ICMRA Capacity Building Working Group

Final Report
November 21, 2017

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MHLW/PMDA

1. Period of Activity

December 2013 through February 2017

2. Participating Regulatory Authorities

MHLW/PMDA (Japan) (Lead)
EMA (EU)
MFDS (Korea)
AIFA (Italy)
Swissmedic (Switzerland)
FDA (USA)
WHO (Observer)

3. Purpose and Desired Outcomes

A) Provide information about training programs conducted by regulators of various countries and regions as well as those of international organizations by creating an online Access Portal.

B) Provide authorized parties with simplified access to this information, and allow those interested in participating in training programs to sign up using this Access Portal.

C) Identify gaps and overlaps in capacity building activities around the world.

D) Identify avenues by which ICMRA can contribute to resolving such gaps and overlaps.

A) and B) were agreed on at the ICMRA Management Committee (MC) meeting in June 2014.

C) and D) were agreed on at the ICMRA MC meeting in June 2015.

4. Achievements

A) Establishment of an Online Access Portal

The WG built an online Access Portal within the internal ICMRA website (Attachment 1). The Access Portal contained a list of training programs provided by ICMRA member organizations and the observer, WHO, geared towards regulators from other countries. The Access Portal linked the users to the providers' respective websites for ease of access to additional information and registration pages. The Access Portal became active in June 2015 and was transferred to the ICMRA public website in March 2016. MHLW/PMDA updated the Access Portal with the information provided from the ICMRA members in June and December 2015.

WHO proposed at the June 2015 ICMRA MC meeting that the ICMRA database could be merged into the WHO training database, which is publicly available on the WHO website. The ICMRA MC decided to accept WHO's proposal at the ICMRA MC meeting in June 2016, and in September 2016, the WG sent a letter to WHO suggesting that the WHO database be expanded to include information on capacity building/training programs provided by ICMRA members. WHO has begun contacting individual regulatory authorities for information regarding their capacity building activities aimed at other countries' regulators.

As the database merger progressed, the WG terminated its work on the Access Portal, which was subsequently removed from the ICMRA public website in 2017.

B) Survey on Capacity Building

I. Survey

To further explore the possibility of a role for ICMRA in facilitating international regulatory capacity building, the WG conducted a survey on ICMRA members (including the observer, WHO) in September 2015 regarding their engagement in capacity building activities during the period between October 2013 and September 2015.

II. Results

The WG received responses from 16 ICMRA members and WHO as an observer.

The major findings were presented to the ICMRA MC in June 2016, and are summarized as follows:

(1) Demand for capacity building from regulatory authorities in a given region tended to be met by other regulatory authorities in the same or neighboring regions.

(2) Various imbalances between the available resources and demand for capacity building activities were observed in terms of modes of training, skill/experience level of trainees, etc. These imbalances varied by region.

(3) WHO provided the largest number of "seminar-style" trainings, which is the most frequently employed format for capacity building activities implemented worldwide.

III. WG Recommendations to the ICMRA MC

Based on the results of the survey, this WG offered the following recommendations:

(1) Regional Capacity Building Clusters with “Hub” authorities
ICMRA should encourage the establishment of regional “hub” authorities, which would support capacity building activities in neighboring countries and regions.

(2) Regarding “Seminar-style” training
ICMRA should cooperate with WHO to eliminate gaps and overlaps between seminar-style training programs offered by WHO and national regulatory authorities.

(3) Facilitation of Staff Exchange/Dispatch Arrangements
ICMRA should consider creating a “message board” for exchanging staff exchange program information on its member-only website to help regulators more efficiently and effectively identify opportunities to dispatch their own staff or host the staff of other regulatory authorities for the purpose of cooperative human resource development and on-the-job training among ICMRA member organizations.

(4) Other recommendations
ICMRA should conduct a triennial survey investigating relevant activities implemented by its members to gain a grasp of the state of global capacity building programs.

Further details concerning the survey results and recommendations are summarized in “ICMRA Survey on Capacity Building” (Attachment 2).

The raw survey response data as well as their graphic representations are accessible on the member-only ICMRA website.

IV. Actions taken by ICMRA

The WG discussed possibilities for its future work based on its recommendations. One possible area was to create a mechanism to facilitate staff exchanges among members ((3) above). Staff exchange programs are most effective when between developed and developing countries. However, developed countries comprise the majority of ICMRA’s current membership. The WG therefore decided to defer further consideration of this initiative until ICMRA expands its membership to include more regulatory authorities from developing countries.

This survey to find a role for ICMRA did not lead to immediate action in the area of international capacity building.

C) Further exploration of possible WG activities

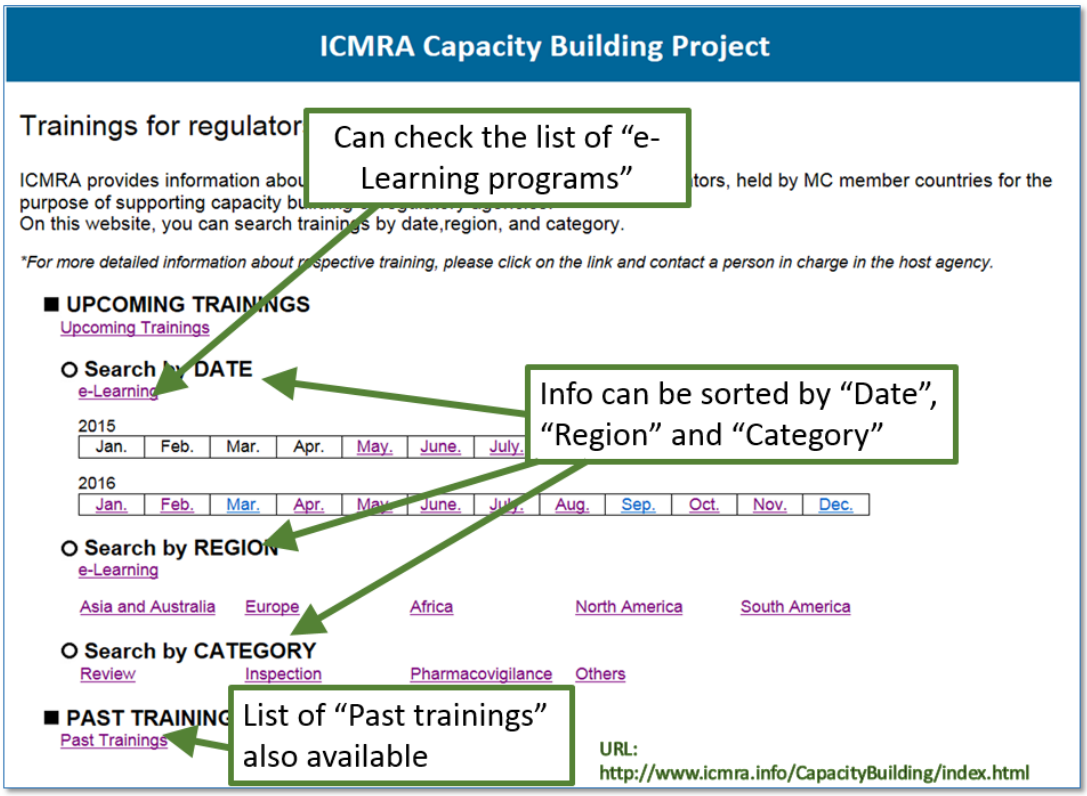
At the June 2016 ICMRA MC meeting, potential collaboration in the area of regulatory leadership training among ICMRA members was suggested. To advance this idea, MHLW/PMDA conducted an additional survey of ICMRA members in late 2016 regarding the respective curricula of executive training programs they may have implemented. However, while HPRA kindly provided detailed information on their executive training program, MHLW/PMDA found that there were too few examples of leadership development programs, and that this topic was not developed enough to pursue further at that time.

5. Completion of WG Activities

As this WG fulfilled its purpose and achieved its objectives, it decided to conclude its activities. Accordingly, this WG proposed to conclude its activities at the ICMRA MC teleconference held in February 2017, and the ICMRA agreed to disband this WG indefinitely. ICMRA may reconvene the WG when the need arises.

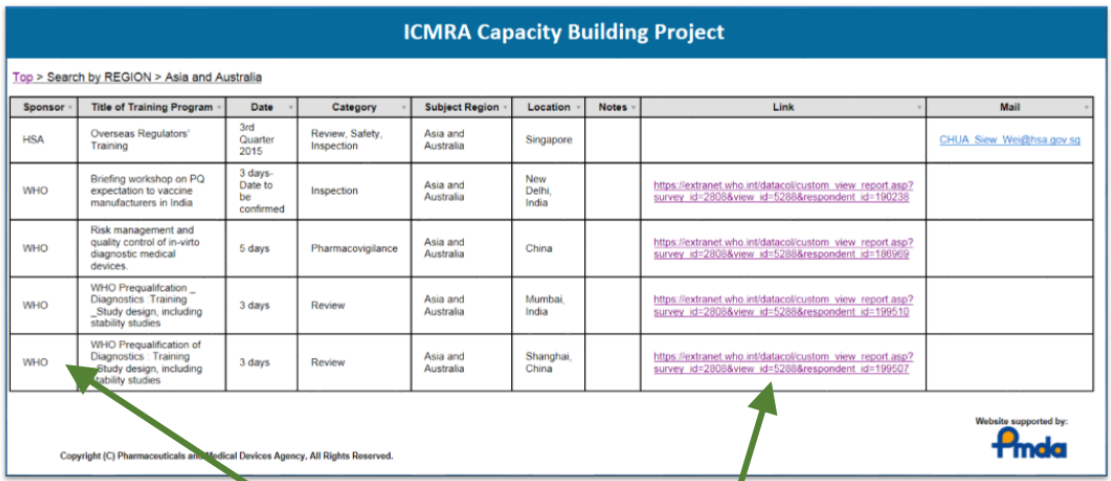
Attachment 1

Access Portal



Example of search result

"Search by REGION _ Asia and Australia"



Attachment 2

ICMRA Survey on Capacity Building

March, 2016 (Revised May, 2016)
ICMRA Capacity Building Working Group

1. Purpose and Method

- In an attempt to explore a role of ICMRA in facilitating international regulatory capacity building, the ICMRA Capacity Building Working Group (WG) conducted a survey on the ICMRA members/observer regarding capacity building activities in which they are involved in the past 24 months (October 2013 to September 2015).
- The survey solicited the ICMRA members/observer for information on the following; (full questions :Appendix 1)
  1) requests received from other authorities to conduct capacity building activities,
  2) capacity building activities actually provided to other authorities,
  3) requests of capacity building that the ICMRA member made to other countries' authorities, and
  4) training seminars provided to other authorities' regulators
- WG sent out the questionnaire to the 22 ICMRA members/observers on September 30, 2015, and 16 members/observer sent back answers as of December 10, 2015. (Appendix 2).

2. Results

(1) A tendency was found that the demand for capacity building observed in one region is met by regulatory authorities in the same or neighboring regions, though there are authorities providing capacity building world-wide, most notably EMA. There were "hub" authorities in each region catering to the need in the region (Fig.1).

(2) There were mismatches in the supply and demand, which varied by the region.
- In Asia-Pacific, capacity building opportunities actually supplied were fewer than requested (Fig.2).
- In Central and South America, the supply exceeded the demand. Mismatches in terms of the field, modus and level of training were observed (Fig.3).
- In Africa, the supply and the demand were relatively well matched, while there were some mismatches in the modus and level of trainings (Fig.4).

3. Recommendations

(1)Regional Capacity Building Clusters with "hub" authorities

Considering the trend observed in the survey and the ease of transportation for the trainees and trainers, the possibilities of "regional" capacity building clusters should be

considered. In the scheme, demand and supply of capacity building could be matched within a region, such as Asia-Pacific, and Americas. Another advantage to the scheme is that this approach can utilize other related capacity building resources in the region, by WHO regional offices, universities and other providers including DIA and RAPS. The "hub" authorities could survey the demand in the region and not only themselves provide trainings according to the demand, but also coordinate the capacity building activities in the region with other providers to collectively meet the demand.

While ICMRA itself should not be involved in matching the demand and supply in any particular region, it could facilitate the communication among the "hubs" in and across region(s), and help them share best practices.

(2)On "Seminar-type" Training

It has been confirmed that WHO is the greatest provider of "seminar-type" trainings, in which instructors give lectures to (usually dozens of) assembled trainees for multiple days. There are several regulatory authorities holding this type of training for other countries' regulators (Fig.5). ICMRA has been compiling information on the seminars and posting it on its member-only Website. Since WHO has on its Website a database of its seminars, and expresses willingness to include national regulatory authorities' seminars in it, ICMRA should terminate its work and ask WHO to maintain a more complete database for the convenience of future trainees.

Because of the importance of the seminar-type training as the principal mode of basic capacity building, ICMRA should consider further contribution to their betterment, in cooperation with WHO. One of the possibilities is to assess the WHO seminars' fitness to the trainees' needs from a neutral viewpoint and to coordinate ICMRA members' efforts to help WHO in its seminars.

(3)Facilitation of Staff Dispatch/Acceptance/Exchange

Another measure of capacity building is to sending regulators from one authority to another, so that they can give or be given on-the-job training in the accepting authority. Though there has been found some mismatch in the demand and supply of this type of capacity building, there is currently no mechanism to pool and match wishes to send and to accept.

ICMRA is recommended to fill this gap and create a system of matchmaking. Realistically this should be first attempted among ICMRA members, when the membership expands to include more authorities from developing countries. One possibility is to create of a "message board," in ICMRA member-only Website, on which the members can write its wish and/or find others' offers (Fig.6). When this scheme is in smooth operation, the function can be transferred to the region-based activities described in (1) above.

(4)Other recommendations

- In the light of saving monetary, human and time costs, web-based training opportunities should be expanded and its utilization should be encouraged.
- Considering the value of information obtained in the survey, it is recommended that ICMRA should conduct a survey on capacity building on a regular basis (e.g. every 3 years) to better grasp the situation and take necessary measures.
- The Capacity Building WG could liaise between the three new projects of ICMRA (Pharmacovigilance, Crisis Management, and Supply Chain) started in 2016, and the suppliers of capacity building activities, such as WHO and the regional hub authorities, regarding the elements of capacity building contained in the projects.

Appendix 1: Questionnaire

1. Requests received from other authorities to conduct capacity building activities

   Information requested on following:

   A） Organization (Specify the country/region of regulatory authority)

   B） Topic of training (Options: Review, Post Market Safety, Inspection and Others)

   C） Topic of training in case of Review (Options: Quality of Drugs, Pharmacopoeia, Pre-clinical Animal Tests, Clinical studies and Not Applicable / Others)

   D） Modus (Options: Formal Lecture, Staff Exchange and Others)

   E） Level of Trainees (Options: Basic, Intermediate, Advanced and Not specified)

   F） Venue (Options: Requesting country, Requested country, and Others)

2. Capacity building activities actually provided to other authorities

   Information requested on following:

   A） Organization (Specify the country/region of regulatory authority)

   B） Topic of training (Options: Review, Post Market Safety, Inspection and Others)

   C） Topic of training in case of Review (Options: Quality of Drugs, Pharmacopoeia, Pre-clinical Animal Tests, Clinical studies and Not Applicable / Others)

   D） Modus (Options: Formal Lecture, Staff Exchange and Others)

   E） Level of Trainees (Options: Basic, Intermediate, Advanced and Not specified)

   F） Venue (Specify the country/region where the training actually executed)

3. Requests of capacity building that the ICMRA member made to other countries' authorities

   Information requested on following:

   A） Organization (Specify the country/region of regulatory authority)

   B） Topic of training (Options: Review, Post Market Safety, Inspection and Others)

   C） Topic of training in case of Review (Options: Quality of Drugs, Pharmacopoeia, Pre-clinical Animal Tests, Clinical studies and Not Applicable / Others)

   D） Modus (Options: Formal Lecture, Staff Exchange and Others)

   E） Level of Trainees (Options: Basic, Intermediate, Advanced and Not specified)

   F） Venue (Options: Requesting country, Requested country and Others)

4. Training seminars provided to other authorities' regulators

   Information requested on following:

   A） Title of training seminar

   B） Topic of training (Options: Review, Post Market Safety, Inspection and Others)

   C） Subject region (Options: E-learning, North America, South America, Asia and Australia, Europe and Africa)

Appendix 2: List of cooperating Member/Observer

Australia (TGA)
Brazil (ANVISA)
Canada (HC)
EU (EMA)
France (ANSM)
Germany (PEI)
Ireland (HPRA)
Italy (AIFA)
Japan (PMDA)
Korea (MFDS)
Mexico (COFEPRIS)
Singapore (HSA)
Sweden (MPA)
Switzerland (Swissmedic)
United Kingdom (MHRA)
WHO

Appendix 3: figures summarizing all the data obtained

Figure 1.
Recipients of Training

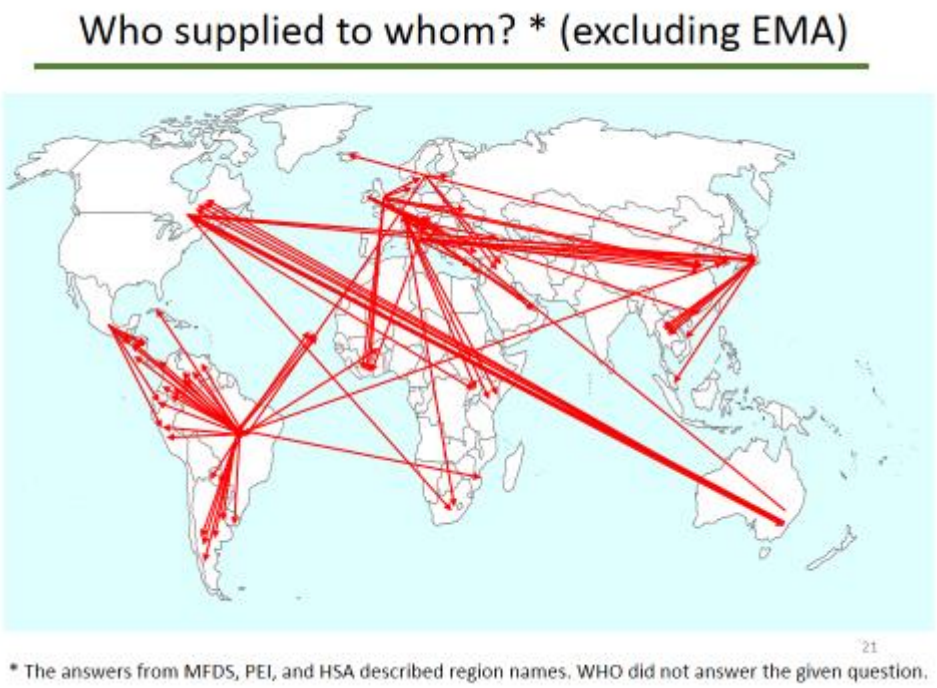


Figure 2.

"Supply and Demand" comparison in number of training in Asia-Pacific

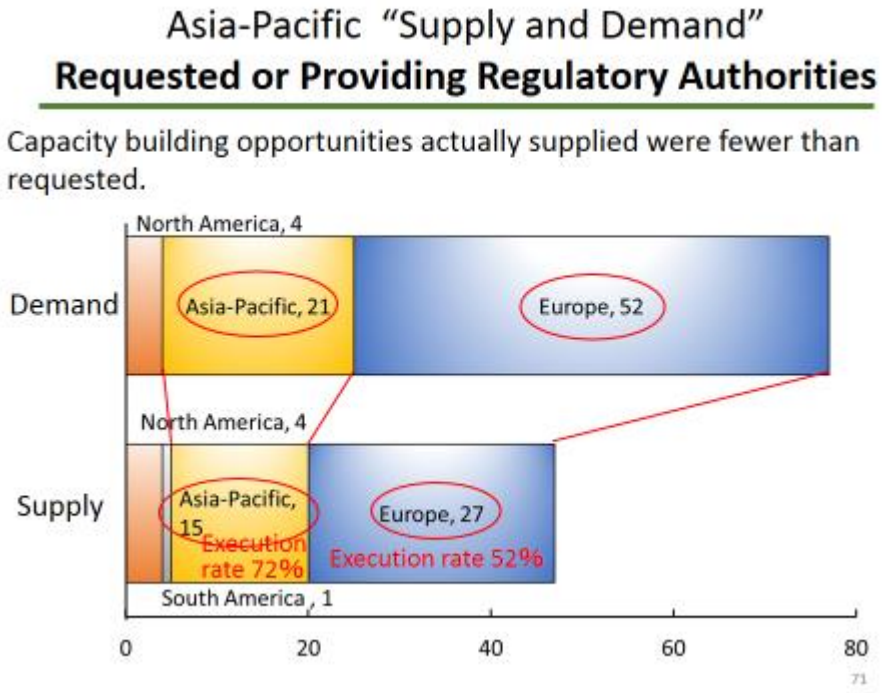
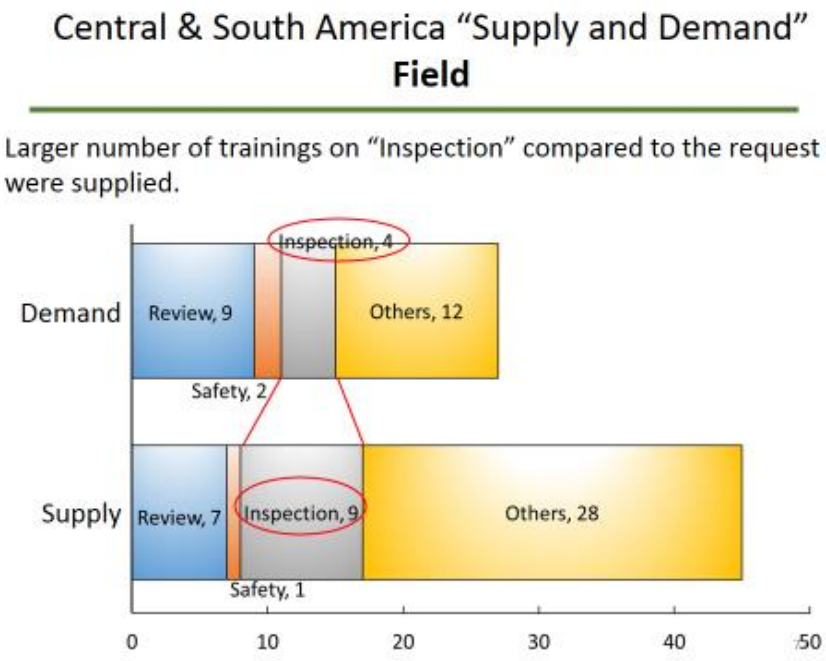
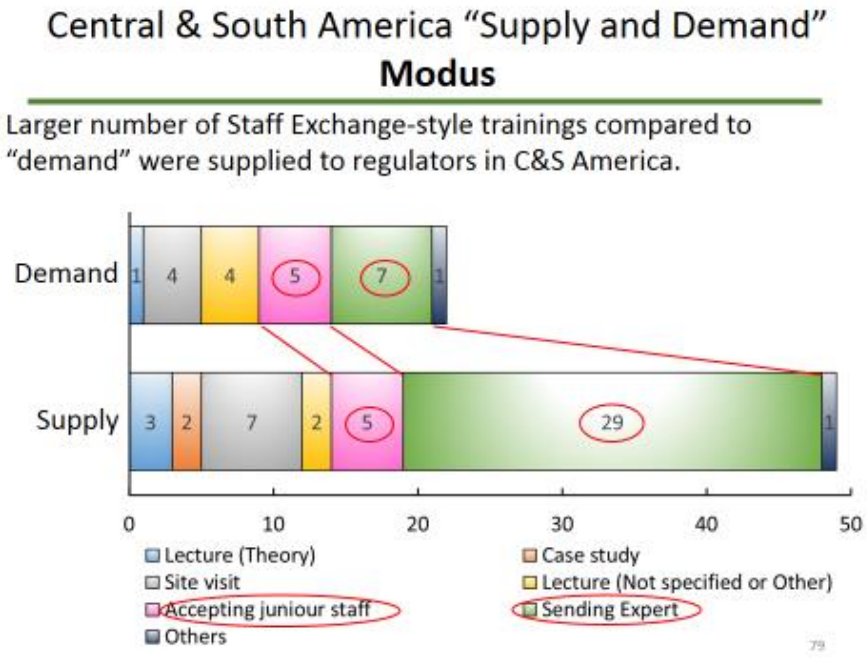


Figure 3.

A) "Supply and Demand" comparison in field of training in Central and South America



B） “Supply and Demand” comparison in modus of training in Central and South America



C） “Supply and Demand” comparison in level of trainees in Central and South America

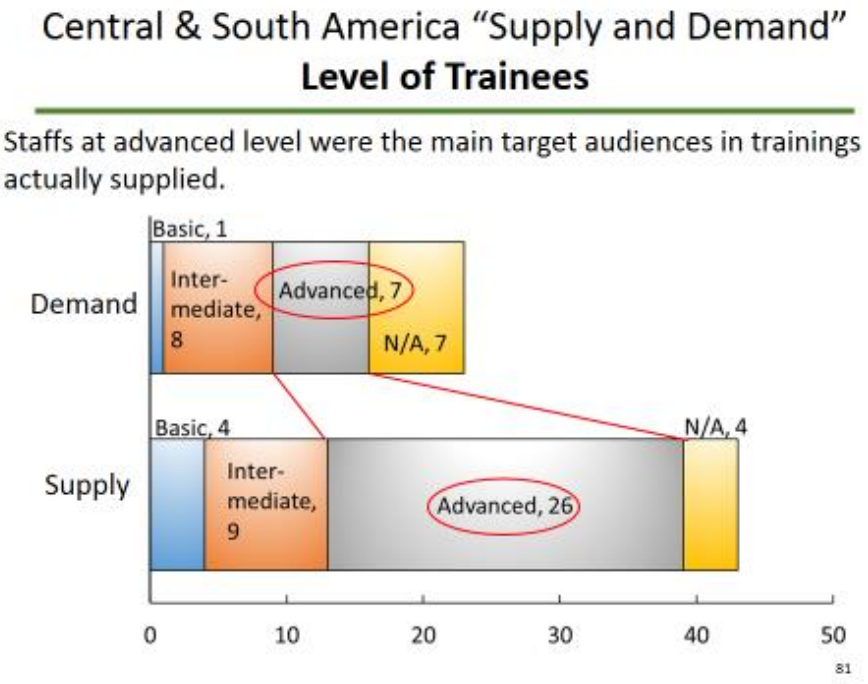
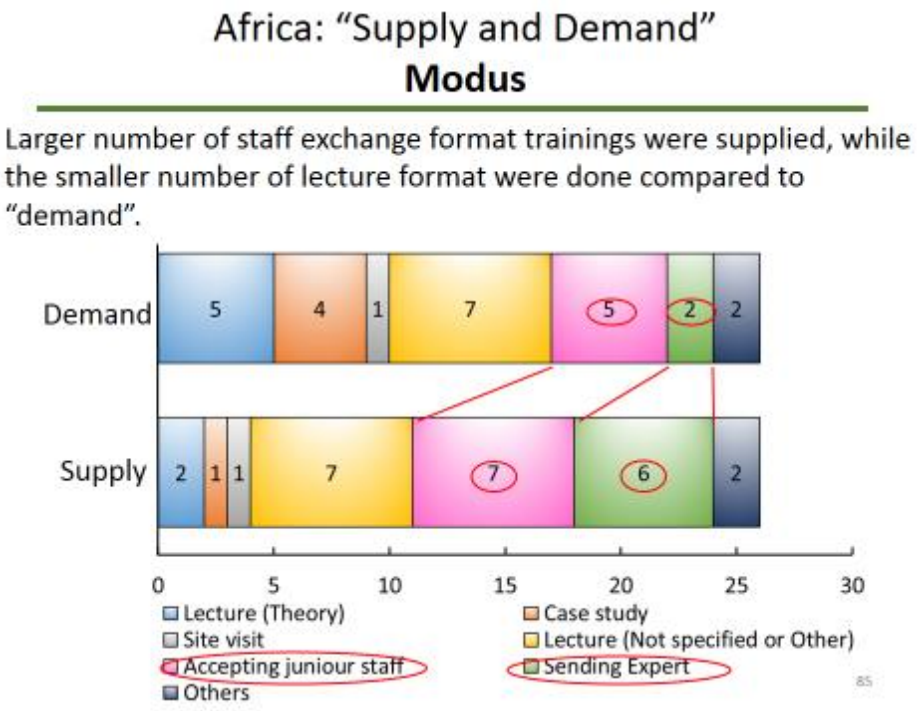


Figure 4.

A） “Supply and Demand” comparison in modus of training in Africa



B） “Supply and Demand” comparison in level of trainees in Africa

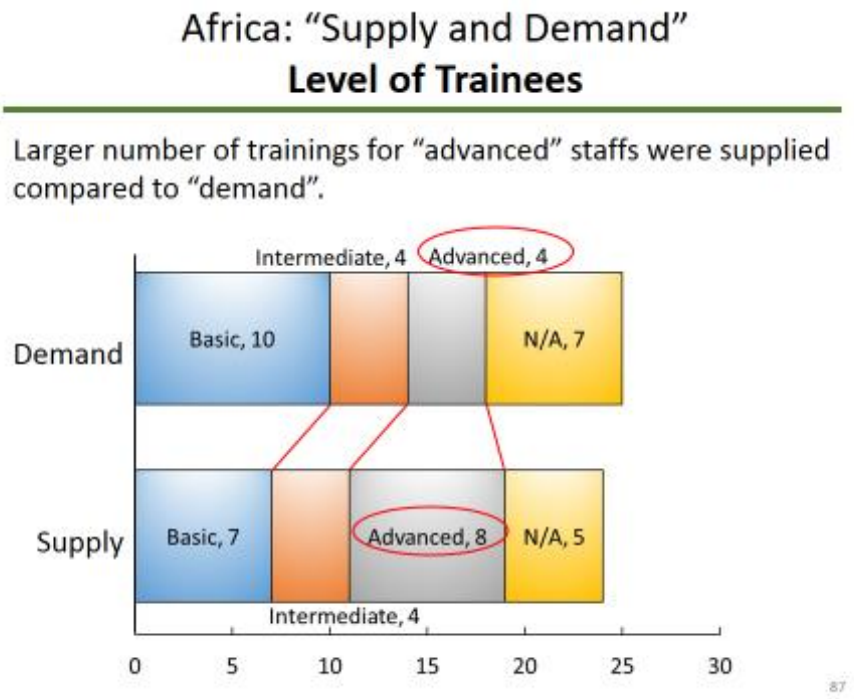


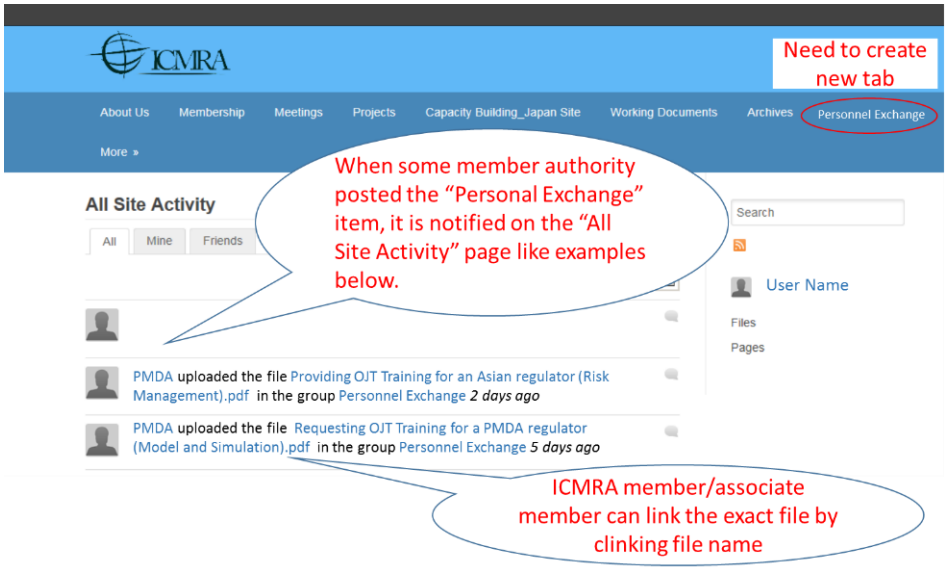
Figure 5.

Image of the “Seminar-type” training.

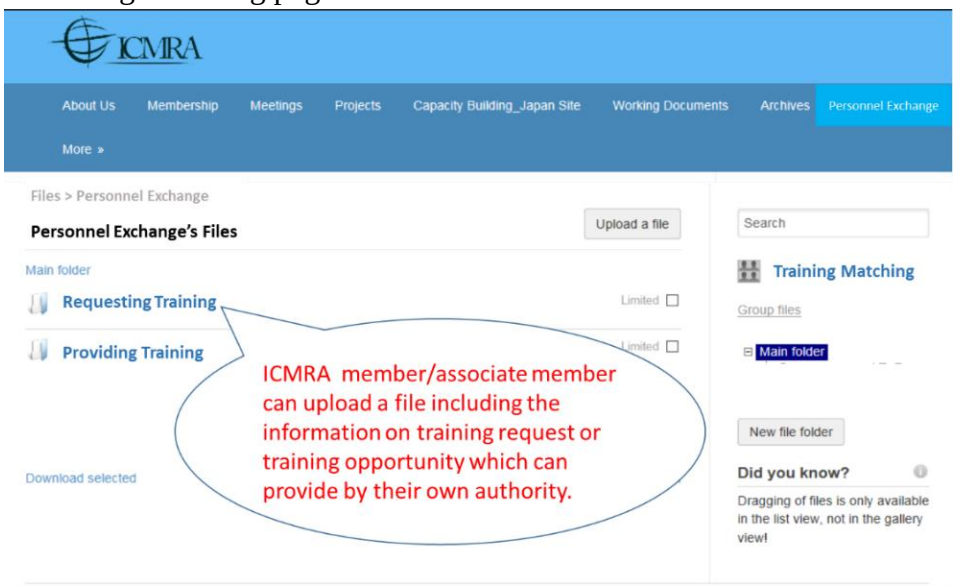
Figure 6.

Images of “message board” on ICMRA member-only website

A） Top page after login



B） Training Matching page



C） File folder and uploaded file on Training Matching page