that this document will help the relevant Ministries to plan and implement strategies accordingly after the approval of the Science Act of Malaysia.

Last, but not least, we would like to extend our sincere appreciation to MOSTI, MOHE and its IHM as well as to all invited speakers, moderators, rapporteurs and participants for their undivided support and assistance in making the development of this Advisory report a success. To Dr Chan Kok Gan from the University of Malaya who prepared, compiled and presented the contents of this document up to the level of the ASM's STI Policy Advisory Committee, chaired by the ASM President, Tan Sri Ahmad Tajuddin Ali and thereafter did editing according to the committee's suggestions; thanks a million.

I hope this document will be used as an important reference and not gather "dust" in a cabinet so as changes can be made to the implementation of new policies on Health Sciences at the national level.

The secret of getting ahead is getting started ~ Mark Twain

Prof Jafri Malin Abdullah, FASc
Chairman
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ASM Task Force on Enhancing Research and Development in Health Sciences

EXECUTIVE SUMMARY

Research and development in health sciences is of paramount importance to any economies, it extends from the provision of world class health-care to her citizens by enhancing prevention and treatment, but also in generating revenue and boosting the reputation of a country. Notwithstanding the fact that R&D in health sciences are essential for Malaysia as a developing nation, there are numerous challenges that the country currently facing which include: minimal research activity in health sciences, over-focus on the delivery of health care instead of a balance between practice and R&D, insufficient investment in health sciences R&D, a lack of R&D participation by private sectors, weak innovation and incentive system, lack of skilled and qualified personnel for R&D, over workload for health practitioners, poor quality of publication in low impact journals, and outdated or inadequate infrastructure required for R&D activity.

The Malaysian government places importance on the expansion and development of health care, putting 5% of the government social sector development budget into public health care. With a rising and aging population, the Government wishes to improve in many areas of health delivery and therefore in line with this there is a compelling need to enhance R&D in health sciences.

It must be recognized that any effective treatment for clinical application must originate from basic and fundamental research in any evidence-based health sciences. At its current state, Malaysian health sciences are clearly lacking of a systematic approach in its R&D activities. If left unattended, this will translate into lack of novel and innovative clinical treatments, medicine, poor health care system and low grade medical sciences and poor reputation of Malaysian health sciences.

Undeniably, Malaysia has been lagging behind in medical and health sciences R&D at both regional and transnational levels. To address these issues, ASM undertook a series of two workshops that involved clinical practitioners, academics, policy makers, researchers, industrialists, pharmacists, dentists, medical scientists and medical journal editors. With this wide spectrum of audience, useful insights have been obtained. Strategy has been suggested to enhance R&D in health sciences in Malaysia, including calling for a more stringent and accountable grant and funding allocation and monitoring, short- and long-term human capital development strategy, suggestion for more pre-clinical and clinical trial, upheld professional and ethical conducts for research, legal support for intellectual properties rights and advice, multi-facility research centre of excellence providing adequate, shared instruments and database management for easy data deposit and retrieval on metadata.

The Terms of Reference of this Task Force are as follows:

a) To summarize and disseminate the findings from the report of *Mega Science Framework for Sustainable National Development: Health and Medicine Sector Study*;
b) To develop the strategies to enhance R&D and publication in medical and health Sciences; and
c) To produce an advisory report (including a roadmap of implementation) on enhancing R&D and publication in Medical and Health Sciences Malaysia for dissemination to the relevant authorities for action.

To enhance R&D in the health sciences in Malaysia, prioritised areas include:

- Natural products;
- Pharmaceutical & traditional complementary medicine;
- Medical devices, diagnostics and vaccine;
- Omics;
- Nanotechnology; and
- Stem cells.

Several strategies have been proposed including:

- Funding for research must be selectively allocated based on the merit of the proposal and researchers, and stringent monitoring systems for progress and outcome;
- Human Resource development which includes the creation of attractive remuneration for researchers;
- Publication in reputable, high impact journals, and monitor citation index;
- To set up a commercialisation centre to assist with the development and commercialisation of R&D products;
- Systematic and independent monitoring on R&D performance; and
- To create long term Research & Innovation policy focusing on priority diseases and issues.

Although six areas have been shortlisted as focus for development, this report opined that one prioritized area namely, natural products, pharmaceutical and traditional complementary medicine, should be given added priority to ensure success of the health research in Malaysia with respect to efficiency and cost-effectiveness. The detailed reason is provided in the report herein. This report further opines that, although six core research areas have been identified, it remains factual that Malaysia is till not ready to promote all these areas in health and medical research. Not only the research funding (both public and private) is lacking or not comparable to the advanced country, the amount of funding received for health sciences research simply cannot sustain all these shortlisted areas. More importantly, lack of proper infrastructure support and highly skilled manpower are another hindrance. This report opines that Malaysia should first focus on the basic research that stress on fundamental research before leaping into application and commercialization. Lesson learnt from advanced countries clearly showed that those economies have invested vast sum of money as per their GDP, and long time to incubate proper infrastructure, trained skill manpower and more importantly research culture. All these are lacking in Malaysia. While schools of matriculation and pre-university students swarm to the "professional courses" or "marketable

courses", this phenomenon strongly indicates the mentality of the pupils and parents that the applied sciences instead of basic sciences, are welcome. In advanced countries, however, the basic sciences are the schools that provide cutting edge ideas, new findings, theories *etc* as the locomotive for the applied sciences. This report also opines that funding from public sector should emphasis more on the fundamental research on health related issues. Without proper understanding of the basic, any application of the work will be flaw eventually.

Due to the lack of research culture, research funding objective are diversified to support a myriad activity of medical researches, lack of properly maintained infrastructure, lack of involvement of advanced countries laboratories and personnel in Malaysia research activities, serious lack of funding from the private sector, poor public perception on basic research and unhealthily skewed towards applied sciences that leads to shortage of suitable and capable human capital for research, serious shortage of good quality scientific literatures in Malaysian society, poor attitude of researchers on good research and hence good publication; are all contributory factors that Malaysia should revisit her research policy in health and medical sciences.

Lack of clinical experts involved in heath research activity originates from the over-workload and insufficient human capital to ease the clinical workload. It is suggested that the relevant authority should divide the clinicians for full time clinical work, and the others will involved in both research activity and clinical duty.

INTRODUCTION

Malaysian health system has always been focusing on increasing the health status of the population, to improve the responsiveness of health services to the population, and to improve the financial fairness of funding for the health system.

As a framework for examining the strengths and weaknesses of the Malaysian R&D in health sciences and possible need for reform, it is recommended that cost efficiency must be borne in mind. Due to the nature of health sciences, myriad areas can be shortlisted for improvement, but for efficiency, this Task Force has identified six areas that warrant attention *viz*.:

- Natural products;
- Pharmaceutical and Traditional Complementary Medicine;
- Medical Devices, Diagnostics & Vaccine;
- Omics;
- Nanotechnology; and
- Stem Cells.

To achieve this, the Task Force had organised two workshops. The first, entitled *To Identify the Strategies to Enhance R&D in Health Sciences,* held in IHM on 14–15 February 2012. The second workshop, entitled *To Identify the Strategies to Enhance Publications in Health Sciences*" was held on 3 March 2012 at the Academy of Sciences Malaysia (ASM), and both were organized by ASM. The aim of the first workshop was to solicit strategies from experts with various fields to formulate strategies to improve R&D in health sciences in this country. The second workshop was aimed specifically to address publication issues of medical and health sciences in Malaysia.

Although a number of problems identified are peculiar to each of the six areas (1 to 6) aforementioned, but all these areas appeared to have common issues, as listed below:

Human capital

There is a general trend that fundamental science subjects are not being emphasized in Malaysia. It is believed that fundamental science is a less practical subject for tertiary education, and this perception will surely take longer time to swift the paradigm. The National S&T Policy II indicated that the 60:40 ratio of students in science, technical and engineering vis-à-vis arts students' fields should remain in order to ensure the success of the national agenda (Vision 2020) whereas the current ratio is merely 20:80 [Science and Technology Human Capital: A Roadmap for Malaysia's S&T Workforce to Achieve Global Competitive by 2020 (MOSTI 2012)]. Due to these biases and prejudices, it is difficult to ensure continuity of skilled personnel in the market. To illustrate, from 1994–2008, on average, there were only 5 researchers per 10 000 population in Malaysia. There is also lack of skilled manpower that can bridge research and commercialization. Malaysia lacks expertise in all fields and areas of research including the basic sciences, clinical, epidemiology as well as social sciences but most particularly in highly specialized and new areas. In 1999, *Majlis Penyelidikan dan Kemajuan Sains Negara* — the predecessor to the current National Science Research Council (or, NSRC) — projected that Malaysia needs 493,830 human capital in researchers, scientists and engineers (RSE) by 2020. This means

that the rate of increase in RSE should reach about 31.30% per year. This is partly a result of less attractive employment package and minimal publicity on career information, and this has created uncertainty where researchers' career which typically requires highest qualification such as doctorate or equivalent but yet there is no assurance of their employment and career development in Malaysia.

There is a distinct lack of a career pathway for researchers who are often forced to undertake contract positions resulting in a lack of job security and a clear career advancement outlook. In addition, bureaucratic hindrance in job application and career development discourage skilled researchers from being involved in local research activities. At the national level, neglected career opportunity planning for national development of a specific research field, added on with the failed research outcome which has no capacity to instil industry development to support the job market have contributed to the poor R&D performance in Malaysia. This view has been reflected in a recent survey done by MOSTI [Science and Technology Human Capital: A Roadmap for Malaysia's S&T Workforce to Achieve Global Competitive by 2020 (MOSTI 2012)].

Fresh lecturers and researchers have insufficient experience and this might affect the quality of performance. This is due to lack of industrial skills or training for the recently graduated doctorates. Thus, sending students to pursue their doctorate degree and/or even post-doctoral degree in foreign universities was encouraged. Unfortunately, the funding for sending local students to foreign universities for postgraduate and/or post-doctoral studies has been minimized. Thus, more funding or scholarships for students to do their postgraduate or post-doctoral in foreign universities is highly needed. Also, it has been pointed out on the projection made for faculty members in Pure Sciences, assuming that there is no increase in the number of jobs as faculty members with PhD qualifications in the 20 Public Higher Learning Institutes (*Institut Pengajian Tinggi Awam*, IPTAs) until 2020, on the assumption of the ratio of 1:15 (faculty/student), it reveals a shortage of 18,777 faculty members in 2020 [Science and Technology Human Capital: A Roadmap for Malaysia's S&T Workforce to Achieve Global Competitive by 2020 (MOSTI 2012)].

Several issues have been discussed which may contribute to the low number of postdoctoral research fellow, such as (1) Questionable mentorship in which the Principal Investigator (PI) has no post-doctoral experience or no experience in the research area; (2) post-doctoral research fellow was used as cheap labour by PI for grant application, research work, publication etc.; and (3) Lack of clear career development. Besides, there are other factors that cause the low number of post-doctoral research fellow, such as (1) Limited vacancy for postdoctoral position; (2) Funding do not accommodate the cost of hiring a post-doctoral; and (3) Lack of proper post-doctoral training programme in Malaysia. Supervisors, or PI, play an crucial role in the recruitment of post-doctoral. Therefore, the PI must have the credentials to supervise post-doctorals (*Figure 1*).

In order to have sufficient human capacity for science and technology in the future, there is a need to instil the interest of science and technology among our younger generation. At the presence, the interest towards science and technology among primary and secondary school children are relatively low. Besides, teachers in secondary schools have low exposure and knowledge about the trend in science and technology, such as nanotechnology.

Figure 1. Human Capital.

Quality of Publications

Malaysian researchers generally have not been contributing articles in highly prestigious journals. In the contrary, cases of publishing in non-reputable journals, with low levels of citation and impact factor with no application at industry or societal level in order to fulfil institutional KPIs for promotions have been reported. Most of the time, this has gone unregulated and unchecked. To illustrate, for Science Fund managed by MOSTI, in its report on the outcome of funding provided by MOSTI, out of the total 12,785 journals published, only 2,697 articles are published in international journals (MOSTI, *Pencapaian Projek Geran R,D&C MOSTI untuk RMK-8*). In RMK-9, out of 14 768, only 4413 articles are published internationally (MOSTI, *Pencapaian Projek Geran R,D&C MOSTI untuk RMK-9*). Similar poor performance has been observed also, as illustrated in RMK-10, (MOSTI, *Pencapaian Projek Geran R,D&C MOSTI Untuk RMK-10*).

This means that merely 21.1% and 29.9%, for RMK8 and RMK9 have resulted in international publication; but note that not all international publications are regarded as reputable. This is worrying because >70% of the articles published that are supported by MOSTI cannot result in high impact, reputable journals.

Publication in such category of journals must be discouraged at the policy level, so as to (i) Ensure public money is well spent for quality output, and (ii) To encourage researchers to strive for better research finding with significant impact instead of involving in an exercise of "re-inventing the wheel". Furthermore, publication in these journals that often require payments is regarded as a waste of taxpayer resources and causes outflow of local currency with no significant and appropriate academic gain. In order to curb this problem, common and standard guidelines for publication should be established, in which the guidelines for the level or tier of publication, Institute for Scientific Information (ISI) journals issues, and impact factors should be implemented at the national level through government enforcement. Again, this will create teething problems at first, but it will be beneficial in the long term for Malaysia's research community and reputation.

Most local universities are looking into publication in high impact journals (i.e. journals with high impact factor). This condition causes local journals not be supported or creating a mentality among local researchers to support local journals as a second choice. But this

reinstates the fact that there is a need for local editors and publishers to strengthen the quality of their journals. To compete internationally, protectionism will not work and hence it is recommended that local journals must strive to increase the quality of the papers accepted for publication.

Publication of research projects is distributed over a wide range of database. Thus, Malaysian Science and Technology Information Centre (MASTIC) has recommended to establish a more comprehensive database for publication in order to provide easier access to all publications done.

Monetary incentive for publication was viewed as unethical, unprofessional and must declare conflict of interest, therefore should be abolished. This happened due to no clear and comprehensive guideline for publication ethics. Thus, a clear guideline on publication ethics, covering topics such as criteria for authorship, ghost-writer and monetary incentive, is essential in order to inculcate a scholarly community with integrity and accountability.

It is recognised that use of foreign/local private services to carry out research e.g. using third party to carry out the entire research and writing of papers — not a prevalent problem in Malaysia but requires attention as this defeat the purpose of nurturing local talent/facility build up. It is observed that cases of publishing in non-reputable journals exist. Publication in non-reputable journals with cash payment is regarded as a waste of taxpayer resources.

There is a call for good monitoring team from institution or government and among the scientific community. It is desirable to have common guidelines e.g. tier of publication, Scopus, ISI implementation shall be firmly implemented at the national level. To implement rules and monitoring via government authority, research grant disbursement shall be accompanied by agreement stating avoidance of data purchase effectively. Also, appropriate education and nurturing of students and researchers on research ethics, conduct and purposes must be carried out. The effective strategy stems from the very basic requirement of professionism and integrity. Failure of which, the funding agency must exercise strict monitoring on underperformed grantees that publish in low impact papers. Funding agency should even consider recall facility should the grantee consistently disregard requirement on good publication.

Funding

Funding is one of the main issues faced by the medical sciences communities even though many grant disbursement bodies are available. From 1992–2008, on average, the gross expenditure on R&D per GDP is only 0.44 (MASTIC, *Kajian Penyelidikan dan Pembangunan (R&D) Kebangsaan 2011*). As compared to advance country such as USA, the ratio is 1.4 which is triple that of Malaysia. The possible factors that contribute to this issue is due to the unique procedures employed for different grant disbursement bodies, such as the requirement of having PI from the Ministry of Health (MoH) and unreasonable request for track records. Due to these factors, some good proposals have previously been rejected.

Gaps exist between funders and applicants, such as the objectives and products of both parties are not aligned, lack of monitoring for multiple applications, and in some cases, funding was cut without reasons given. In these conditions, grant review process and mechanism needed to be revised. There is a need for many researchers to improve their grant proposals with a better description of research proposal, clear-cut objectives and

methodologies. Effort must be taken to improve the level of English in these grant proposals. A proper monitoring system for grant submissions and other ethical issues need to be considered and reviewed to establish a transparent system (*Figure 2*).

Disproportionate allocation of funds and lack of corrective actions to fund-receivers who fail to perform have indicated the failure of monitoring of local research projects and evaluation of research performance.

Besides, there is a need to have priority setting from the top level of management and funding agencies. In order to avoid bias and unfair review mechanism, reviewers from the region rather than local experts should be invited to review local progression, policies and direction of nanotechnology research.

The process of grant application is always is always doubtful. Several issues have been brought out, such as questionable rationale and worthiness, proposal without preliminary data, Grantee has no track record in the field, collaborators with no contribution, unconstructive comments from reviewers, limited time for the reviewers to make a wise and quality judgement and inconsistent decision from the reviewers as well as the management. The reviewers need to be able to make wise decision at the short period of time and able to provide quality comments and justification to the applicants, especially during the rejection of proposal. The main objective is to establish an accountable, ethical and professional preview process with transparency.

In addition to these common problems, a number of recommendations have been made, arising from the deliberation and brainstorming from the two workshops which include:

a) Funding for research must be allocated based on the merit of the proposal and track record of the researchers, with stringent monitoring systems on progress and outcome;
b) Human resource development which includes the creation of attractive remuneration for researchers;
c) Developing ways to assist researchers on publication in reputable, high impact journals, and monitor citation index;
d) Commercialisation centre to assist with the development and commercialisation of R&D products;
e) Systematic & independent monitoring on R&D performance; and
f) Creating long term research and innovation policy focusing on priority diseases and issues.

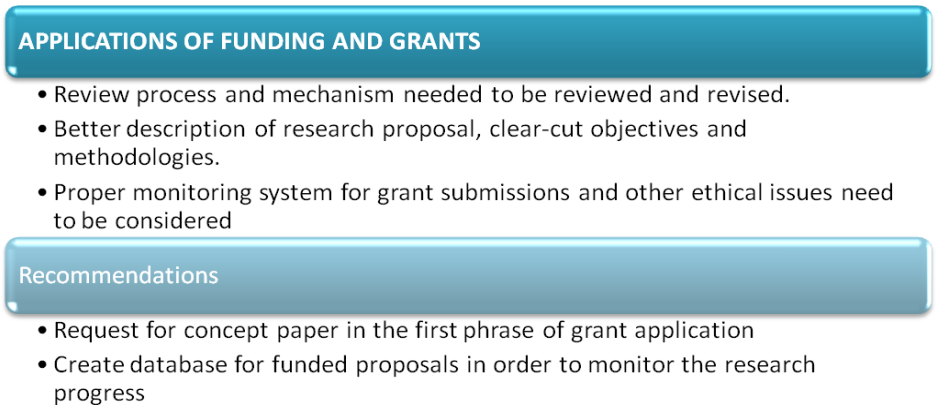

Figure 2. Funding and grants applications issues and its recommendation.

Logical Framework Analysis of Scientific R&D in Malaysia

The objectives of the discussion were (1) To identify the strategies to enhance R&D in Malaysia; (2) To identify R&D needs arising from the findings of the reports of ASM Mega Science Framework for Sustained National Development 2010 – 2050; and (3) To produce a roadmap to enhance R&D in Malaysia and disseminate to the relevant authorities for action.

Part A: Identification of Strategies to Enhance R&D in Malaysia

Research and Innovation

Co-ordination of funding and facilities for local R&D. Currently, the research output of Malaysia is low and only confined to a rather narrow area of expertise of a particular research group. This is partially due to a lack of effective coordination mechanism on research flow, expertise or researchers and resources in Malaysia, especially at the university and institutional level. The outcome of poor coordination is associated with a lack of understanding of frame work on intellectual properties and other modes of benefit sharing. On the note that integrating research groups with different expertises shall be emphasized, cross-disciplinary collaboration with prior intellectual properties rights or benefit issues clarified should be encouraged. In the long run, this in turn is envisaged to allow researchers to perform all aspects of research through the involvement of various expertises e.g. standardization, isolation, structural determination, formulation, preclinical data study (*i.e. in vivo* assay, *in vitro* assay, toxicology test etc.) in development of a natural product.

Poor project planning and low levels of collaboration between researchers resulting in multiple grant applications on the same topic. This has resulted in minimal output from a large outlay of financial grant. There is a need to set up a functional society or association to facilitate researchers to meet, interact and establish potential multi-disciplinary collaborations. National Science Research Council, society, association, university and/or institution can be the main players in coordination, implementation, and facilitation of gelling of research, expertise, facility and equipment sharing. Additional incentives can be given to gelled expertise, based on positive and remarkable research outcome of the applied grant.

Under specific circumstances, the available facilities or instruments are not being shared among the researchers. This is ascribed to the territorial behaviour of researchers, faculties and/or universities, as a result of negative competition between universities for research university ranking. There is a need to streamline and synchronize the existing governing organization. With reference to IPHARM that possesses advanced research facilities or equipment for sharing, the relevant authorities could publicize and facilitate access to the existing resources with prior intellectual properties or benefit issues clarified.

International Collaboration and Research Expertise

In traditional Chinese medicine, herbal extract, and natural compound research etc, the research activities often do not go beyond screening and *in vivo* assay. Preclinical and safety data are always not available. The latter is the prerequisite for product commercialization.

Inappropriate coordination of funding and facility is one factor which negates the process of research and commercialization.

Another reason for poor data collection is the lack of expertise or experienced researchers in the relevant field of research. This issue may be resolved through collaboration with international experts where there are no local experts or critical benefits can be obtained from partnership with overseas partners. A strategic plan must be developed to create a pool of researchers in specific fields particularly in new areas of medical research such as bioinformatics, genomics, nanotechnology to name a few. On-going development of skilled personnel in traditional fields such as epidemiology and biostatistics to support good research must also be continued and enhanced. To this end it is imperative that the local universities develop quality national experts through postgraduate, postdoctoral fellowship, and on-the-job training programmes. In addition, local research companies shall be provided with tax incentives with respect to their effort in building research facilities and relevant consultation. Companies must be encouraged to have government links for ease of access by local or international, public or private organizations for collaboration.

Grant Proposal Evaluation and Disbursement

Research concept/area and grant monopoly by specific researchers, poor fund or grant disbursement and lack of qualified grant proposal evaluators are some common examples of pitfalls in research grant application. Engaging international reviewers for grant application might not be a long term idea as there is a risk of having such project ideas being hijacked. Further, grant proposal evaluations are often conducted with no respect for confidentiality or ethics. Attention must be paid to the issue of conflicts of interest during the grant application and review process. Several recommendations are suggested, namely:

1. Annual call for new research proposal evaluators based on curriculum vitae where analysis can be effected based on advice at the international level;

2. All evaluators are required to sign a confidentiality, ethics and/or conflict of interest bound agreement prior to evaluating proposals;

3. Call for proposal evaluations and grant disbursement shall be effected by neutral bodies; and

4. A summary of grant disbursement and outcome shall be publicized effectively, with rationalized reasons of grant proposal rejection.

Cases where mega grants are awarded to researchers, who lack strong research experience, research grants awarded to research project which lacks novelty, and mega grants for research team which generates unclear or unpublicized reports, are reported. Low levels of transparency in grant disbursement and monitoring process will severely jeopardize the quality of local research and the development of science and technology in Malaysia. Stringent control right from the research grant application level can aid to eradicate such unnecessary practice.

Ethical Practice in Local Research

Implementation of scientific research ethics in Malaysia is at its infancy stage despite the availability of guidance. Cases where riders with no intellectual contribution appear in research project and research output have been observed. The existence of riders in research is a fruit of power struggle at grant application level where advancement of career is jeopardized if there is no involvement of riders. There is a need to review the ethical practise and management system at university, institution and national levels. Grant providers, such as Ministry of Science, Technology and Innovation, Ministry of Higher Education and MOH, are encouraged to set up channels for complaints and follow up by action and/or investigation. A proper/thorough evaluation of current research related rules and regulations of the university and institution are required, in order to maintain a healthy and transparent research culture in Malaysia.

Human Resource

Please see the general problems in the Introduction section.

Business Matching and Commercialization

Lack of preclinical/clinical data for products. Currently, there is no strong entity to conduct preclinical/clinical assessment from the perspectives of commercialization. This might be due to a lack of human resource etc. Proper coordination and management of human resource, facilities and equipment are required in order to facilitate the commercialization process of research outcomes. There is a need to set up a local commercialization centre where final testing of research outcomes, drafting business plan and performing market survey for the relevant research outcome which is ready to be commercialized can take place. Such centre for commercialization can be set up at different scales at university, industry and national level. It functions to facilitate commercialization based on mutually agreed terms and conditions, thus indirectly exerting positive competition among institutions for betterment of product and economic growth. In association with such set up, international technical and economic experts are recommended to be invited as the advisory members at the early phase of commercialization and set up of centre. The centre for commercialization is recommended to involve both local and international business entities to the fullest possibilities.

Proper and established mechanism for commercialization of research outcome. There is incomplete and inadequate guidance on the route to commercialization. There is a serious lack of proper guidance for writing business proposals, conduct market survey and relevant tests as well as contacting the relevant involving agencies in the process of commercialization. Currently, researchers are expected to act as business entity. This can be an excessive task and is a burden for most researchers. In an optimal condition, national and private commercialization entity should be present. Therefore, a centre for commercialization, as discussed above (Lack of Preclinical/Clinical Data for Products) is one of the recommended strategies. The centre for commercialization of research outcomes will play a role in establishing strong ties to local business entities who wish to commercialize locally made products *via* providing incentive, convenience or promotion in the associated business development.

Research and Innovation (Policies, R&D and IT Healthcare)

Applications of funding and grants.

Several recommendations were suggested, such as choosing the right research groups to perform the suitable and appropriate research. Revision of the review process was suggested in order to yield a transparent, critical and creditable review committee. Even though there are many grant disbursement bodies, but there are many research groups that receive no grant to perform quality research. Therefore, there is a need to increase funding to fuel the research in our nation. Besides application for grant via submission of research proposal, interview with the grant applicants was recommended. Two strategies were recommended, one, request for concept paper in the first phase of grant application in order to reduce paperwork and for better grant application screening; two, create database for funded proposals in order to monitor the research progress, unethical practices and duplication.

Lack of collaboration among researchers.

Duplication of funding, facilities and even infrastructure were observed and these indicate funding is not optimized and therefore leads to slow progression in research (Figure 3). A better research culture needs to be cultivated and enhanced especially focusing on collaborative and multi-sectorial research projects and programmes. Sharing of research facilities and findings should be encouraged. Thus, recommendation of establishment of proper database for researchers and/or research groups in order to encourage research exchanges through active connections. Therefore, establishment of database and encouragement of multi-disciplinary projects will create chances for collaboration, enhance collaboration and exchange of information and this will increase the quality of local research collectively (*Figure 4*).

Figure 3. Effects of lack of collaboration among researchers.

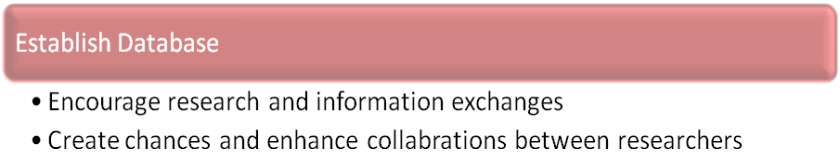

Figure 4: Recommendation of establishing database

Towards sustainable research.

One of the problems of current research in Malaysia is that research fields are not properly aligned to problems such as non-communicable diseases, emerging and/or re-emerging of diseases including zoonotic diseases. This might due to short term funding policy, insufficient research funding and researchers to venture into these areas. Therefore, creating a halo zone in training researchers in emerging diseases and technologies of the future is essential. We are in urgent need to train more researchers in these areas. One of the recommended action plans is to increase funding for the relevant research areas, such as biomarkers for non-communicable diseases, and medical devices for senior citizens as well as those who are physically impaired.

Status of local products

Most instruments, products and goods used in research are imported due to several factors, i.e., difficulty to get buy-in for local products and a lack of local products for the relevant research projects. Imported products are always more expensive and more superior compared to local products due to the negative perception towards local products. Thus, there is a need to increase the number as well as the quality of local products. Besides, there is a need to encourage local researchers to use local products *via* publicity and promotion. Several strategies are recommended in order to increase the status of local products, i.e. create awareness of local products, ensure that local products undergo appropriate validation and accreditation process by local agencies, involve local regulatory bodies to play a more active role in providing guidance and to create driver and champion from top management to use local products (*Figure 5*).

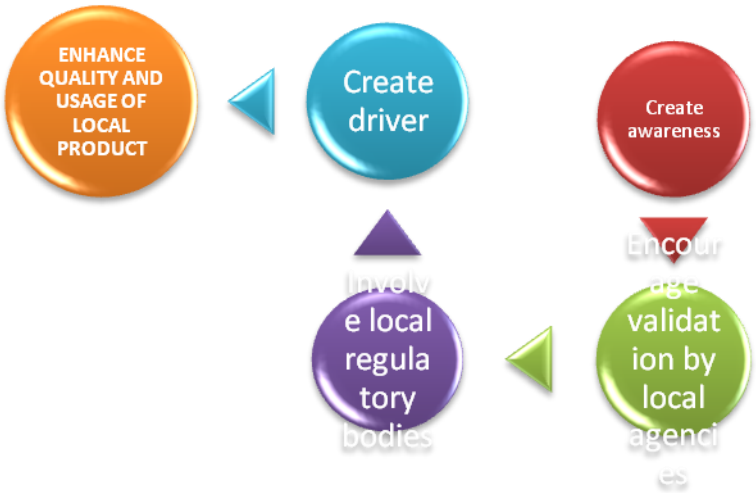

Figure 5. Enhancing the quality and usage of local product.

Sharing of information.

There are barriers in the sharing of information among agencies, institutions, and research centres, which might due to a lack of trust among these bodies. Therefore, during outbreaks, diseases are not being handled immediately and effectively, e.g., Nipah Virus outbreak. Thus, transparency is needed and a sharing of information between agencies is encouraged. Besides, linking between medical doctors, pharmacists, veterinarians and researchers are highly encouraged in order to create better healthcare and safer environments. Therefore, open access database that is free and credible should be established in order to encourage free flow of information.

Project nature and grant responding.

In some condition, researchers are forced to merge projects to fulfil particular criteria of the grants with the objective of encouraging collaboration and sharing of information. There are conditions where the researchers are not familiar with the collaborators and this might not be workable in the long run. Thus, in order to foster real and meaningful collaboration, funding bodies should take the leading roles in fostering meaningful and productive collaborations as well as interdisciplinary research, such as encouraging researchers to look for their own preferred collaborators.

Human Resource

Shortage of skilled researchers.

Please see the general problem in the Introduction section.
Several recommendations are suggested to resolve the issue of shortage in skilled researchers, namely:

1. Doctorate holders shall undergo postdoctoral training for 2 to 3 years at a different reputable institution prior to joining the relevant research institution or academic sector;

2. A higher salary should be provided for skilled personnel or postdoctoral fellows in order to retain these talents within the country;

3. Setting a higher entry requirements of global standard when hiring academic, researcher and/or supporting staff for research work to avoid incompetent leading the competent cohorts;

4. Enhance publicity in the area of science and technology careers;

5. Establishing a good system of mentorship for young researchers, by merit and experience;

6. Appropriate and strategic planning with stake holders with respect to the education system, academician and researcher employment systems as well as research field creation or emphasis for future economic growth;

7. Contract requirement of trained post-doctoral fellow and/or experts to join local

research team;

8. Establish mechanism for human resource quality audit, in which employment and reward shall be based on research merit.

9. Revision of secondary and undergraduate education system, pertaining to fundamental subjects such as physics, biology and chemistry;

10. Evaluation of research examination standard annually by a neutral body, and comparison among universities and/or institution can be effected with the involvement of international expertise invited by the neutral body;

11. Implementation of guidelines on ethical training and graduation; and

12. Involvement of industries in national planning of the country direction with respect to research and economic growth.

Business Matching and Commercialization

Commercialisation of university technology.

In Malaysia, the commercialization rate of university technologies is relatively low as the funded research projects have little or no relevance to industry and humanity needs (*Figure 6*). Thus, researchers including those in fundamental research need to be aware of industry and economic needs. Furthermore, the researchers need to think of the final application of the science before designing the research. Besides, local academicians are not in touch with industrial needs, thus, creating a gap between university technologies and industrial applications. Several action plans have been recommended, such as to provide funding to bring industrial experienced people to the university ecosystem, encourage academicians to do sabbatical in industry, getting the industry to evaluate university technologies, train and establish new set of expertise for technology transfer offices which are able to understand both technologies and business, encourage and enhance interaction between industry and university research, increase pre-commercialization fund, exposure of university research to industry, and set up agencies and bodies in matching people with the right people with the right technology. Besides, strategies such as tax incentives for companies which take up university technologies, good legal office to advice the researchers, and establishment of a more flexible and efficient mechanism for disbursement of funds are recommended.

Status of provisional patent.

Provisional patent is not available in Malaysia and therefore technologies are not being protected at the idea stage. Thus, there is a need to put up for a provisional patent.

Dependence on foreign import in local community.

Local community remains very dependent on foreign imported goods, such as medical devices, diagnostics, vaccines and drugs. Several action plans have been recommended, e.g. own production of veterinary vaccines and anti-venom drugs, development of halal vaccines, and the establishment of an infrastructure in Malaysia for the production of veterinary and human vaccines using bacteria.

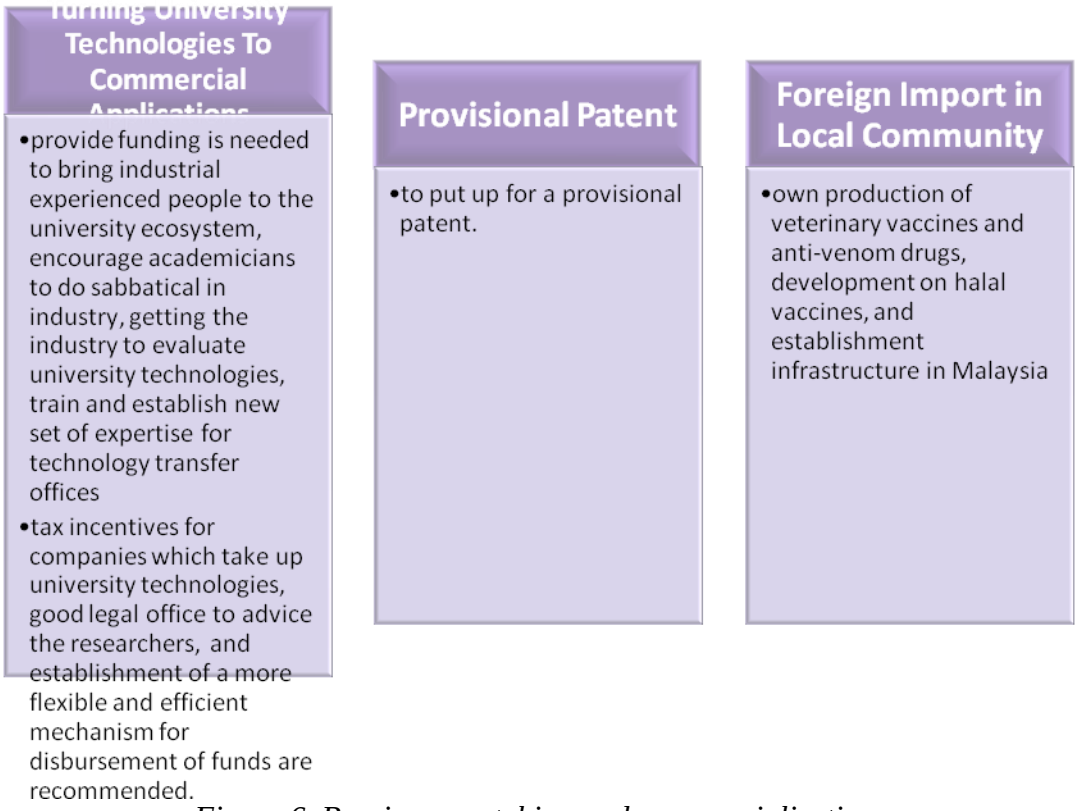

Figure 6. Bussiness matching and commercialization.

Monitoring and Accountability

Monitoring of funded research.

At the current stage of reporting system, local funding agencies are weak or not able to monitor the grant expenditures. In some cases, even projects are being monitored, proper feedbacks area not provided. This indicates the failure of the monitoring mechanism. Therefore, regular reporting at reasonable intervals is recommended in order to monitor the progression of the project. Besides, feedback after monitoring is important. A good monitoring mechanism is crucial for both project funders and researchers.

Information sharing and reporting mechanism of projects.

In some conditions, huge amount of money are being invested on certain mega projects and people are not informed of how the funds are spent and the outcomes or products of the projects. This shows that there is room for improvement in the reporting mechanism and sharing of information. Duplication of funds and facilities has been reported and this is a clear indication of weak monitoring mechanism.

Publication

See general problems in the Introduction section.

Roadmap for a Better R&D in Medical Devices

Development of medical devices that address high burden diseases needed by the tropical countries.

At the current stage, R&D agenda with a focus on medical devices with high demand and high potential for commercialization in tropical countries should be established. Besides, there is a need to upgrade existing laboratories to World Health Organization certified level and establishment of biohazard level 3 (BSL-3) and level 4 (BSL-4) laboratories in order to perform high impact R&D.

In the long run, the goal of these strategies is to establish a world class Centre of Excellence for medical devices (*Figure 7*).

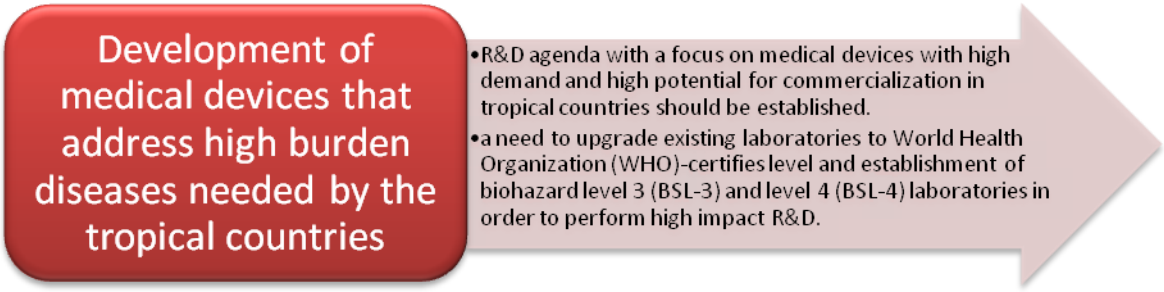

Figure 7. Development of medical devices that address high burden diseases needed by the tropical countries.

Development of critical mass of human capital of R&D in medical devices.

In order to develop research on the development of medical devices in Malaysia, several steps have been recommended, including the recruitment of biomedical engineers from countries with more advanced medical device industries. Besides importing technologies to Malaysia, advance training in developed nations should be offered to selected local biomedical engineers.

The ultimate objective for this strategy is to produce highly skilled local scientists in biomedical engineering through basic and post-graduate training, by establishing and enhancing biomedical engineering courses in local universities.

Steps towards successful commercialization of locally produced medical devices.

A policy to guide the development and commercialization of locally produced, medical devices should be prepared. Local health institutions should be encouraged to procure and use medical devices produced by local manufacturers. Medical Device Bureau of MoH should be appointed and more proactive in endorsement and promotion of local medical devices.

Roadmap to a Economic and Quality Medical Diagnostics

Development of quality medical diagnostics.

R&D agenda with a focus on medical diagnostics with high demand and have shorter production time, shorter detection time, e.g., tools for cancer detection, genetic testing and HPV detections, should be established. Besides, existing laboratories should be upgraded to WHO-certified and biohazard level 3 (BSL-3) and level 4 (BSL-4). All these strategies lead us towards a world class Centre of Excellence for medical diagnostics.

Development of critical mass of human capital in medical diagnostics.

Biomedical scientists from countries with more advanced medical devices industries should be recruited. Advanced training in the developed nations should be offered to selected local researchers. The main goal of all these strategies is to produce highly skilled local scientists in biomedical engineering through fundamental and advanced training courses.

Ensure successful commercialization of locally produced diagnostic tool.

Local health institutions should be encouraged to procure and use diagnostic tools produced by local manufacturers. Besides, Medical Device Bureau of MoH should be appointed to ne more proactive in endorsement and promotion of local products. Furthermore, a policy to guide the development and commercialization of locally produced medical diagnostics should be established.

Roadmap to Development and Vaccines in Malaysia

Determination of capacity in vaccine development.

Evaluation of previous and existing R&D and commercialization activities in vaccines development should be conducted, including the extent of R&D outcomes, the capacity of human resources, as well as the enablers and obstacles. This enables us to evaluate the mileage of the research and potential of commercializing the vaccines.

Vaccines developments and improving cost-effectiveness of existing vaccines.

It has been proposed that vaccines for critical diseases should be set as the target of development. R&D should be performed in order to improve the cost-effectiveness of existing vaccines (*Figure 8*).

R&D on vaccines and commercialization of vaccines should be integrated into National Science, Technology and Innovation policy and health policy to ensure allocation of adequate and long term funding for R&D of vaccines.

Institutions are encouraged to collaborate and/or getting financial support from the private sector. In order to encourage private sector involvement and investment in vaccines R&D, incentives, such as tax incentives should be offered. Besides funding, human resource is another crucial factor. Human resource capacity to strengthen competencies related to vaccines development and commercialization should be enhanced.

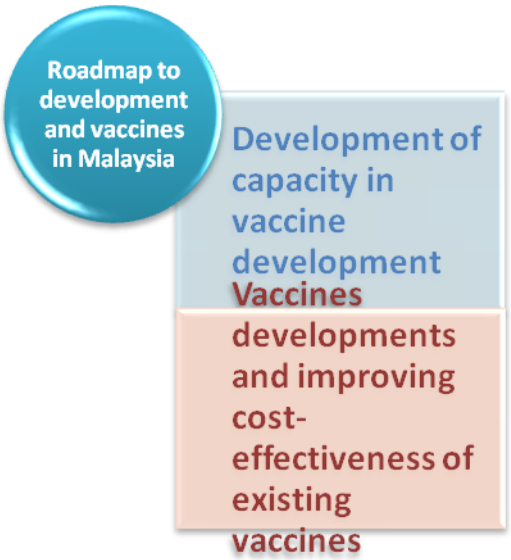

Figure 8. Roadmap to development of vaccines in Malaysia.

Logical Framework Analysis of Omics Research

Part A: Identification of Strategies to Enhance R&D in Omics Research and R&D Needs

Research and Innovation (Policies, R&D and IT Healthcare)

The proposed framework is shown in *Figure 9.*

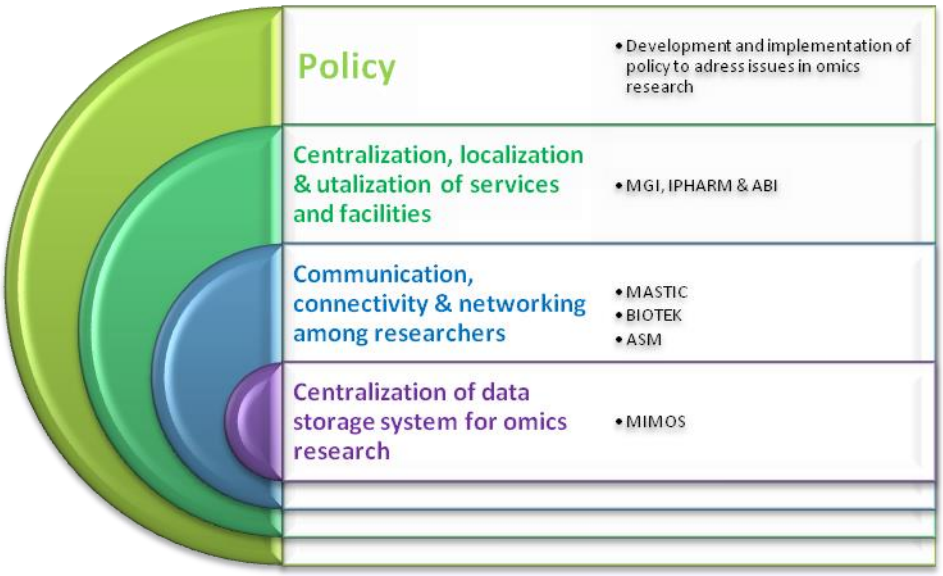

Figure 9. Reseach and innovation.

Policy of omics research in Malaysia.

At the current stage, there is no policy on Omics research. Besides, there are always changes of implemented policies or strategies when there is a change of leadership. This will severely leads to obvious loss of investment and capital from other authorities or bodies. Therefore, there is an urgent need for the development and implementation of a policy that address issues in Omics research. Thus, long term commitment and dedicated policy makers towards well-thought-out and sustainable plans instead of short-term projects are required. Using South Korea as a reference, they have committed programmes towards enhancing the national R&D capacities as the model.

In order to strengthen and enhance local Omics research, there is a need to create a consortium/ panel/ committee to identify expertise from different groups and the experts together in a more synergistic projects, instead of small projects from individual institutes, creating a multidisciplinary research consortium and therefore increase the quality of all participating teams collectively. Besides, there is a need to incorporate the Science, Technology and Innovation policy as a long-term commitment.

Centralization, localization and utilization of services and facilities.

Availability and accessibility of services and facilities play important roles in quality and speed of research. At the present condition, there is a lack of centralized centre or institute where facilities and services are available and openly-accessible. Besides, there is a very low visibility of existing infrastructures and equipments. Therefore, there is a need for the dissemination of availability and permission for usage.

In term of services, specifically molecular sequencing service, Malaysian Genome Institute (MGI) needs to play a more proactive and prominent role as the hub for Omics research and increase the marketability of the services available, enhance collaboration with academic institute and other relevant bodies. Besides, MGI needs to play a more proactive role in the national governance of R&D in order to encourage and ensure quality Omics research.

At the regional, three major institutes, i.e. MGI, IPHARM and ABI (soon to be CLG Institute) play important roles as a regional hub of Omics research. In the discussion, these three bodies were recommended to increase autonomy in order to provide better Omics services without affiliation bias to research projects throughout the nation. Besides, these three bodies play important role in the localization of high-end equipments in the institutes. Taking Beijing Genome Institute as a reference, in order to produce quality and sustainable Omics research, sustainable funding is one of the crucial factors.

Centralization of data storage system for omics research.

The output of Omics research is massive and thus, a sustainable data storage system for data generated by Omics research is very important. At the current condition, accessibility to existing data storage is very low and the doubt about the presence of data storage system for Omics research present. These indicate lack of centralized data repository or storage system for Omics research and the poor accessibility of the data in the system. Therefore, data repository and storage system or facility should be centralized and a more accessible data storage system should be established. One of the recommendations is to involve Malaysian

Institute of Microelectronic Systems (MIMOS), or other relevant bodies, may provide solution to this issue.

Communication, connectivity and networking among researchers.

Local researchers tend to work in isolation and thus generating fragmented information in different Omics research areas. There is a severe lack of networking, communication, openness and collaborations between researchers, research teams, organizations, and relevant institutions. Integration and meaningful collaboration are encouraged and different fields of Omics research should be integrated or connected within a systems biology approach. Database of information regarding local Omics research and management mechanism for local Omics research should be established. These were recommended to be managed by MASTIC, The National Biotechnology Division (BIOTEK) as well as ASM.

Human Resource in Omics Research

Please see the general problem in the Introduction section.

Several recommendations were proposed, such as the recruitment of up-and-coming researchers as associate fellows in ASM in order to have diversity in expertise and opinion. Recognition of full fellowship of ASM should be evaluated over the time. This is believed to be an essential step towards development of leaders in the field, i.e. Omics research. A second opinion in order to develop Omics research in Malaysia is to include Omics research to consult or serve on the committees. In summary, formation of committee in which the member of the committee are Omics researcher or Omics expert, and development of fellows, helps to lead, monitor and consult local Omics research.

Implementation of bioinformatics syllabus.

The output of Omics research is massive data which need to be handled by advanced bioinformatics tools. Therefore, bioinformatics experts are at a very high demand in the era of Omics research. Thus, there is a need to train bioinformatics expert via local universities. At the current stage, the syllabus of computational biology and bioinformatics courses in local universities are found to be inadequate to handle the massive Omics research data. Therefore, there is a need to revamp or redesign bioinformatics syllabus of local universities with the consultation with accredited academicians and omic researchers, in order to produce internationally-recognized graduates from local universities.

Absence of Omics-related academic courses at the tertiary education and above in Malaysia.

In Malaysia, there are bioinformatics courses at the universities level but sadly, not at the tertiary education and above. This might due to the shortage of well-trained Omics-researches, as well as bioinformatics researchers. One of the recommended strategies for this problem is to invite international expert Omics researchers or scientists to conduct intensive training courses locally for local students. Besides, there is a need to work together with scholarship bodies, e.g. Public Service Department (JPA), to send local students to overseas for Omics-related courses that are not available in Malaysia.

The goals of these strategies are to be able to conduct Omics-related courses in a long run and thus producing independent and internationally recognized local Omics-researchers or scientists to perform Omics research and to manage the data output of Omics research.

Mentorship programme for new Omics-researchers.

At the current stage, mentorship programme are only limited to individual universities, indicating a serious lacking of mentorship programmes in most local universities. Thus, one of the recommended strategies is to form open collaboration between senior and fresh Omics researchers.

Insufficient positions of Omics researchers, students or scientists.

As Omics research is a relatively new field of research in science and thus most positions of omic research personal are limited to university-based. There are insufficient researchers, scientists and post-doctorates positions. Besides, tenured position for research staff should be encouraged instead of contractual positions. Thus, the university management authorities should create research-exclusive posts within universities, inclusive of post-doctorates and research scientists. Furthermore, a tenureship evaluation system instead of being granted immediate permanent positions should be implemented. Besides, creation of positions should be included within the new STI policy.

Nurture interest towards science in future generation.

In order to nurture more students who have interest in science and technology, instilling interest among the younger generation is believed will achieve this goal. Several suggestions have been proposed, such as the increase of funding for "Bringing Science to School" or similar programmes or roadshow, recruiting retired researchers, scientists, or lecturers to educate and expose local secondary students towards the importance of science.

Public awareness towards science and technology.

In order to educate the society and creating awareness among the citizen, several steps are recommended such as promotion of Omics research and science to the public by thought-provoking issues.

Business Matching and Commercialization

The proposed framework is shown in *Figure 10*.

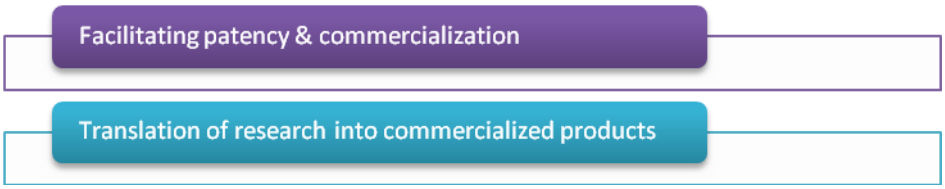

Figure 10. Business matching and commercialization.

Facilitating patent and commercialization.

Conflicts exist between publication of Omics research and patens as well as commercialization. In order to move into commercialization, open access and sharing of information will create barriers and difficulties for it. Thus, a balance between commercialization and publication should be evaluated and framework to guide researchers into commercialization shall be drafted and implemented as a policy. Therefore, establishment of committee at the university level and national level would facilitate the process and patency and commercialization. Besides, Omics research is a huge area of research and thus, there is a need for the exploitation of the rich biodiversity of Malaysia by identifying niche or less-explored areas to be studied with a particular area, as opposed to repeating experiments by slight modifications.

Translation of research into commercialized products.

Translational research develop rapid in the recent years, but sadly, not all research in Malaysia able to move into translational stage and only limited number of local universities were successfully moved into translational research. Thus, several recommended plans were discussed, such as to increase support for university spin-off companies to offer services nationally and internationally, as well as to increase affiliation between market-established companies and research projects of the universities. Establishment of licensing offices at the university as well as at the national level are strongly encouraged in order to facilitate the translational mechanism from research to commercialization.

Monitoring and Accountability

Proper and effective evaluation of research projects.

At the presence, the evaluation mechanism for research projects in Malaysia is relatively weak. Overlapping of research projects due to lack of clear directory of research, categorization of Omics research under other branches of sciences, lack of database of all current undergoing research, all these have led to the failure of research and hence, establishing an effective monitoring mechanism for local research projects is needed. Recommendation such as appointing an independent, autonomous and neutral body to monitor local research projects regardless the origin of funding. ASM has been recommended as one of the suitable governing body to monitor research project progress.

Under-utilization of equipment and lack of equipment sharing.

Cases of under-utilization of government-funded equipments and infrastructures have been reported due to unprofessional and selfish attitude of main equipments users. Therefore, barriers between institutions and organizations should be broken down and thus increase the accessibility to equipments to all parties. Thus, an independent, autonomous and neutral body should be established in order to monitor all equipment are not under-utilization, and not under sole usage of a single party if the equipment or infrastructures are funded by government. Therefore, a comprehensive database with all equipments and services funded by government should be established, for the purpose of publicity, increase accessibility and being transparent.

Professionalism and ethics of research and researchers.

Issues of professionalism and ethics of researchers have always been debated, especially lack of protection of intellectual properties rights in Malaysia causes plagiarism and stealing of research ideas. Thus, there is an urgent need to establish neutral body to evaluate and review local research and to conduct professional ethical review for research projects of the universities.

Revision and evaluation of research proposal and funding.

See general problem in the introduction section.

In this heading, it is proposed a more effective and transparent evaluation and review mechanism to be enforced in order to evaluate research proposal and performance of nationally-funded research projects.

Publication

See general problems in the Introduction section.

Logical Framework Analysis of Nanotechnology in Malaysia

Part A: Identification of Strategies to Enhance R&D in Nanotechnology and R&D Needs

Research and Innovation (Policies, R&D and IT Healthcare)

Allocation of funding.

In the Third Industrial Master Plan (IMP) that will span a 15-year (2005–2020) has recognised nanotechnology as one of the key technologies. At the end of 8th Malaysia Plan, MOSTI has awarded a total of RM160 mil to support nanotechnology projects. Also, nanotechnology has been included as the priority area under the 9th Malaysia Plan. High proportion of funding was allocated for capacity building which is necessary as the field is relatively new in Malaysia. The downside of this is, only a limited number of projects are being funded. The existing funding is insufficient to support the emerging fields in nanotechnology in Malaysia, and more funds are needed to fuel the development of nanotechnological research in Malaysia. Besides, the proportional funding should be allocated based on the market share, i.e. 1% of global market share, which is approximately

USD26 billion, and priority in each area of research. Furthermore, in order to further develop nanotechnology in Malaysia, collaboration with the industry.

Fundamental and applied research.

Because recent government emphasis on commercialization of research product, therefore applied research is being encouraged as compared to fundamental research. Because most scientists are too focused on their products, it therefore losses track of global scientific interest. These have created a scenario where fundamental research in nanotechnology is being ignored. Therefore, more fundamental research in nanotechnology should be encouraged and emphasized as fundamental research serve as the basis of good translational research. At the same, commercialization of new nanomaterials shall not be neglected and further development in the commercialization of research product shall be done. In the nutshell, awareness of the importance of fundamental research shall be increased as the basis for scientific discovery.

Grant scheme and grant applications.

There are numerous grant offering bodies in Malaysia, e.g. MOSTI, MOHE, National Nanotechnology Directorate and etc. Similarly, there is a diverse type of grant, including eScience Grant, Techno Fund, Fundamental Research Grant Scheme, Exploratory Research Grant Scheme (ERGS), Prototype Research Grant Scheme, Long-term Research Grant Scheme (LRGS), and MOH. Even thought with these diversity of funders and grants to be applied, there are several drawback that is unsolved, such as ambiguous objectives stated in the grant, limited funding for research, multiple red tape and bureaucracy issues, lack of financial support from the international bodies, lack of funding opportunity for young PIs, high risk research are not being reviewed properly, failure to meet industrial challenges and the researchers are unclear about the nature of the grant. For example, top-down grant focuses on generating solutions for current problems, while investigator initiated grants are meant for scientific creativity and discovery. Researchers have to know that different types of grants suit specific purpose and research agenda.

Several recommendations have been discussed, such as to initiate young investigator grants, initiation of "challenge" grant, establishment of equal proportion of programme grants, i.e. top-down grant and investigator initiated grant. High risk project should not be rejected and neglected. Specific grant scheme for this type of research should be established. Besides, there is a need to develop a mechanism for supporting the international grants applications.

Establishment of centre for excellence (CoE).

In the past, there are some well-equipped nanotechnology research centres, for example: the Ibnu Sina Institute for Fundamental Science Studies, Universiti Teknologi Malaysia; Institute of Microengineering and Nanotechnology, Universiti Kebangsaan Malaysia; Advanced Materials Research Centre of SIRIM Bhd; and the Combinatorial Technology and Catalysis Research Centre, Universiti Malaya. Cutting edge of nanotechnology are expensive and required highly trained and skilled personnel. Therefore, most of the centre of excellence focuses mainly on industrial nanotechnology application and thus generating chances for commercialization. Only a small number of CoEs are directly involved in nanomedicine research and zero CoE focuses on nanotoxicity and environmental toxicity, which both have

implications on health industries. For example, cosmoceuticals products are in the market and the long term effect of these products are not being investigated. Therefore, there is a need to develop CoE for nanomedicine and develop core expertise in nanomedicine. The need to establish CoE for nanotechnology is been reported by MIMOS in *National Nanoelectronics Technology Roadmap* (MIMOS 2008).

Nanotechnological research policy in Malaysia.

At the current stage, there is no appropriate guideline on the safety in handling nanomaterials and no guideline on the application of nanomaterials. Therefore, there is a need to establish a comprehensive occupational safety and health administration (OSHA) guideline and training on handling nanomaterials and a clear guideline for pharmaceutical and/or cosmoceutical applications by nanotechnology expert.

Sustainability of nanotechnology research.

Nanotechnology research in Malaysia faces several challenges that interrupted the growth and sustainability of research, such as ambiguous scientific agenda; inconsistent or variable research direction and priority; research priority is not coherent with global direction; interruptive funding cycle; and no sustainable effort in pursuing the scientific agenda; and the management authority demand for quick results and lose sight on long term benefit.

Several recommendations have been discussed, e.g. (1) Policy makers need to be sensitive about the global movement and trend in nanotechnology research; (2) Panel of policy makers should be independent and neutral from any influences such as institution and personal interest; and (3) Permission to be awarded more than one research grant at a time provided the researcher has a proven track records in order to speed up the process of producing quality research findings. In the nutshell, steps shall be taken into action in order to develop a sustainable nanotechnology research strategy for a long term growth of the nation's scientific agenda. Besides, nanotechnology research priority shall be aligned with the global trend and producing competent research team in the field of nanotechnology.

Research culture: ethics and professionalism.

In any scientific research, research ethics should be up-hold. Therefore, researchers must be educated to obey research ethics, research professionalism and appropriate scientific conduct. Information silo and data privacy and confidentiality shall be respected but research ethics shall not be abused. Therefore, an ethical board should be initiated; internal investigation should be performed if there is claim of scientific misconduct; and current ethical review mechanism should be revised in order to be a more comprehensive and rigorous. All these serve the objective of establishing a healthy research culture with openness, ethical and professional.

Human Resource

Please see the general problem in the Introduction section. Based on the nanotechnology sector roadmap, this sector will stake a claim for 9,500 S&T workers who it is believed will focus totally on R&D activities and commercialization [Science and Technology Human Capital: A Roadmap for Malaysia's S&T Workforce to Achieve Global Competitive by 2020 (MOSTI 2012)].

Research quality and research nature of nanotechnology in Malaysia.

Most of the researchers are relatively new to this area of science, therefore, most researchers are using nanotechnology as tools but not contribute to the fundamental research of nanotechnology due to lack of experience.

Thus, several suggestions were discussed, such as (1) Invite distinguished researchers from nations where nanotechnology is very developed to lead the trend in local context and to build up the expertise locally; (2) Offer lab setting and funding for international distinguished researchers; (3) Encourage sabbatical in renown research institute especially in the field of nanotechnology; and (4) To provide training to project leaders in respective area to insightful and better knowledge of global trend.

Remuneration scheme.

At the current stage, there is no or less incentive and recognition for the research in nanotechnology. In some cases, professional and active researchers are given the same remuneration and salary as the non-research active staff. Thus, the pay scale for researcher is not competitive, and a better remuneration schemes for researchers are required. Several recommendations have been proposed, e.g. (1) introduction of research track professorship; (2) allow research grant to pay part of the salary; and (2) affiliation programmes with institutes of higher learning. The outcome of these steps should establish a competitive remuneration scheme for researchers.

Figure 11. Research and innovation.

Human resource and human capacity to fuel nanotechnology research.

See general problems in the Introduction section.

Business Matching and Commercialization

Lack of commercialization.

One of the barriers to commercialization of nanotechnology research product is the lacking of researchers who are sensitive towards business and commercialization. Local researchers are not sensitive and familiar with the importance and mechanism of commercialization. Furthermore, there is no translational research and bodies which facilitate the process of commercialization. Therefore, there is a need to create awareness among researchers and introduce the importance and benefits of commercialization of research products. Participation in the science and innovation carnivals, or similar events, should be encourages. Besides, industrial linkages with local universities and research institutions should be established, overseas venture capital should be introduce about the progression and potential of nanotechnology research in Malaysia in order to encourage investment in local research, and, consortia should be formed to address issues in nanotechnology, specifically, nanomedicine. Nano Malaysia Sdn. Bhd. was recommended as a suitable one-stop-centre for the commercialization of R&D of nanotechnology in Malaysia.

Over emphasis on commercialization of nanotechnology research.

Commercialization of research product is important, but over emphasis of research would be inappropriate as not all research has the commercialization value. Some discoveries take a longer period of time to be developed into a commercialized product. Panel of policy makers should be educated and aware about this issue, i.e. translate fundamental research into applied research is a time consuming process. Therefore, research proposal and projects should be evaluated based on its scientific merits and not solely depending on its commercial value. At the same time, they need to know consider the development of human resource and improvement of knowledge in order to serve the national scientific agenda.

The panel of policy makers, proposal reviewers, the scientific community as well as the public society should be informed and educated that science should serve for the betterment of humanities instead of viewing science as an area of revenue-generating industry.

Infringement of intellectual properties.

In Malaysia, there is still no support mechanism for intellectual properties filing, no allocation for intellectual properties filing, and the implementation for incentive is poor. Therefore, there is a need to establish special authorities, agencies or bodies to support and draft a comprehensive intellectual properties policy, as well as planning a mechanism for intellectual properties filing.

Monitoring and Accountability

Establishment of national research monitoring system.

At the current stage, the progressions of the research projects are monitored by funding bodies whereby there is no centralized and comprehensive database regarding the diversity of research projects and the progression for research team in Malaysia. Therefore, there is insufficient data and information for the local policy makers to make informed decisions. There is a need to establish a comprehensive and centralized national monitoring system for the progression of research, regardless the origin of funding, with a standardized reporting mechanism. MASTIC was recommended as the suitable authority-in-charge for the research database in Malaysia.

International scientific advisory board for Malaysian policies on science, technology and innovation.

In order to develop Malaysia to a nation with strong international competitiveness, Malaysia needs to have comprehensive policies, clear and effective strategies, and experienced policy makers. Therefore, there is a need to invite expert panel of advisors specific areas of research to review local strategies and policies for the development of science and technology in Malaysia. As science and technology progress rapidly internationally, we need advice and reviews from the international expert to evaluate our policies for science and technology timely, to ensure Malaysian research are not behind the global trend, meaningful and able to compete internationally. Therefore, establishment of international advisory panel to serve as advisor to evaluate and recommend to our strategies in a timely basis was strongly encouraged and supported.

Quality and impact of research outcomes.

At the current stage, research outcomes are measured in term of quantity instead of quality, such as number of postgraduate and publications. Research output should not be measure according to these two parameters, but impact and quality of research should be emphasized, i.e. total scientific merits of the findings is up most important. A framework for the evaluation of quality and research impact should be established.

Publications

See general problems in the Introduction section.

Logical Framework Analysis of Stem Cell Research in Malaysia

Part A: Identification of Strategies to Enhance R&D in Stem Cell Research and R&D Needs

Research and Innovation (Policies, R&D and IT Healthcare)

Collective efforts in developing local stem cell research.

Stem cell research is relatively new and emerging in Malaysia. Research and the facilities to assess the safety, efficacy, quality and establishment of stem cell research products are still inadequate. There are several challenges and issues remained unsolved in local stem cell research, such as (1) Insufficient of stem cell research expert to advice, audit and/or monitor the good manufacturing practice facilities as this is a relatively new scope for the regulatory authority; (2) Lacking of knowledge or expertise to monitor or audit the facilities; (3) Presence of gap in sharing local and overseas expertise in the area of stem cell research leads to slow knowledge and technology transfer; (4) Difficulties in retaining talents and insufficient permanent positions for stem cell research; (5) Rampant advertising for stem cell and cell-based therapies either for medical treatment or cosmetic applications, and thus fundamental stem cell research is neglected; and (6) Challenges in conducting randomized control trails on stem cell therapy.

Several suggestions were discussed, such as (1) Getting priority setting from the top management and funding bodies to justify the importance of stem cell research in Malaysia; (2) Establishment of policies on human resource training and development and to attract the expert of stem cell research to work in Malaysia; (3) Getting researchers to work collectively instead of individually in order to combine resources, facilities and enhance the sharing of ideas; and (4) Establishment of a network system of different centres, research groups, facilities and institutions etc.

The outcomes of all the mentioned suggestions would be (1) Establishment of national stem cell research centre and more funding schemes for stem cell research; (2) Establishment of educational programmes for both medical doctors and research scientists in both science and ethics stem cell research and therapies; (3) Establishment of database, recommended to be in-charged by MASTIC, on stem cell research and the involved-researchers in order to facilitate networking and for the public to know about the local research fraternity; and (4) Establishment of Malaysian Stem Cell Society to bring local stem cell researchers , medical doctors and the relevant industries together.

Policies, regulations and guidelines for stem cell research.

At the current stage, there are four private companies are licensed to do banking of stem cell. However, several other companies have started stem cell clinical trials, and local researchers and clinicians are already submitted proposals for clinical trial of stem cell therapies. All these are performed under a condition with no proper, clear and comprehensive policy, especially on licensing of allogenic and manipulated autologous stem cell therapy, as well as the designation of stem cell products as biologics, hence equivalent to drug therapies. Therefore, a gap exists in the current guideline in addressing the issue of manipulation of autologous expansion of stem cell.

There is a need for the relevant authorities to expand or to improve the current guidelines, drafting out policies from pertaining to the applications of autologous stem cells for indications which have yet to be proven and for the conduct of clinical trials. Besides, local researchers, scientists, clinicians and the industries need to be educated on self-regulation whilst working to improve the current guidelines and incorporating them into the *Organ Transplantation Act 1991*.

Funding for fundamental stem cell research and applied research.

Fundamental stem cell research is being neglected or not being emphasized. Therefore, there is a need for more funding for fundamental stem cell research in Malaysia. Panel of reviewers of the funding bodies must have experts with stem cell research background in order to evaluate and assess research proposal as there are many technical aspects in stem cell research.

Guidelines and regulations for the application of stem cell research.

There is a trend for local researchers, clinicians and private companies to advance from *in vitro* study to clinical trial even when the data on safety, toxicity and efficacy is inadequate. This occurs mainly due to inexistence of regulation for the application of stem cell research as a therapy. Guideline for application of stem cell research is available but there is no responsible authority to enforce the guideline. Furthermore, the current guidelines covers only stem cell research but not cell-based or advanced cellular therapies, including tissue engineered products. Therefore, there is an urgent need to develop a comprehensive regulation or act, for stem cell research and cell-based therapies. Besides, the public society needs to be educated or informed about stem cell therapy. In the meanwhile, a review on existing regulations and acts (e.g. Medical Personal Act) to accommodate the stem cell policies and guidelines is needed.

Human Resource

Please see the general problems in the Introduction section.

Several recommendations have been suggested, namely

(1) Revision of secondary and undergraduate education system, pertaining to fundamental subjects such as physics, biology and chemistry;

(2) Evaluation of research examination standard annually by a neutral body, and comparison among universities and/or institution can be effected with the involvement of international expertise invited by the neutral body;

(3) Implementation of guidelines on ethical training and graduation;

(4) Involvement of industries in national planning of the country direction with respect to research and economic growth;

(5) Doctorate holders shall undergo post-doctoral training for 2 to 3 years at a different reputable institution prior to joining the relevant research institution or academic sector;

(6) A higher salary should be provided for skilled personnel or post-doctoral fellows in order to retain these talents within the country;

(7) Setting a higher entry requirements of global standard when hiring academic, researcher and/or supporting staff for research work to avoid incompetent leading the competent cohorts;

(8) Enhance publicity in the area of science and technology careers;

(9) Establishing a good system of mentorship for young researchers, by merit and experience;

(10) Appropriate and strategic planning with stake holders with respect to the education system, academician and researcher employment systems as well as research field creation or emphasis for future economic growth;

(11) Contract requirement of trained postdoctoral fellow and/or experts to join local research team; and

(12) Establish mechanism for human resource quality audit, in which employment and reward shall be based on research merit.

Business Matching and Commercialization

There is a lack of this activity.

Consolidation of public-private partnership via comprehensive database.

Some local private companies are already collaborating with private and public hospitals to conduct clinical trials on stem cell research. There are also international-based companies partnering with local companies for clinical trials or stem cell products. There is no or lack of information or database on the number of companies and scope of business as well as the list of products offered. Furthermore, there is a lacking of body to assess, certify, evaluate and monitor the protocols and products from private companies offering therapies to the public. Therefore, there is a need to establish a database for stem cell related services provided by the industry.

Several recommendations were discussed, such as (1) Consolidation of resources from private and public to do multi-centred trials, multi-company partnership and provide control study; (2) Setting up more consolidation of public-private partnership between private companies and researchers; and (3) Drafting a national roadmap, blueprint and direction for stem cell research as well as services, via inter-ministry committee, i.e. MOH, MOHE and MOSTI.

Clinical trials: funding, ethics and business matching.

At the current stage, there is available funding from MOSTI for pre-commercialization of stem cells products, and there is no government funding for clinical trials as the cost is relatively higher. On the other hand, private companies which do not want to raise their own funds to conduct clinical trials and yet charge patients for participating in the clinical trials. This issue should be address via regular dialogue between the regulatory bodies and the industry.

As the stem cell research in Malaysia is relatively new, there is a lack of coordination mechanism for funding of stem cell research and/or pre-commercialization as well as business matching. Besides, the industries, authorities or agencies involved in business matching must be aware of the need for stringent assessment of the proposed therapy, in terms of safety, quality and efficacy, before proposing for clinical trials, offering grants, or matching the companies with researchers/ clinicians, respectively. Furthermore, there is a need for the establishment of ethical committee of private hospitals prior approval of clinical trials, especially when conflict of interest present. More training for local researchers and clinicians should be conducted, especially in the area of commercialization, scientific training and ethical issues.

Service providing using output of stem cell research.

Local applied and translational research of stem cell study is not ready to provide better treatments options for local patients. Government should play the leading and proactive role tapping into technologies from other countries to build up Malaysian resources, transforming Malaysia as a hub for clinical trials and cell therapy services. Service centres should be established to provide stem cell therapies for patients. This can generate revenue for the nation and facilitate the development of the stem cell technology in Malaysia. At the same time, public should be educated and informed regarding stem cell therapy and awareness on ethics and quality of stem cell therapy should be intensified.

Monitoring and accountability

Regulation and policies to prevent unethical practice.

As the public is not well aware of stem cell therapy, certain unscrupulous private companies exploits the naivety of patients by working on the loopholes of the current system, such as utilizing stem cell products from non-human sources, i.e. xeno-transplatation, on patients. Some private companies have the support of the state government despite the unethical practice of xeno-transplatation being performed.

There are limited number of resources to monitor the stem cell research, services and related-business, and there are multiple obstacles in research processes due to bureaucracy. Currently, there is no solid evidence to support efficacy of xeno-transplatation, and thus, the issue of xeno-transplantation still being debated.

Therefore, revision of existing regulation to accommodate the stem cell research and application policies and guidelines is urgently needed, and the assessment of stem cell proposal must be reviewed by competent experts. Government should take up the proactive role in encouraging local clinical research organizations (CROs) to collaborate with overseas

CROs in order to perform clinical trials directly on local patients. To summarise, local government plays an important role in encouraging ethical stem cell research and therapy, to stop unethical practice in stem cell therapy and to monitor the development of stem cell research.

Publications

See general problems in the Introduction section.

In Malaysia, publications of stem cell research by local researchers remained poor. Most publications are in the lower impact factor journals or not in any indexed journals. Therefore, more funding for stem cell research is required in order to produce quality data and high impact discovery. Besides, collaboration with local and international research teams are strongly encouraged in order to produce high quality and multidiscipline stem cell research, and therefore good publication in high impact factor journals.

Logical Framework Analysis of Natural Product, Pharmaceutical and Traditional Complementary Medicine in Malaysia

Part A. Identification of Strategies to Enhance R&D in Natural Product, Pharmaceutical and Traditional Complementary Medicine and R&D Needs

Research and Innovation (Policies, R&D and IT Healthcare)

Collective efforts in developing Natural Product, Pharmaceutical and Traditional Complementary Medicine research.

Natural products, pharmaceutical and traditional complementary medicine research are established and important fields in Malaysia. This area provides means for drug discovery from hit-to-lead. But challenges and issues remained unsolved, for instance:

1) Uncoordinated research works carried out in Malaysia - the research output is only confined to a rather narrow area of expertise of a particular research group.

2) Inadequate financial support.

3) Limited equipment and facility sharing.

4) Preclinical data/safety data are not available (prerequisite for commercialization).

5) Lack of evidence- based research on health claims (TCM, herbal extract, natural compounds, health or functional foods) – Research often does not go beyond the screening and in vivo assay stages.

6) Concept and associated grant monopoly by first population of researchers causing the second generation researchers of the same expert area (younger and capable cohort) are unable to obtain research grant/recognition.

7) Poor fund disbursement & financial management.

8) Mega grants are awarded to specific researchers with no strong research experience at a global scale/standard.

9) Lack of novelty in project awarded with research grant.

10) Unclear/unpublicised report on outcome generated from research project awarded with mega grant vs bottom-up grants amounting to a sum equal to that of mega grant.

11) Rider in research project and outcome with no intellectual contribution.

Several suggestions were discussed, such as (1) International expert partnering only after considering no local expertise or receiving critical benefits from the overseas partners. Help local research companies set up via government providing link for local or international public-private collaboration; (2) Call for proposal evaluators, summarise research outcome and grant disbursement shall be conducted by a neutral body, (3) Rules and regulation at university/institution level are required.

Human Resource

Please see general problems in the Introduction section.

Business Matching and Commercialization

It is opined that there is a clear lacking of (1) Preclinical data for products; and (2) Effective commercialization system. There is no known/strong entity to conduct preclinical assessment from the perspectives of commercialization. Also, there is inadequate guidance on route to commercialize e.g. business proposal, market survey, relevant tests; agency contact has also retard the commercialisation process.

To overcome these issues, several strategies have been identified: international technical and economy expert can be invited as advisory members at the early phase of commercialization and centre set up. Also, commercialization centre shall involve both local and overseas business entities to the fullest possible. There is a call for s stronger tie to local business entities who wish to commercialise locally made products can be made via providing incentive/convenience/promotion in the associated business development.

Publication

See general problems in the Introduction section.

Prioritize Area

This report opined that the research of "Natural Product, Pharmaceutical and Traditional Complementary Medicine" in Malaysia should be given priority. This area is prioritized because Malaysia, as a mega-biodiversity country, has numerous flora and fauna that can be medically important. Flora, for instance, can be an important source of drug discovery, as well as microorganism from our marine, soil, and rain forest terrestrial ecosystem are of great

importance for new magic bullet discovery. Also, strategically Malaysia should maximize the abundance of her biodiversity for research activities in "Natural Product, Pharmaceutical and Traditional Complementary Medicine", this will a competitive advantage as compared those countries that lack of such privileged natural resources.

CONCLUSION

Not only health sciences concern treatment and health care, it is also fundamental human rights that proper and adequate medical services be given to the needy. It concerns the very human lives. Quality health care stems from quality R&D in health sciences, or otherwise Malaysians will need to face the risk of outdated and old-fashioned health services. The strategies proposed in this task force report aims not only to eradicate these problems, but also addressing the need to publish in high impact, reputable journals. This will surely ensure quality research, dissemination of knowledge, and increase competitiveness of Malaysian health sciences at the global scale. Or Malaysia risks lagging behind in quality R&D in health sciences and this will be stumbling block for nation development.

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