International Journal for Quality Research 8(1) 107–120
ISSN 1800-6450

Revathy U. Thandapani [1]
S. Sivasangari
Jamaiyah Haniff

Article info:
Received 05.07.2014
Accepted 13.03.2014

UDC – 638.124.8

EVOLUTION OF MEDICAL RESEARCH REGISTRY IN A DEVELOPING COUNTRY: MALAYSIA

Abstract: *The International Committee of Medical Journal Editor (ICJMJE) members require all clinical trials to register as a condition for publication. This policy applies to clinical trial starting enrolment after July 1, 2005. The National Medical Research Register (NMRR) was designed to meet this requirement yet extending it to include all types of medical research beyond clinical trials. Characteristics and flow of registered medical research as reported in the NMRR system is analysed; in terms of time trend time and differences in characteristics as a function of clinical specialty. A dataset comprising all research registered from year 2007 until 2012 in NMRR was downloaded on 26 Dec, 2012, and entered into a relational database to analyze aggregate data. The number of registered researches in NMRR system increased from 206 (September 2007) to 5107 (September 2007–Dec 2012), and the number of missing values in the data elements has generally declined. Most researches registered are those from student (57%; 2888/5107) and the rest from Ministry of Health (MOH) site researches (43%; 2219/5107). Most of the Interventional trials were phase III (56 %) and very small number of phase I. Heterogeneity in the reported methods by clinical specialty, sponsor type, therapeutic area, disease area, and research type was evident.*

Keywords: *Medical Research, Registry, Ethic Approval, Regulatory, Go Green, Online Registration, NMRR*

1. Introduction

To give a full stop for long dragging ethical approval, the Clinical Research Centre (CRC), Ministry of Health (MOH) of Malaysia designed a web-based portal in the first quarter of 2006. This web-based portal mainly created to coordinate all clinical research and activities conducted by the CRC and emphasis ‘Go-Green’. This idea caught the attention of the then Director General of Health and was thus upscaled, enhanced and implemented across all the six National Institute of Health (NIH); namely Institute of Public Health, Institute of Health Management, Institute of Health Behaviour, Institute of Medical Research and Institute of Health System Research and Clinical Research Centre. Later it was extended to all Ministry of Health (MOH) Malaysia facilities with the name National Medical Research Register (NMRR). There was a written directive from the Director General

[1] Corresponding author: Revathy U. Thandapani
email: revathy@clinicalresearch.my

of Health making NMRR the compulsory research registration portal for all research activities conducted under the Ministry of Health. Three main criteria for compulsory registration is 1) research conducted by MOH staff, 2) research conducted in MOH premise with MOH facilitating or using MOH patients 3) research that funded by National Institutes Health.

The NMRR system was revamped after a pilot test over a period of 6 months. Subsequently, the Medical Review and Ethics Committee, Ministry of Health Malaysia system was also reviewed to incorporated the NMRR system. NMRR help to streamline electronically and systematically the registration of all research protocols to be conducted in the MOH, submission and review for ethics approval, submission and approval for manuscripts publication. Clinical trial registration cause trial results free from publication bias based (Simes and Oncol, 1986). NMRR will published in web portal after protocol reviewed and approved by MREC. In 2010, private and university based review boards and independent ethical committees were encouraged to get on board the NMRR. This initiative received complement from Mrs. Davina, from ex-team leader of WHO clinical trial registry platforms who highlighted that there are not many research registry who had successfully incorporate the regulatory boards like that done in the NMRR. Thus, NMRR is the first database for research registry in the South-East Asia region. Meanwhile, registered trials in a registry should be compliant with the criteria set by the World Health Organization (Ghervasi *et al.*, 2008).

The Malaysian National Pharmaceutical Control Bureau (NPCB) issued a directive to the industry making the registration of clinical trials on NMRR compulsory for drug registration and Clinical Trial Import License (CTIL) application. The NMRR system is an open access database of a large percentage of research projects conducted in the country and represents the growing medical research field of the nation. It is jointly maintained by the NIH institutes, each bearing the responsibility on the research projects conducted in their area of expertise. There are two types of researches, Investigator Initiated Research (IIR) and Industry Sponsored Research (ISR) registered in the NMRR. NIH defined (IIR) as research initiated by investigators. The research protocol and data belong to the investigator. Funding or source of grant be from MOH, universities, NGO, or industry. Meanwhile, Industry sponsored research (ISR) are research funded by industry and where the research protocol and data belong to the industry. This includes both interventional and observational study. As per the NIH guideline requirement, investigator must submit all research documents and investigator documents via online NMRR portal.

Normally after submission is completed, the applicants are given an NMRR id number. The NMRR administrator will screen and forward to respective secretariats for further scientific review and institutional approval. Generally reviewers are given 2 weeks to give recommendation to secretariat to make decision. Table 2 shows the work flowchart and turn round time for each step taken. Initially, the Secretariat will decide on research type that applicant submitted in system, but, with current interface and features, applicant should be able to classify their research type due to simple definition guide in the system (MREC SOP, 2008).

The NMRR is still a growing system and some technical hiccups such as duplication of data still occurs. Two distinct duplications tend to occur: intentional and unintentional duplication. Unintentional occurs due to poor communication within the research team and studies are registered on NMRR more than once. Meanwhile, intentional duplication refers to duplicate registration in several registries beside NMRR. This is because sponsors have to comply with requirements of the local regulatory board in the various countries for multi-countries

clinical trials. Beside that, transparency of plagiarism, fabrication falsification or other deviations from research report could raise (Smith, 1997). This paper aims to examine the users and the research projects profile over a time trend as well as the quality in terms of completeness and record duplications.

2. Method

This is cross sectional study of five years retrospective database based study. All users and research projects registered via the NMRR from 5th September 2007 to 31 st December 2012 are included in the analysis. All details of registered users and existing documents were abstracted from the NMRR system. Also, all type of research (Investigator initiated research and industry sponsored research) that registered successfully and unsuccessfully were included in analysis. Industry sponsored research is defined as any interventional study (including Bio-equivalence) or observational study (including registry) that is sponsored by industry, either pharmaceutical, medical device or biotechnology companies (NIH Guidance, 2008). Meanwhile, Investigator initiated research (IIR) is any research that is initiated by investigators. The research protocol and data collected from the study is owned by the investigator, although funding or grant can be from MOH, universities, NGO, industry or other sources. The stage of submission status determines the successfulness of registration. All proposals that initially submitted into system will screen by NMRR administrator to issue the NMRR ID to all completed submission before forward to respective authorities. Those proposals that forward considered registered successfully and the application of approval in processed. Once the NIH secretariat make final decision, all submitted proposal would be updated by the investigator on post-trials under stage three (NIH Guidance, 2008). Thus, notification or reports to MREC should be submitted if involve human being in research and these will increase transparency in clinical research among management or steering committee as expected to serve many different purposes.
(Tse, 2007).

2.1. User registration

The users of NMRR are categorized as registered investigator, sponsor and project team member. Some could play more than one role concurrently. The registered investigator will be listed in the Investigator directory with their general detail and contact detail such institution name and specialty. Sponsor option should be choose by contact person from Clinical trial associate or clinical trial organization or pharmaceutical company. Lastly, project team option open to all member of certain research project. Role if user chooses as sponsor to be contact person for sponsorship. Therefore, the all clinical trial organization, clinical trial associate from Pharmaceutical Company will be categories under this group. But, project team is large pool where all members beside investigator, will be count in this category. After completed verification email user could use NMRR system to register research. However, user who provides invalid email ID would need to be registered again. As a result, duplicated user registration may occur. A good quality ethical research is incumbent on researchers, sponsors and funders to further the wider knowledge in their area of study, through the publication and dissemination of research findings, publishing all results, making data accessible to others and registering clinical trials (Wisely, 2013).

3. Results and discussion

The main finding of this study is that in the past 5 years, there has been a gradual increase in the number of users pool in NMRR system. We were also able to derive a living database of all clinical investigators in Malaysia.

Figure 1 illustrates the registration of new users on the NMRR system since 2006. The system is able to capture vital information such as the Investigator's name, institution, specialty and their Good Clinical Practice certification status. There was a rapid increase of user registration on the system in 2009, almost 11 % out of total registered user, sparked by a directive from the then Director General of Health to all other Review Boards and Independent Ethics Committees to get on board the NMRR to make it a truly regional research database (DeAngelis *et al.*, 2005). Since the NMRR system was implemented in 2006, the number of new users (investigators) grew from 294 to 15074 users. Out of total 12256 users 81% are registered investigators as stated end December 2012 and their names published in Investigator directory in NMRR website. Meanwhile, other are addressed as registered sponsor and project team. Even though, there are more than 5000 personals has been trained GCP but only 2561 registered in NMRR and involved in clinical research. Part of GCP holder is from Non MOH based and involved in non MOH studies. However, our former Direct general has directive all other Institute review board or independent ethical review to collaborate and support our NMRR system to become truly region database for clinical trials. As the result, National committee of Clinical Research decided to conduct more GCP courses to produce potential principal investigator. Also, our DG has directive all IRB/ IEC via letter dated 8 October 2010 to make sure all clinical trial in Malaysia conducted by GCP trained investigators. The pharma could get contacts on GCP trained via check under investigator directory. Where, investigator contacts and detail are available in system for reference with their specialties. This was also stimulated by the NPCB mandatory registration policy. On a periodical basis, regulatory bodies follow up on the endorsement of these directives to ensure compliance. This is further strengthened by the current NIH guideline on commitment to establish NMRR in line with international standards (Davidoff, 2007). The backgrounds of users were so heterogeneous. Majority (20%) users classified themselves as "other specialty" most was from non-clinical back ground and conducting non clinical or observational research such as behavioral research, bioscience, and health system or health management. The second larger group was from the Pharmacist (13%) of total users. Followed by 1343 investigators from medical and health sciences qualifications. Quite a sizeable portion was "missing" in specialty (Refer to figure 2). This is because; initially NMRR system was created to coordinate the CRC's networks activities. At that time, system allows the free text and there are a lot of elements that were not compulsory to full in.. However, the specialties categorization is still using the clinical investigator system even though NMRR has been opened up to non-clinical investigator. Thus users often have no choice but to select "Others" as specialty if they fail to find theirs. Hence the NMRR system should extend the specialties area to non-clinical investigators too.

According to World Health Organization (WHO) accreditation for standard clinical trial registry warrants that clinical trial should be registered in open database and all details is made transparent for public access (Wondemagegnehu, 1999). Therefore, NMRR system has implemented to list all clinical trials with additional information required to comply with the WHO criteria. Besides that, all researches that have been reviewed and ethical clearance granted will be listed under research directory with title, and type of research and research ID and the year that conducted (Laine and Horton, 2007).

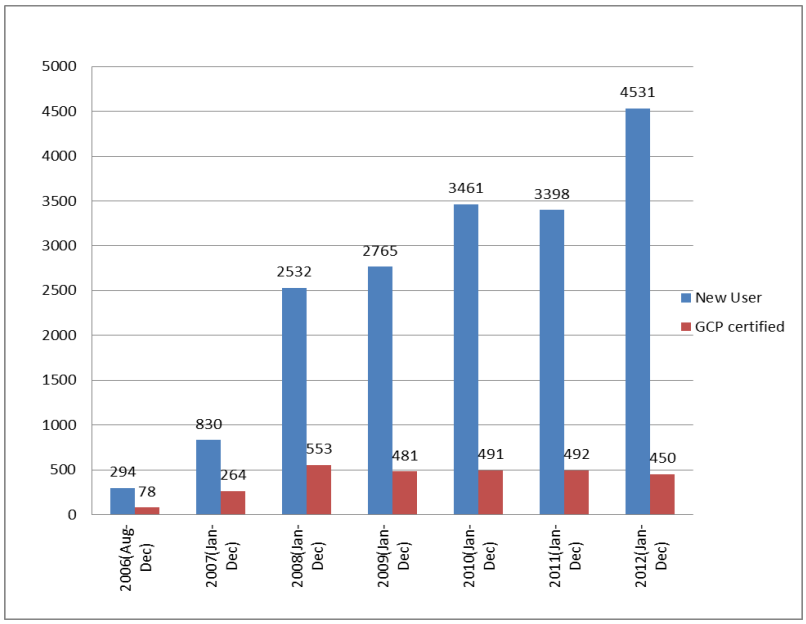

Figure 1. Number of new users (and number with GCP certification) registered in NMRR (Aug) 2006-(Dec) 2012

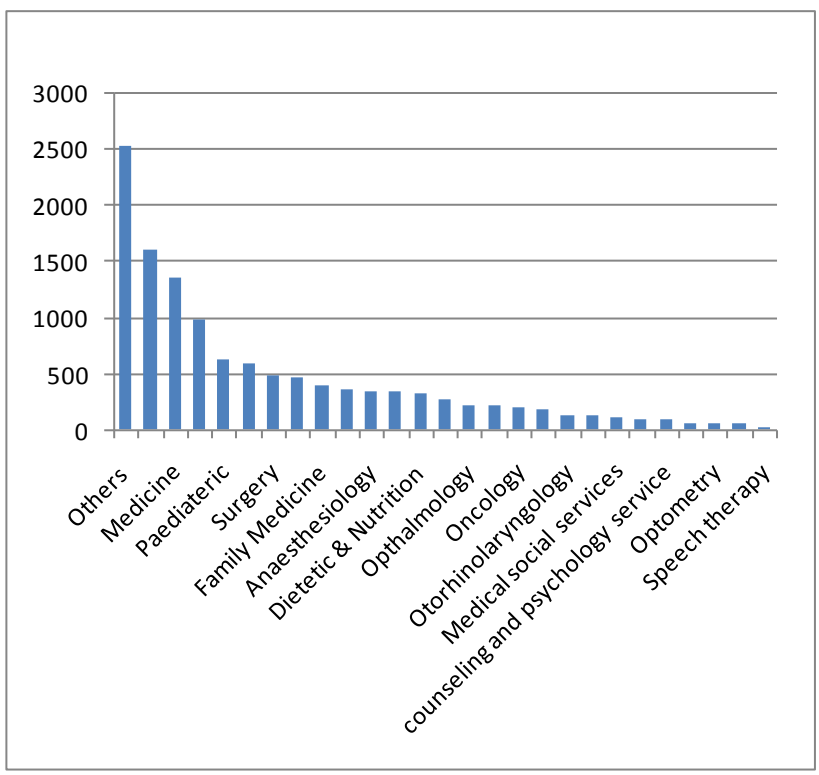

Figure 2. NMRR registered user's clinical specialties from 2007(Sep)-2012(Dec)

4. Research registration

Figure 3 shows out of the 9520 registered studies only 5107 (53.6%) number of studies complete registration successfully. In the year 2008 and 2009, rapid changes on total researched that submitted and registered in NMRR because investigator was directed to register their studies retrospectively. From year 2007 and 2011, 2.6% of the studies were duplicates. The issue of duplication is handled thru a manual clean up exercise by the NMRR secretariat team. The team periodically cleans the database to maintain the integrity of the data and duly issues a notification e-mail to the application in the event of duplication. The deletion of a research record on NMRR is only performed when verification is successfully completed with the applicant.

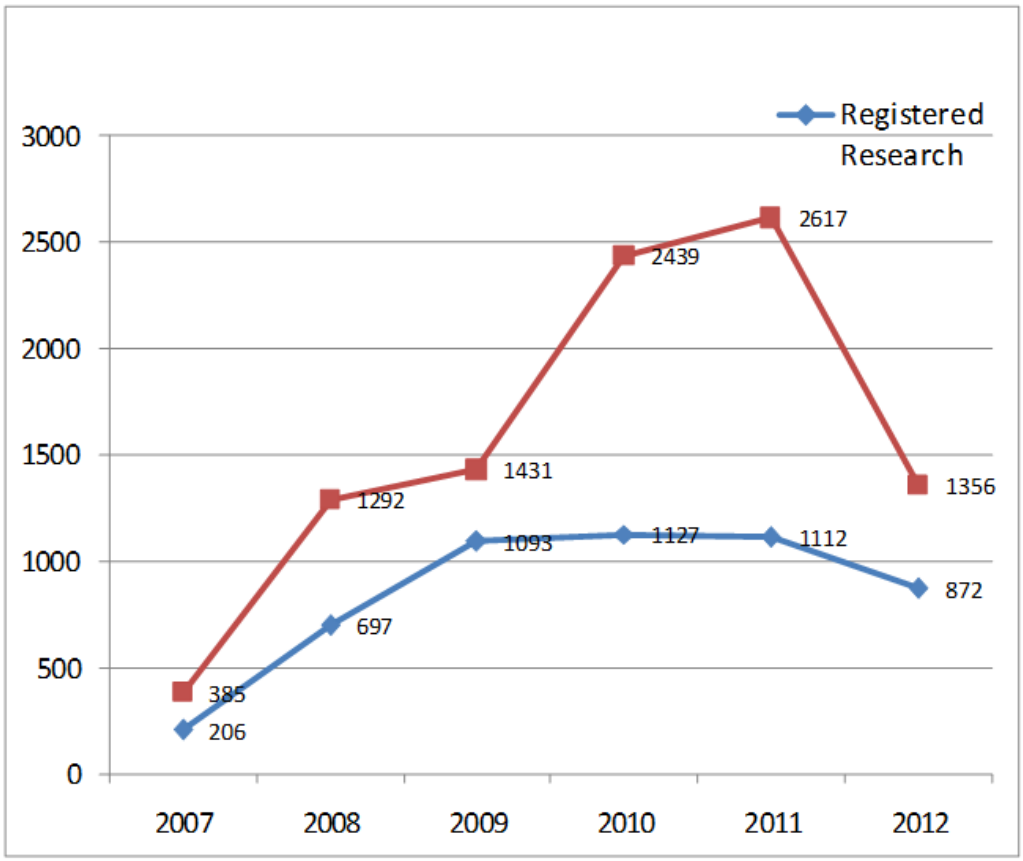

Figure 3. Cumulative number of submitted and registered research proposal in NMRR

Majority 57% (2888/5107) of registration are from students using the MOH facilities. The rest are from of studies that involved MOH investigator 43% (2219/5107). The highest number by type of research came from clinical side 50% (2599/5107) compared with other research types. This is probably because the Clinical Research Centre was the first research institution that adopted NMRR as part of its research process.

Table 1. Type of registered MOH- Investigator involved researches (Include ISR and IIR research) and Student's research in NMRR

Number of research conducted by MOH staff in MOH- Site													
Research types	2007	˚%	2008	˚%	2009	˚%	2010	˚%	2011	˚%	2012	Subtotal (2007-2012 (a))	-
Clinical trial	150	75	224	71	210	53	248	61	335	67	272	1439	-
Biomedical Science	4	2	18	6	50	13	25	6	33	7	30	160	-
Health Management	2	1	6	2	19	5	17	4	17	3	31	92	-
Behavioral Health	10	5	7	2	25	6	31	8	29	6	3	105	-
Health System	9	5	24	8	26	7	25	6	18	4	18	105	-
Public Health	26	13	35	11	63	16	63	15	69	13	47	303	-
Total	201	100	314	100	393	100	409	100	501	100	401	2219	-
Number of research conducted by Student's Studies													
Research types	2007	˚%	2008	˚%	2009	˚%	2010	˚%	2011	˚%	2012	Subtotal (2007-2012 (a))	Total (a+b)
Clinical trial	1	2	143	37	286	41	312	43	245	4	173	1160	2599
Biomedical Science	1	2	27	7	80	11	80	11	56	9	43	287	447
Health Management	-	0	45	12	54	8	59	8	54	4	51	263	355

Behavioral Health	1	2	68	18	112	16	112	16	117	19	100	510	615
Health System	-	0	13	3	33	5	28	4	23	4	26	123	243
Public Health	2	4	87	23	135	19	127	18	116	19	78	545	848
Total	5	100	383	100	700	100	718	100	611	95	471	2888	5107

Table 1 illustrates the types of researches that registered and all these submitted to national institutes health. Clinical research is on top in list since 2007. There were a few phases of enhancement implemented since 2007. Well trained users were able to do registration and provide valid information in this web based registration. However NMRR continues to get several feedbacks from public on how to make NMRR more user friendly. Therefore, the management has planned and has done more changes for the interface of the system. However since NMRR incorporated with the MREC, the system became more complicated and even regular users finds difficulty using it. Thus, NIH has scheduled national wide trainings and road shows on how to register and use this system.

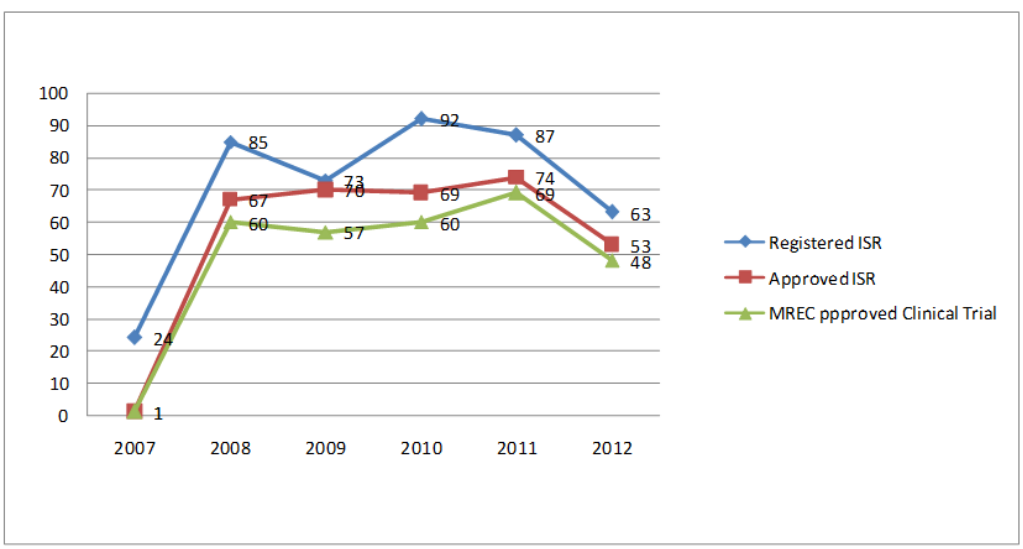

Figure 4. Industry sponsored researches in NMRR

As a result (refer to figure 5), all clinical researches that conducted in MOH special "contract research" or Industry sponsored trials were successfully registered in NMRR. Of the 424 ISR protocol registered to NMRR, 334 (78.8%) were approved by MREC. Industry sponsored research is defined as any interventional study (including Bio-equivalence) or observational study (including registry) that is sponsored

by industry, either pharmaceutical, medical device or biotechnology companies. Among approved ISR, 295 Clinical trials are those initiated in MOH sites.

Among the top 10 therapeutic areas, diabetes mellitus (35, 12.5%) and oncology (31, 11.1%) has the highest number of protocols. Table 2 show the list of therapeutic area of clinical research that registered in system. Table 3 illustrates that Phase III (195, 58.6%) was the commonest type of clinical trials. The number of ISR does not increase much from 2008 to 2012.

Table 2. 10 Top therapeutic area of clinical research that registered in NMRR (2008-2011)

#	Therapeutic area	2008		2009		2010		2011		2008-2011	Over all
		No	%	No	%	No	%	No	%	No	%
1	Diabetes Mellitus	6	10	5	8.8	14	23.3	10	14.5	35	12.5
2	Oncology	5	8.3	7	12.3	11	18.3	8	11.6	31	11.1
3	Cardiology	8	13.3	8	14	10	16.7	4	5.8	30	10.7
4	Psychiatry	14	23.3	6	10.5	2	3.3	6	8.7	28	10.0
5	Haematology	6	10	6	10.5	4	6.7	7	10.1	23	8.2
6	Endocrine/ Metabolic	3	5	7	12.3	7	11.7	2	2.9	19	6.8
7	Rheumatology	0	0	7	12.3	4	6.7	8	11.6	19	6.8
8	Infectious Disease	4	6.6	2	3.5	6	10	3	4.3	15	5.4
9	Neurology	1	1.7	5	8.8	2	3.3	3	4.3	11	3.9
10	Respiratology	2	3.3	5	8.8	1	1.6	1	1.4	9	3.2

Table 3. Types of clinical research that are registered in NMRR (2008-2012)

Types of Trial	2008	2009	2010	2011	2012	No	%
Bioavailability/Bioequivalent study	-		3	8	6	1	4.5
Phase I	-	-	-	1		1	0.3
Phase II	10	12	10	10	9	50	15.0
Phase III	46	40	45	44	26	195	58.6
Phase IV	4	6	3	7	7	23	6.9
Observational study and registry	7	12	8	4	5	49	14.7
Total	67	70	69	74	53	333	100

5. NMRR challenges

Timeline of approval depends on multiple factors; the users, Secretariat and reviewers. Users are those who submit application, while secretariat coordinates the submission and reviewers do scientific merit review and rate the proposal submission on allocated time period. Table 4 describe that average days to get approval from each regulatory

such MREC and DCA. In current version, user could register their completed, ongoing and proposed research in NMRR system (Lim *et al.*, 2010). Once they have completed their submission, the NMRR administrator will screen the documents to ensure it gets forwarded to relevant secretariats if documents are adequate. Then, Secretariat will assigned reviewers, follow up with reviewer and user/investigator until a decision is made based on their comments and recommendation. Overall average turn around period are 1 to 2 months for NIH scientific review and 2 to 2½ months for MREC. The NIH secretariat plays multiple roles as MREC secretariat, Major research grant (MRG) secretariat and secretary for Publication-DG approval. Due to lack of man power in NIH secretariat, the timelines are not meet consistently. There are only 1-2 persons in charge for all over national submission for each category except for MREC and NMRR administrators. So, the MRG and DG approval can take almost 3 months. Besides that, training for staff who works as secretariats and time consumes for if staff is poor in IT application. The worst is the staffs are temporary workers who get replaced every 6 months. However, current timeline is acceptable and effective. Each clinical trial proposal will go through regulatory review and its takes more than 3 months to get ethical clearance referring WHO survey on effective drug regulatory in multi countries in 2002 report. Indirectly, Malaysia is compatible with other Asian countries such India, Thailand and China (Ratanawijitrasin and Wondemagegnehu, 2002).

Table 4. Average Timeline of approval period for respective secretariats

Year	NIH approval (days)	MREC approval (days)	MRG approval (days)	Publication DG approval (days)
2006	-	-	-	-
2007	5	-	-	-
2008	12	52	-	-
2009	53	94	98	99
2010	36	77	101	214
2011	28	72	109	45
2012	30	70	119	NA

As result of successfulness clinical trial registration in NMRR, users are not updating their research current status such recruiting and completed.

Title for Figure 9 is secretariat decision which user should revise their documents and do resubmission into NMRR system. Active reviewers and secretariat work hard to produce research proposal that have sense of scientifically value and ethical research. The accuracy of information in any system depends a lot on the user's inputs. Giving valid information is equally as important as conducting the study as good research practice (DeAngelis *et al*., 2004). Besides that, NMRR promote more efficient allocation of research fields and ensure trial information is disseminated and incorporated into clinical funding and ethical decision-making.

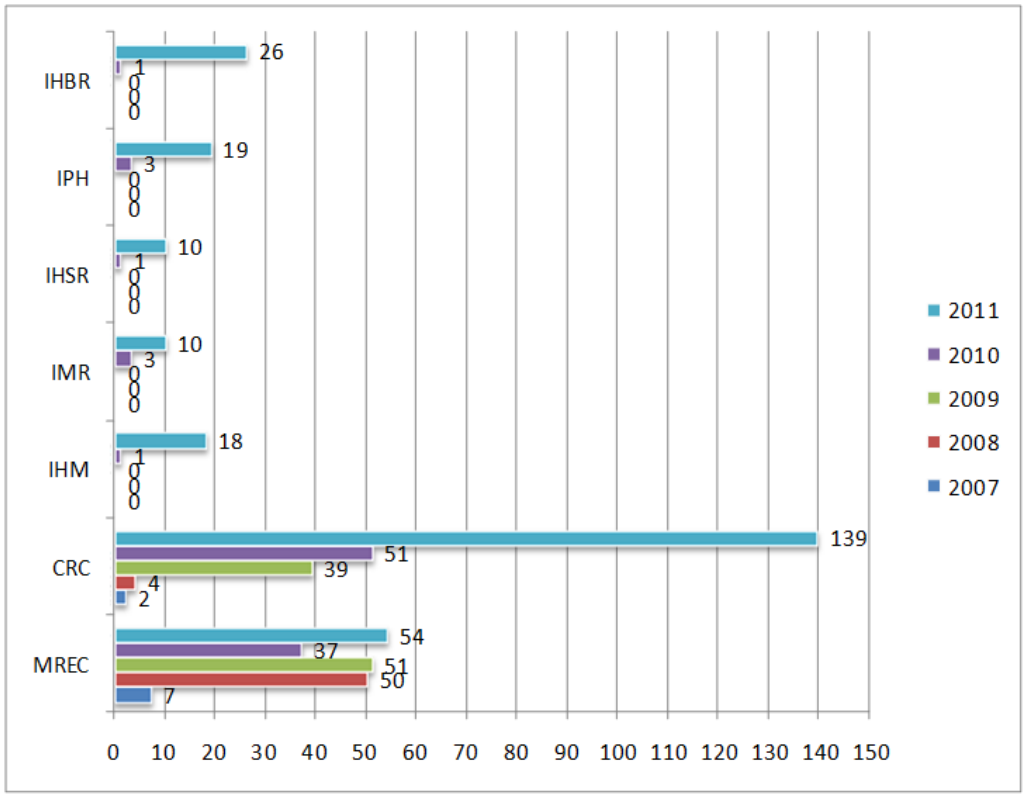

Figure 5. Proposal that required revision from regulatory

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For publication, DG approval is a must. For oral presentation or journal publication, the applicant could refer to research ID that they have submitted in NMRR system to forward their application to DG approval. However, the current system does not support electronic reviews although one can register research outputs including publication. So, users are advised to send hardcopy for reviews besides concurrently registering the publication using the NMRR system. Understandably the out puts can be more than 1 for one study. Currently the NMRR system only allows up to 10 outputs per project.Even, international communities of journal editor (ICJE) encourage authors to registered their clinical trial before conduct it and provide referral id as evidence of registered research in region database or clinicaltrial gov (Ghersi *et al.*, 2008). Furthermore, the value of a registry is illustrated by comparing a review of published clinical trials located by a literature search with a review of registered trials contained in and also illustrate an approach to reviewing the clinical trial

literature, which is free from publication bias, and demonstrate the value and importance of an international registry of all clinical trials (Uscinski, 2013).

Post-trial-report are very weak where, the applicant are still not familiar to apply in NMRR system. By the way, some of the applicants do not return back to update their studies after initial submission or approval is completed. Majority are not aware on important of post-trial reporting to MREC. All Severe unexpected adverse reaction (SUSAR) or Severe adverse events should be reported to ethics to observe closely to make sure compliance with GCP and investigate reason if any complaints. If there are faults, MREC could take legal action on investigator or sponsor. Also, clinical trial subject could sue the sponsor if they found that had been recruited in non registered clinical trial (Zarin, 2007).

6. Conclusion

This time trend analysis has proven that the National Medical Research register NMRR has over time, gained its usefulness to advance medical and health research in the country; for both the actual research conduct and also research oversight. However more can be done to upscale it 1) scope to include beyond MOH 2) interface so that it is more user friendly 3) functionality to also include output registration. In short, NMRR has the potential to grow into the one stop centre for medical and health research for Malaysia or even for the region.

Acknowledgment: We acknowledge Director General of Ministry of Malaysia who approved this manuscript to publish in journal. Also Dr Looi Irene, team member from CRC HSJ and CRC national who help in this report.

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Revathy U. Thandapani
Clinical Research Malaysia,
Hospital Seberang Jaya
Malaysia
revathy@clinicalresearch.my

S. Sivasangari
Clinical Research Centre,
Hospital Pualau Penang
Malaysia
sivasangari@crc.gov.my

Jamaiyah Haniff
Clinical Epidiamology Unit,
Clinical research center
Hospital Kuala Lumpur
Malaysia
jamaiyah@crc.gov.my