Thursday, 19 September 2019

REGULATORY SUMMIT DAY I Hall B

(Closed Workshop, on Invitation only)

At last year's CVCT MEMA Regulatory summit 2018, the following essential action items were identified, with the aim of achieving a regulatory framework in the Region matching the international standards.

The aim of CVCT MEMA Regulatory Summit 2019 is to examine challenges and hurdles and, importantly, practical ways for implementing these recommendations, across different countries in the Region.

This full day "Regulatory Summit" will involve key officials from regulatory agencies in the region, as well from the European Medicine Agency (MEA) and the US Food and Drug Administration (FDA), governments' officials, major pharma and CROs, members of ethics committees, international advisors and key experienced investigators

Thursday, 19 September 2019

Roadmap for improving Clinical Research in Africa and Middle East
(Closed Workshop, on Invitation only)

Chairpersons:
Anne Cecile Bisseck, Cameroun
Ashraf Elfiky, USA
Dina Shokry, Egypt
Ines Fradi, Tunisia
Maciej Kostrubiec, EMA
Manal Milhem, USA
Meriem Kadri, Tunisia

11:00-12:10 Bioequivalence studies Hall B

Moderators:
Anne Cecile Bisseck, Cameroun
Dina Shokry, Egypt

11:00-11:10 **Overview of generic quality regulations in the Region**
Sahar Ibrahim, Egypt

11:10-11:50 **Current experience in the Region**

11:10-11:20 **Tunisia Experience**
Chokri Jeribi

11:20-11:30 **Egypt Experience**
Mosaad Morsi

11:30-11:40 **Cameroon Experience**
Anne Cecile Bisseck

11:40-11:50 **International grade practices**
Maciej Kostrubiec

11:50-12:00 **Panel discussion: Progressing from local bioequivalence centers to regional hubs**

Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Helen Springford (UK), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

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12:00-13:20 Informed consent: Literacy, Language and cultural issues with consenting procedures. Hall B

Moderators:

Ines Fradi, Tunisia
Manal Milhem, USA

12:00-12:10	Souad Dziri, Tunisia
12:10-12:20	Walid Zaher, UAE
12:20-12:30	Maha Ghanem, Egypt
12:30-12:40	Beno Nyam Yakubu, Nigeria
12:40-12:50	Rana Musa Al-ali Malkawi, Jordan
12:50-13:00	Aymen Garaali, Tunisia
13:00-13:10	Helen Springford, UK
13:10-13:20	Panel Discussion

Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Helen Springford (UK), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

13:20-14:00 Coffee Break
OFFICIAL OPENING

14:00-15:10 Clinical trials review boards (ethics committees and institutional review boards) Hall B

Moderators:
Maciej Kostrubiec, EMA
Rana Musa Al-ali Malkawi, Jordan

14:00-14:10 Rules for membership, accreditation
Ashraf El Fiky, USA

14:10-14:20 Training
Rana Musa Al-ali Malkawi, Jordan

14:20-14:30 Functioning, reviewing protocol and monitoring studies
Meriem Kadri, Tunisia

14:30-14:40 Alignment: National *vs.* local
Bartlomiej Piechowski-Jozwiak, UAE

14:40-14:50 Relationships and alignment with competent authorities
Anne Cecile Bisseck, Cameroun

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14:50-15:10 Panel Discussion

Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Helen Springford (UK), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

15:10-16:20 Legal framework for biobanking and material transfer agreements, including across national borders — Hall B

Moderators:
Ashraf Elfiky, USA
Moez Ben Ali, France

15:10-15:20 The regulation of biosamples during and after a Clinical trial: International Standards
Ashraf Elfiky, USA

15:20-15:30 Why do we need to share data and biosamples?
Moez Ben Ali, France

15:30-15:55 Legal framework for biosample sharing in collaborative studies in various countries Country level experiences.

15:30-15:35 Egypt Experience
Dina Shokry, Egypt

15:35-15:40 Tunisia Experience
Meriem Kadri, Tunisia

15:40-15:45 Saudi Arabia Experience
Nasser Alqahtani, Saudi Arabia

15:45-15:50 Morocco Experience
Ghizlane Lyamani, Morocco

15:50-15:55 Nigeria Experience
Margaret Mafe, Nigeria

15:55-16:20 Panel discussion How to harmonize national legislations?

Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Helen Springford (UK),Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

16.20-16.40 Lunch

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16:40-17:50	Approval procedures for non-interventional (observational) studies.	Hall B

Moderators:
Ines Fradi, Tunisia
Walid Zaher, UAE

16:40-Legal framework for biosample sharing in collaborative studies in various countries
Country level experiences.

16:40-16:45 Ines Fradi, Tunisia
16:45-16:50 Ghizlane Lyamani, Morocco
16:50-16:355 Walid Zaher, UAE
16:-55-17:00 Dina Shokry, Egypt
17:00-17:05 Margaret Mafe, Nigeria

17:05-17:40 Panel discussion How to harmonize national legislations?
Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

17:40-19:00	Mechanisms for sponsors to provide long-term post-trial access to trials treatments proven beneficial	Hall B

17:40-17:50 **Industry viewopoint**
Moez Ben Ali, France

17:50-18:20 **CRO viewpoint**
Mosaad Morsi, Egypt
Chokri Jeribi, Tunisia

18:20-18:30 **International viewpoint**
Ashraf Elfeky, USA

18:30-19:00 Panel discussion How to harmonize national legislations?
Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

Friday, 20 September 2019

DAY II THE REGULATORY SUMMIT MULTI-STAKEHOLDERS FORUM

At this half a day session key official from governments' officials, regulatory agencies in the region, as well from the European Medicine Agency (MEA) and the US Food and Drug Administration (FDA), experts from major pharma and CROs, members of ethics committees, international advisors and key experienced investigators will report back to the general audience discussing with all, in an open forum format, the recommendations they have reached on Day 1 "Regulatory Summit".

13:00-16:20	**Roadmap for Reform – Harmonization of the Regulatory Framework. Plenary Session**	**Main Hall**

Moderators:
Faiez Zannad, Nancy, France
Habib Gamra, Monastir, Tunisia
Mohamed Sobhy, Alexandria

13:00-15:00	**Reports and discussion of recommendations reached on Day 1 Regulatory Summit - Reforming the regulatory framework**	**Main Hall**

IMPORTANT: Presentation time includes discussion for each topic

13:00-13:20 **Bioequivalence studies: Securing quality grade generic drugs?**
Maciej Kostrubiec, EMA

13:20-13:40 **Informed consent issues**
Rana Musa Al-ali Malkawi, Jordan

13:40-14:00 **Clinical trials review boards issues**
Ashraf El Fiky, USA

14:00-14:20 **Final version of the new research law and sample transfer**
Dina Shokry, Egypt

14:20-14:40 **Non-interventional (observational) studies.**
Ines Fradi, Tunisia

14:40-15:00 **Mechanisms for sponsors to provide long-term post-trial access to trials treatments proven beneficial**
Moez Ben Ali, France

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15:00-16:00	**The CVCT Forum: Moderated multi-stakeholder discussion** **Is there any chance that the Region may move to an overarching unified regulatory framework?**	**Main Hall**

Abdelrahman Zekry (Egypt), Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Azza Saleh (Egypt) Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Ghizlane Lyamani (Morocco), Ines Fradi (Tunisia), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mosaad Morsi (Egypt), Nihal Habashi (Egypt), Ossama Badary (Egypt), Radwa Mehanna (Egypt), Rana Musa Al-ali Malkawi (Jordan), Souad Dziri (Tunisia), Tamer Essam (Egypt), Walid Zaher (UAE)

16:00-16:20	**Closing Remarks**

Faiez Zannad, Nancy, France
Habib Gamra, Monastir, Tunisia
Mohamed Sobhy, Alexandria