



MIDDLE EAST, MEDITERRANEAN & AFRICA
CARDIOVASCULAR CLINICAL
TRIALISTS FORUM

Pyramisa Suites Hotel Cairo - Egypt

19-20
SEPTEMBER
2019

CardioVascular Clinical Trialists

Middle East, Mediterranean & Africa

CVCT MEMA 2019

19-20 September - Cairo, Egypt

Scientific Program



MIDDLE EAST, MEDITERRANEAN & AFRICA CARDIOVASCULAR CLINICAL TRIALISTS FORUM

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Thursday, 19 September 2019

LATEST GAME CHANGER CV CLINICAL TRIALS

DAY I

Main Hall

In this section, international trialists will present an overview of the latest trials (both drug and interventional), in CV respective sub-specialty areas and a panel of 3 regional academic faculty members and one industry speaker will discuss potential implementation issues of the results of these trials in different MEMA regions (Middle East, North Africa, Sub Saharan Africa and Minor Asia), potentially highlighting regional registry and observational data.

11:00-12:10 Hypertension: Diet, Drugs, Devices

Main Hall

Chairpersons:

Faiez Zannad, USA

Fouad El Nawawy, Egypt

Omer Goktekin, Turkey

Tamer Mostafa, Egypt

Wael Almahmeed, UAE

11:00-11:10 International viewpoint

Faiez Zannad

Boston, USA

11:10-11:20 Is the use of generics the main obstacle for the non-control of hypertension in Africa?

Salem Abdessalem

Tunis, Tunisia

11:20-11:30 Is there a need for African guidelines for the control of hypertension?

Albertino Damasceno

Maputo, Mozambique

11:30-11:40 Hypertension in the Middle East

Tarek El Zawawy

Alexandria, Egypt

11:40-11:45 Renal Denervation

Medtronic

11:45-11:50 Industry Perspective

Mohamed Yehia

Bayer

11:50-12:00 Industry Perspective - Non-Communicable Diseases Burden in Egypt

Ashraf Shehata

Pfizer

12:00-12:10 Discussion



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12:10-13:20 Heart Failure: Latest International and Regional Data Main Hall

Chairpersons:

Anastase Dzudie, Cameroun

Ayman Saleh, Egypt

Mahmoud Hassanein, Egypt

Mohamed Sobhy, Egypt

Wolfgang Koenig, Germany

12:10-12:20 International viewpoint: Hot Results in HFpEF and HFrEF (PARAGON and DAPA-HF)

Faiez Zannad

Boston, USA

12:20-12:30 Insights from the Tunisian registry on heart failure (NATURE-AF)

Leila Abid

Sfax, Tunisia

12:30-12:40 The PEACE MENA Registry

Habib Gamra

Monastir, Tunisia

12:40-12:50 Insights from Sub-Saharan Africa: The THESUS-HF Registry

Anastase Dzudie

Douala, Cameroun

12:50-13:00 Industry Perspective

Gehan Ramadan

Novartis, Egypt

13:00-13:20 Discussion

13:20-14:00 Coffee Break

OFFICIAL OPENING



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14.00-15.10 Diabetes and Cardiorenal outcomes trials

Main Hall

Chairpersons:

Ashraf Reda, Egypt

Mirvat AlAsnag, KSA

Habib Gamra, Tunisia

Samir Naeem, Egypt

Nabil Elkafrawy, Egypt

14:00-14:10 Metabolic Health in the Middle East and North Africa

Davood Khalili

Tehran, Iran

14:10-14:20 Endocrinologist viewpoint

Ines Khochtali

Monastir, Tunisia

14:20-14:30 Cardiologist perspective

Wael Almahmeed

Abu Dhabi, UAE

14:30-14:40 Cardiorenal perspective

Faiez Zannad

Boston, USA

14:40-14:50 Industry perspective

Afshin Salsali

Boehringer, Germany

14:50-15:10 Discussion

15.10-16.20 Atherosclerosis and Dyslipidemia Trials and Implementation Issues

Main Hall

Chairpersons:

Atef Elbahry, Egypt

Leila Abid, Tunisia

Elsayed Farag, Egypt

Wolfgang Koenig, Germany

Ibrahim Ali Toure, Niger

15:10-15:20 International viewpoint

Wolfgang Koenig

Munich, Germany

15:20-15:30 Middle East experience

Ashraf Reda

Menoufia, Egypt

15:30-15:40 North Africa experience

Mohamed El Alamy

Casablanca, Morocco

15:40-15:50 Insights from Sub-saharan Africa

Abdoul Kane

Dakar, Senegal

15:50-16:00 Industry perspective

Hala Ramzy

SANOFI, Egypt

16:00-16:20 Discussion



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16.20-16.40 Lunch

16:40-17:50 **Coronary Artery Disease . Peripheral Artery Disease. NOACS
and Interventional Therapy**

Main Hall

Chairpersons

Ahmed Suliman, Sudan

Albertinho Damasceno, Mozambique

Hany Ragy, Egypt

Hazem Khamis, Egypt

Mohamed Balghith, KSA

16:40-16:50 **International viewpoint**

Wolfgang Koenig

Munich, Germany

16:50-17:00 **Interventional cardiology latest trials**

Mohamed Sobhy

Alexandria, Egypt

17:00-17:10 **Coronary Artery Disease in the Middle East**

Mirvat AlAsnag

Jeddah, KSA

17:10-17:20 **Interventional cardiology in North Africa**

Habib Gamra

Monastir, Tunisia

17:20-17:30 **Insights from Sub-Saharan Africa**

Elijah Ogola

Nairobi, Kenya

17:30-17:40 **Industry perspective**

Bayer

17:40-17:50 **Discussion**



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17:50-19:00 Atrial Fibrillation. Ablation and Stroke Prevention

Main Hall

Chairpersons:

Abdoul Kane, Senegal

Hesham Salah, Egypt

Magdy Elmasry, Egypt

Mehmet Birhan, Turkey

17:50-18:00 Latest and ongoing electrophysiology and anti-thrombotic trials

Faiez Zannad

Boston, USA

18:00-18:10 How best to implement drug therapy?

Hany Ragy

Cairo, Egypt

18:10-18:20 AF ablation best practices in the Middle East

Mohamed Sanhory

Alexandria, Egypt

18:20-18:30 DOACs vs Warfarin in limited resources countries

Saad Subahi

Khartoum, Sudan

18:30-18:40 Industry Perspective

Sherif Hafez

Pfizer, Egypt

18:40-19:00 Discussion



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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



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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 Bissec (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 Bissec, 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

16:50-16:55 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 Bissec (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 viewpoint

Moez Ben Ali, France

17:50-18:20 CRO viewpoint

Mosaad Morsi, Egypt

Chokri Jeribi, Tunisia

18:20-18:30 International viewpoint

Ashraf Elfiky, USA

18:30-19:00 Panel discussion How to harmonize national legislations?

Abdelrahman Zekry (Egypt), Anne Cecile Bissec (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)



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LATEST GAME CHANGER CV CLINICAL TRIALS DAY II Main Hall

09:00-10:10 Arrhythmias and Sudden Death Main Hall

Chairpersons:

Hesham Aboul Enein, Egypt

Moataz Zaki, Egypt

Sameh Emil, Egypt

Salem Abdessalem, Tunisia

Tarek El Zawawy, Egypt

09:00-09:10 International viewpoint

Mehmet Birhan

Izmir, Turkey

09:10-09:20 Burden and management of arrhythmias and sudden cardiac death in the Middle East

Hayam El Damahoury

Ain Shams, Egypt

09:20-09:30 Experience from Turkey

Mehmet Birhan

Izmir, Turkey

09:30-09:40 The PASCAR initiative on the reuse of pace makers in Africa

Mahmoud Sani

Kano, Nigeria

09:40-09:50 Industry Perspective

Medtronic

09:50-10:10 Discussion

10:10-11:10 Rheumatic Fever/ Valve Disease - Preventive Strategies (PASCAR Session) Main Hall

Chairpersons:

Elijah Ogola, Kenya

Faiez Zannad, USA

Habib Gamra, Tunisia

Mahmoud Sani, Nigeria

Mohamed Sobhy, Egypt

Saad Subahi, Sudan

10:10-10:20 Strategies to eradicate rheumatic fever in Africa

Sulafa Ali

Khartoum, Sudan

10:20-10:30 Strategies in the Middle East

Alaa El Ghamrawy

Mansoura, Egypt

10:30-10:40 Strategies in North Africa - Tunisian Experience

Habib Gamra

Monastir, Tunisia

10:40-10:50 Surgical Management of Rheumatic Valve Disease in Africa

Mohamed Elfiky

Ain Shams, Egypt

10:50-11:10 Discussion



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11:10-11:30

BREAK

11:30-14:00

Pediatric and Structural Heart Disease

Main Hall

Chairpersons:

Amal El Sisi, Egypt

Ines Kochtali, Tunisia

Mohamed Al Alami, Morocco

Mohamed Sobhy, Egypt

Nabil Farag, Egypt

Salim Ben Khedda, Algeria

Regional implementation

11:30-11:40

Left Atrial Appendage Closure

Habib Gamra

Monastir, Tunisia

11:40-11:50

TAVI in the Middle East

Mohamed Balghith

Riyadh, KSA

11:50-12:00

Interventions for Congenital Heart Disease

Azza Elfiky

Ain Shams, Egypt

12:00-12:10

Percutaneous Mitral and Tricuspid Valve Repair

Omer Goktekin

Istanbul, Turkey

12:10-12:20

Industry perspective

Medtronic, Egypt

12:20-12:40

Discussion

12:40-13:00

Coffee Break



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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 (EMA) 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.** **Main Hall**
Plenary Session

Moderators:

Faiez Zannad, Nancy, France

Habib Gamra, Monastir, Tunisia

Mohamed Sobhy, Alexandria

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

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** **Main Hall**
Is there any chance that the Region may move to an overarching unified regulatory framework?

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