

# Algeria: A Destination for Global Clinical Research



**June 8 & 9, 2011**  
**Algiers**

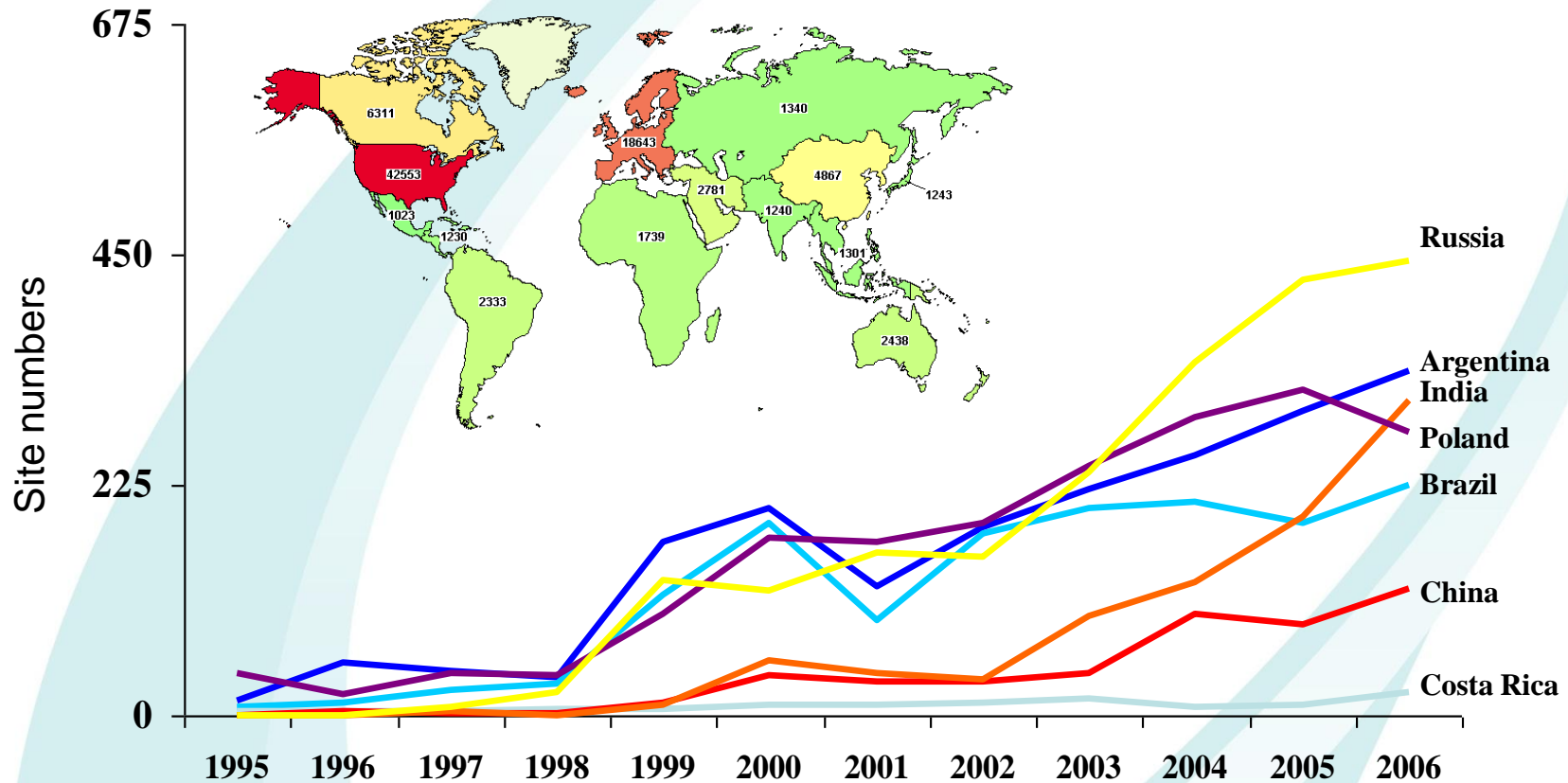
Cellia K. Habita, MD, PhD  
CEO of ARIANNE Corp

# Historical View



DIA 40<sup>th</sup> Annual Meeting - Washington, DC - June 13-17, 2004

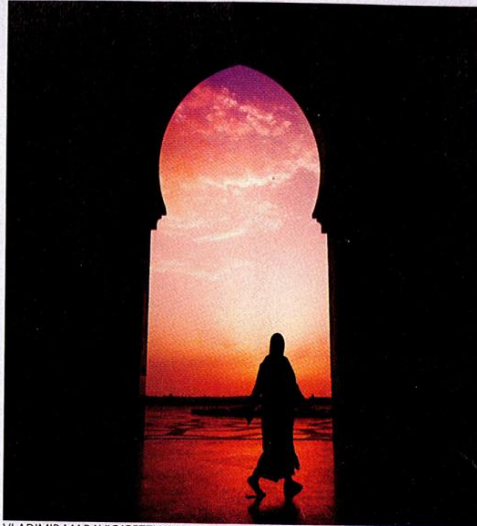
# Clinical Trial World Expansion



Source: Tufts CSDD

- Many ongoing trials in MENA; but not referenced

# MENA – “the Final Frontier”



VLADIMIR MARAVIC/GETTY IMAGES

Rani Abraham

## MENA: The Dawn of a New Era

.....  
The Middle East and North Africa region has seen a recent increase in clinical trials research.  
.....

the MENA region is thought to be on the edge of a cardiovascular disease epidemic. Turkey, Saudi Arabia, and Egypt are considered the biggest recipients of Foreign Direct Investment (FDI) with investments ranging from \$2 billion to \$2.7 billion in order to address this issue. The

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# Algeria Amongst MENA

Country	Population (M) 2005	# of Trials
USA	298	55,291
<b>India</b>	<b>1,180</b>	<b>1,658</b>
Egypt	74	248
<b>Algeria</b>	<b>32.8</b>	<b>17</b>
Morocco	31	55
S. Arabia	24.5	167
Tunisia	10	101
Jordan	5.7	326
<b>Lebanon</b>	<b>3.5</b>	<b>1181</b>
Dubai	2.2	20

# Clinical Trials in Algeria

- 107,260 trials in 174 countries trials registered
  - April 2011; [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- **Only 17 registered in Algeria!!!**
  - 1<sup>st</sup> clinical activities documented in 2008
  - 6 trials were completed and 5 recruiting

Indications	# Trials
Diabetes	5
Oncology	5
Hematology	3
Cardiovascular	2
Infectious	1
CNS	1

# Who Are the Sponsors?

Sponsor	# Trials	Regions
NovoNordisk	6	1 study in Algeria only, rest international
Sanofi	5	MENA, NEE
Novartis	2	International (MENA/NEE)
Bayer	1	International
INSERM	1	France, N.A, S.A and Serbia
USAID	1	Africa and S. Africa
NCI	1	N. Africa

**There is no Biotech company doing business in Algeria!**

# Example of Successful New Emerging Economy in Clinical Research - India

- 20% of global trials estimated to be conducted in India by 2010
  - *“Industry Report CYGNUS Business Consulting & Research, Nov 2005”*
- Indian clinical research segment currently valued at \$200M and growing at 84% annum. Estimated \$1B industry by 2010
  - *“CDSCO Mar 2009”*
- Major ongoing clinical trials include India
- New drugs registered in the last 15 years developed by pharma included data from India
- New biologics developed in oncology **all included India!**

# Acceptability of Foreign Data

- Studies must be conducted with regulations that apply to US IND (21 CFR312.120)
- FDA will accept data if:
  - Compliance with IND regulations
  - High commitment to human subjects protection
  - Studies representative of the disease for which the product is being registered in USA
  - Respect of racial balance

# Clinical Trials in New Emerging Economies

## Pros

- Large patient populations
- Fewer competitor trials
- Keen investigators
- Potential for cost savings
- High growth markets of tomorrow
- High data quality

## Cons

- Nascent clinical development environments
- “Prolonged” regulatory processes
- Relatively poor commercialisation potential
- Ethical dilemmas
- Concerns regarding Intellectual Property protection

# The Environment

## N. Africa vs Middle East (AUE)

### M. East/Emirates

- Political stability
- Wealth
- Friendly to international corporations
  - Legal entities
  - Taxations, etc
- High education
- Strong infrastructure
- **English speaker**
- Well connected to rest of the world
- Presence of nascent venture capitals



### N. Africa

- ?
- ?
- Morocco and Tunisia
- Well educated population
- Fair infrastructure
- Egypt, remaining French speaker
- **Closer to Europe and N. America**
- ?

# Key Points to Consider When Developing Clinical Research in Algeria

- Regulatory Applications
  - Time lines to approval
  - Process
- Ethics Committees
- Investigators & Site Personnel
- Site Infrastructure
- Peripheral activities
- Education
  - Site personnel/Compliance
  - CRO personnel
- Training

# Global Regulatory Approval Times

- USA – 30 days
- **India 45 – 90 days\***
- Russia and Ukraine 60 – 90 days
- South Africa 90 – 120 days
- China – up to 270 days
- Central/South America 60 – 360 days
- **Algeria???**

# Regulatory Models for Consideration

- **Australia**

- Gov provides approval within 2 weeks, procedural, always granted
- Approval done at site level; each site provides approval for their site



- **Lebanon**

- **Only EC approval required, obtained within one month**
- **Import licenses obtained separately/parallel filing**

- **US FDA**

- **30 days, EC approvals obtained separately**

- **India**

- 3 to 5 months
- EC approvals obtained in parallel, conditional until DCGI approves study

- **S. Africa**

- Parallel application to EC and MCC
- 5 months to approval
- Specific calendar for filing

# Ethical Committees

- In nascent environments, critical to set up good systems:
  - Ethic committees are key
    - Structure must be well established
  - Need to remain independent
  - Models vary:
    - ★ **Centralized**
      - Local
      - Commercial
    - ★ **Institutional**

# Type of Trials to Consider for Algeria

- Phase 1 clinical trials
  - Permitted by the actual regulatory requirements in Algeria
  - Not permitted in some NEEs such as India, Russia and Ukraine
- Interventional trials
  - All 17 trials conducted to date are observational trials
  - **No benefit to local population!**
- Therapeutics focus:
  - Oncology
  - Hematology
  - Cardiovascular
  - Metabolic disorders (diabetes etc)

# Selling Points for Algeria

As new comer in clinical research, Algeria **must** be “attractive to international sponsors”

- Faster Regulatory timelines which convert into fast start-up trials
- Ease of importation of new investigational product and export of samples outside of Algeria for analysis
- Center of Excellences: High quality clinical sites and investigators
- Quality: Education and training of all personnel involved is key
  - Medical personnel
  - Public education and awareness through publications in general press
- Fast patient Enrollment
  - Importance of databases
  - Referrals between doctors
- Costs remain competitive in international market place

# What Are The Benefits of Clinical Research?

- To the general population
  - Access to latest drugs, and/or at least access to standard of care provided in advanced countries
  - Better follow-up of medical conditions
  - Overall improvement of health
- To the medical community
  - Become member of global scientific community
  - Publish in peer review journals
  - Improve local standard of care
  - Inspire research and collaboration with international centers/pharma/biotechs and universities
  - Development of new generation of researchers

# R&D in General

- With development of clinical research activities, other CROs providing supporting activities flourish:
  - Central laboratories with national and international certifications
  - Sophisticated imaging centers
  - Independent imaging groups
  - Drug depots
  - Distributions of study supplies
  - Storage of biological samples
  - Couriers
  - Translators
- New SMOs
- New local Biotechs

# ARIANNE's plans - A multiple layered involvement

1. CRO Activities
  - I. Set key center of excellence throughout relationships with key hospitals in Algeria
  - II. Provide training, support and projects
2. Phase I –BA/BE Unit
  - I. Set up a state of the art facility for within a hospital or as a stand alone facility, for local pharma but also international companies
3. Manufacturing R&D
  - I. Development of formulation
  - II. Manufacturing of generics and new chemical entities for FDA registrations
4. Education programs
  - I. Provide training for clinical researchers
    - i. Investigators, sub-investigators, study coordinators
    - ii. CRAs, PMs etc