

# WELCOM TO



IN COLLABORATION WITH



CardioVascular Research.. Education.. Prevention

**19-20 SEPTEMBER 2019**  
**PYRAMISA SUITES HOTEL**  
**CAIRO, EGYPT**

## WELCOME MESSAGE



We are delighted to welcome you in Cairo in CVCT MEMA, 19-20 September 2019

CVCT MEMA, the single event assembling a think tank of high-profile multiple stakeholder experts aiming at producing, promoting and applying evidence-based Cardiovascular medicine in the Region

CVCT meetings are oriented toward brainstorming and intense interaction, among leaders from various backgrounds assembling in a unique think tank. Rather than simple lecturing, and beyond the educational aims, sessions provide ample time for panel discussion among the think tank members and with delegates. Pharmaceutical and health industry should view this initiative differently from a simple promotional/educational meeting. Supporting/ attending CVCT will contribute to better understanding local health care systems and governmental policies, disease burden, clinical practice patterns and unmet needs as well as ways for the optimal implementation of major recent therapeutic innovations.

The CVCT MEMA Forum follows the successful example of the main CVCT meetings in Paris, Singapore and Washington DC, which enjoy large representation from Europe, the US and Asia.

CVCT-MEMA aims to bring together top Middle East and African cardiovascular trialists, investigators, statisticians, industry R&D experts, national regulators and practitioners across the region.

CVCT meetings have become a new energetic and motivating unique type of meeting. The specific aim is to examine important and timely CV trial issues relating to methodology, interpretation, approval and implementation of recent, ongoing and future trials in specific CV therapeutic areas.

We hope you will enjoy and benefit from this unique event

**CVCT MEMA Board**

# CVCT MEMA BOARD



## **FAIEZ ZANNAD**

FOUNDER & CHAIRMAN

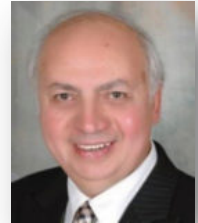
Eugene Braunwald Scholar, Visiting Professor, Harvard Medical School, Boston, USA



## **MOHAMED SOBHY**

CO-CHAIRMAN

Professor of Cardiology, Alexandria University  
President of Cardiovascular Research, Education, Prevention Foundation (CVREP)  
Past President of the Egyptian Society of Cardiology  
Governor of ACC Chapter in Egypt  
CardioAlex Chairman



## **HABIB GAMRA**

CO-CHAIRMAN

Past President of The African Heart Network  
President of The Tunisian Heart Foundation  
Chairman of PAFCIC  
Head of Cardiology A Department  
Fattouma Bourguiba University Hospital  
Monastir, Tunisia



## **UNDER PATRONAGE OF**

H.E. Prof. Khaled Abdel Ghaffar  
Minister of Higher Education & Scientific Research



# CVCT MEMA 2019 FACULTY

## CARDIOVASCULAR DAY



Abdul Kane	Dakar, Senegal
Afshin Salsali	Boehringer, Germany
Ahmed Suliman	Khartoum, Sudan
Alaa El Ghamrawy	Mansourah, Egypt
Albertinho Damasceno	Mozambique
Amal El Sisi	Ain Shams, Egypt
Anastase Dzudie	Cameroun
Ashraf Reda	Menoufia, Egypt
Ashraf Shehata	Pfizer, Egypt
Atef Elbahry	Portsaid, Egypt
Ayman Saleh	Cairo, Egypt
Azza El Fiky	Ain Shams, Egypt
Davood Khalili	Tehran, Iran
Elijah Ogola	Nairobi, Kenya
Elsayed Farag	Zagazig, Egypt
Faiez Zannad	Nancy, France
Fouad El Nawawy	Cairo, Egypt
Gehan Ramadan	Novartis, Egypt
Habib Gamra	Monastir, Tunisia
Hala Ramzy	SANOFI, Egypt
Hany Ragy	NHI, Egypt
Hayam El Damanhoury	Ain Shams, Egypt
Hesham Salah	Cairo, Egypt
Ibrahim Ali Toure	Niamey, Niger
Ines Khochtali	Monastir, Tunisia
Kinga Skoczylas	Medtronic, Eastern Europe

# CVCT MEMA 2019 FACULTY

## CARDIOVASCULAR DAY



Leila ABID	Sfax, Tunisia
Magdy Elmasry	Tanta, Egypt
Mahmoud Hassanein	Alexandria, Egypt
Mahmoud Sani	Kano, Nigeria
Mehmet Birhan	Izmir, Turkey
Mirvat AlAsnag	Jedda, KSA
Moataz Zaki	Alexandria, Egypt
Mohamed Alami	Casablanca, Morocco
Mohamed Balghith	Ryadh, KSA
Mohamed Elfiky	Ain Shams, Egypt
Mohamed Sanhory	Alexandria, Egypt
Mohamed Sobhy	Alexandria, Egypt
Mohamed Yehia	Bayer, Egypt
Nabil Farag	Ain Shams, Egypt
Omer Goketkin	Istanbul, Turkey
Saad Subahi	Khartoum, Sudan
Salem Abdessalem	Tunis, Tunisia
Sameh Emil	Cairo, Egypt
Sherif Emad	Bayer, Egypt
Sherif Hafez	Pfizer, Egypt
Sulafa Ali	Khartoum, Sudan
Tamer Mostafa	Zagazig, Egypt
Tarek El Zawawy	Alexandria, Egypt
Wael Almahameed	Abu Dhabi, UAE
Wolfgang Koenig	Munich, Germany

# CVCT MEMA 2019 FACULTY

## REGULATORY SUMMIT



Abdelrahman Zekry	Egypt
Alaa Assem	Egypt
Anne Cecile Bissec	Cameroun
Ashraf ElFikhy	USA
Aymen Garaali	Tunisia
Bartlomiej Piechowski-Jozwiak	UAE
Basma Hammad	Egypt
Chokri Jeribi	Tunisia
Dina Shokry	Egypt
Hany Hafez	Egypt
Hazem Desouky	Egypt
Helen Springford	UK
Ines Fradi	Tunisia
Khalid Al Moaikel	KSA
Maciej Kostrubiec	Poland
Maha Ghanem	Egypt
Manal Milhem	USA
Margeret Mafe	Nigeria
Mariam Kadri	Tunisia
Michael Nabil	Egypt
Moez Bin Ali	France
Mossad Morsi	Egypt
Nihal Habachi	Egypt
Ossama Badary	Egypt
Rana Musa Al-ali Malkawi	Jordan
Sahar Ebrahim	Egypt
Souad Dziri	Tunisia
Tamer Essam	Egypt
Walid Zaher	UAE

# GENERAL INFORMATION



## MEETING VENUE

PYRAMISA SUITES HOTEL

**Main Hall:** Versailles Meeting Room

**Regulatory Summit:** Louvre Meeting Room

## HOUSING

PYRAMISA SUITES HOTEL

All rooms are on bed & breakfast basis

Check in Time 2:00 PM - Check out Time 12:00 PM

## ELECTRICITY

The electricity supply in Egypt is 220 Volts, 50 Hz.

Most hotels also provide 110 Volts outlets for shavers

## CURRENCY BANKING

(RATES ARE SUBJECTS TO MARKET FLUCTUATIONS)

Egyptian Pound (EGP) is the official currency in Egypt.

Foreign currency exchange is available in most of the hotels, banks and currency exchange offices.

ATM machines are available all through the city, at the convention center and at the vicinity of all Meeting hotels

## LANGUAGE

The official language is English.

All lectures and presentations will be held in the English language only.

There will be no translation available



## GENERAL INFORMATION

### MEALS TIMINGS

#### THURSDAY, 19<sup>TH</sup> OF SEPTEMBER 2019

Coffee Break 13:20-14:00

Lunch 16:20-16:40

#### FRIDAY, 20<sup>TH</sup> OF SEPTEMBER 2019

Coffee Break 12:10-13:00

Lunch 16:20-17:00

### REGISTRATION HOURS

#### THURSDAY, 19<sup>TH</sup> OF SEPTEMBER 2019

09:30-18:00

#### FRIDAY, 20<sup>TH</sup> OF SEPTEMBER 2019

08:30-14:00

### SCIENTIFIC HOURS

#### THURSDAY, 19<sup>TH</sup> OF SEPTEMBER 2019

11:00-19:00

#### FRIDAY, 20<sup>TH</sup> OF SEPTEMBER 2019

09:00-16:20

### BADGE

All registrants must wear their name badge to have access to forum sessions

### BARCODE

Barcode will be printed on all badges of participants.

All access to Halls of the Meeting will be with the badge.

Please make sure that you scanned your badge before every session, as this is the only way to assure your attendance and taking your certificate

### WEBSITE

[www.cvctmiddleeast.com](http://www.cvctmiddleeast.com)



## CERTIFICATION



Attendance of all program sessions is mandatory to be legible to receive your certificate.

Please make sure that you scanned your badge before every session, as this is the only way to assure your attendance and taking your certificate

Attendance Certificate will be delivered to all delegates on Friday, 20th of September 2019 from Registration Desk from 15:00-16:00

## ACKNOWLEDGEMENT



**SANOFI**  
*Empowering Life*



**NOVARTIS**

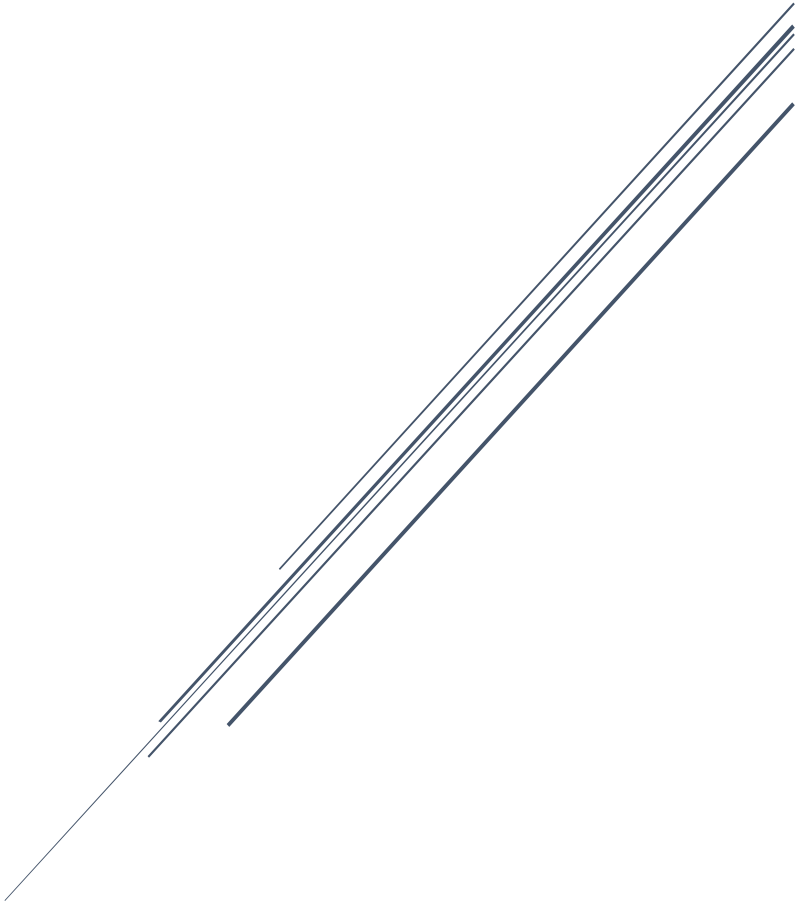


**Medtronic**



**MSD**

# SCIENTIFIC AGENDA



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: Versailles](#)

#### Chairpersons:

Faiez Zannad, USA

Fouad El Nawawy, Egypt

Omer Goktekin, Turkey

Tamer Mostafa, Egypt

Wael Almahmeed, UAE

- |             |  |                                  |
|-------------|--|----------------------------------|
| 11:00-11:10 | International viewpoint<br><b>Faiez Zannad</b>   | <b>Boston, USA</b>               |
| 11:10-11:20 | Is the use of generics the main obstacle for the non-control of hypertension in Africa?<br><b>Salem Abdessalem</b> | <b>Tunis, Tunisia</b>            |
| 11:20-11:30 | Is there a need for African guidelines for the control of hypertension?<br><b>Albertino Damasceno</b>              | <b>Maputo, Mozambique</b>        |
| 11:30-11:40 | Hypertension in the Middle East<br>Tarek El Zawawy   | Alexandria, Egypt                |
| 11:40-11:45 | Renal Denervation<br><b>Kinga Skoczylas</b>  | <b>Medtronic, Eastern Europe</b> |
| 11:45-11:50 | Industry Perspective<br><b>Mohamed Yehia</b>   | <b>Bayer, Egypt</b>              |
| 11:50-12:00 | Industry Perspective - Non-Communicable Diseases Burden in Egypt<br><b>Ashraf Shehata</b>                          | <b>Pfizer, Egypt</b>             |
| 12:00-12:10 | Discussion   |                                  |

# THURSDAY, 19 SEPTEMBER 2019



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

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## 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

**Aly Omar Novartis, Egypt**

13:00-13:20 Discussion

**13:20-14:00 COFFEE BREAK  
OFFICIAL OPENING**

# THURSDAY, 19 SEPTEMBER 2019



14.00-15.10 Diabetes and Cardiorenal Outcomes Trials

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Main Hall: Versailles

## Chairpersons:

Ashraf Reda, Egypt

Nabil Farag, Egypt

Habib Gamra, Tunisia

Mirvat AlAsnag, KSA

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

# THURSDAY, 19 SEPTEMBER 2019



15.10-16.20      **Atherosclerosis and Dyslipidemia Trials and Implementation Issues**

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**Main Hall: Versailles**

## Chairpersons:

Atef Elbahry, Egypt

Elsayed Farag, Egypt

Ibrahim Ali Toure, Niger

Leila Abid, Tunisia

Wolfgang Koenig, Germany

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

**16.20-16.40      LUNCH**

# THURSDAY, 19 SEPTEMBER 2019



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

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**Main Hall: Versailles**

## Chairpersons:

Ahmed Suliman, Sudan                                      Hazem Khamis, Egypt  
Albertinho Damasceno, Mozambique    Mohamed Balghith, KSA  
Hany Ragy, Egypt

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**

17:30-17:45      Industry perspective  
**Sherif Emad**                      **Bayer, Egypt**

17:45-17:55      Industry perspective  
**Abbott, Egypt**

17:50-18:00      Discussion

# THURSDAY, 19 SEPTEMBER 2019



18:00-19:00      **Atrial Fibrillation. Ablation and Stroke Prevention**

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**Main Hall: Versailles**

## Chairpersons:

Abdoul Kane, Senegal

Magdy Elmasry, Egypt

Hesham Salah, Egypt

Mehmet Birhan , Turkey

18:00-18:10      Latest and ongoing electrophysiology and anti-thrombotic trials

**Faiez Zannad**                      **Boston, USA**

18:10-18:20      How best to implement drug therapy?

**Hany Ragy**                              **Cairo, Egypt**

18:20-18:30      AF ablation best practices in the Middle East

**Mohamed Sanhory**              **Alexandria, Egypt**

18:30-18:40      DOACs vs Warfarin in limited resources countries

**Saad Subahi**                              **Khartoum, Sudan**

18:40-18:50      Industry Perspective

**Sherif Hafez**                              **Pfizer, Egypt**

18:50-19:00      Discussion



# THURSDAY, 19 SEPTEMBER 2019



**REGULATORY SUMMIT**

**DAY I**

*(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: Louvre

### 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), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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)

# THURSDAY, 19 SEPTEMBER 2019



12:00-13:20 Informed Consent: Literacy, Language and Cultural Issues  
with Consenting Procedures.

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Hall: Louvre

## 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), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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

# THURSDAY, 19 SEPTEMBER 2019



14:00-15:10 Clinical Trials Review Boards (Ethics Committees and Institutional Review Boards)

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Hall: Louvre

## 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**

14:50-15:10 Panel Discussion

Abdelrahman Zekry (Egypt), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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)

# THURSDAY, 19 SEPTEMBER 2019



15:10-16:20      **Legal Framework for Biobanking And Material Transfer Agreements, Including Across National Borders**

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**Hall: Louvre**

## **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), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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)

# THURSDAY, 19 SEPTEMBER 2019



16.20-16.40 LUNCH

16:40-17:50 Approval Procedures for Non-interventional (Observational) Studies

Hall: Louvre

## Moderators:

Ines Fradi, Tunisia

Walid Zaher, UAE

16:40-17:05 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), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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)

## THURSDAY, 19 SEPTEMBER 2019



17:40-19:00      **Mechanisms for Sponsors to Provide Long-Term Post-Trial Access to Trials Treatments Proven Beneficial**

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**Hall: Louvre**

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), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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)

### 09.00-10:10 Arrhythmias and Sudden Death

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Main Hall: Versailles

#### Chairpersons:

Moataz Zaki, Egypt

Salem Abdessalem, Tunisia

Sameh Emil, Egypt

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 Damanhoury** 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

**Kinga Skoczylas** Medtronic, Eastern Europe

09:50-10:10 Discussion



## FRIDAY, 20 SEPTEMBER 2019



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

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Main Hall: Versailles

### 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

11:10-14:00 Pediatric and Structural Heart Disease

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Main Hall: Versailles

### Chairpersons:

Amal El Sisi, Egypt

Ines Kochtali, Tunisia

Mohamed Al Alami, Morocco

Mohamed Sobhy, Egypt

Nabil Farag, Egypt

Salim Ben Khedda, Algeria

### Regional implementation

11:10-11:20 Left Atrial Appendage Closure

**Habib Gamra**

**Monastir, Tunisia**

11:20-11:30 TAVI in the Middle East

**Mohamed Balghith**

**Riyadh, KSA**

11:30-11:40 Interventions for Congenital Heart Disease

**Azza Elfiky**

**Ain Shams, Egypt**

11:40-11:50 Percutaneous Mitral and Tricuspid Valve Repair

**Omer Goktekin**

**Istanbul, Turkey**

11:50-12:00 Industry perspective

**Kinga Skoczylas**

**Medtronic, Eastern Europe**

12:00-12:10 Discussion

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: Versailles](#)

**Moderators:**

Faiez Zannad, Nancy, France

Mohamed Sobhy, Alexandria

Habib Gamra, Monastir, Tunisia

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

[Main Hall: Versailles](#)

**Presentation time includes discussion for each topic**

13:00-13:20 Bioequivalence studies: Securing quality grade generic drugs?

**Maciej Kostrubiec** Poland

13:20-13:40 Informed consent issues

**Rana 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

## FRIDAY, 20 SEPTEMBER 2019



**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?**

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**Main Hall: Versailles**

Abdelrahman Zekry (Egypt), Alaa Assem (Egypt) Anne Cecile Bisseck (Cameroun), Ashraf Elfiky (USA), Aymen Garaali (Tunisia), Bartlomiej Piechowski-Jozwiak (UAE), Basma Hammad (Egypt), Beno Nyam Yakubu (Nigeria), Chokri Jeribi (Tunisia), Dina Shokry (Egypt), Hany Hafez (Egypt), Hazem Desouky (Egypt), Helen Springford (UK), Ines Fradi (Tunisia), Khalid Al Moaikel (KSA), Maha Ghanem (Egypt), Maciej Kostrubiec (EMA), Manal Milhem (USA), Margaret Mafe (Nigeria), Meriem Kadri (Tunisia), Michael Nabil (Egypt), Moez Ben Ali (France), Mohamed Mostafa (Egypt), 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**

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**Main Hall: Versailles**

**16:20:17:00**      **LUNCH**