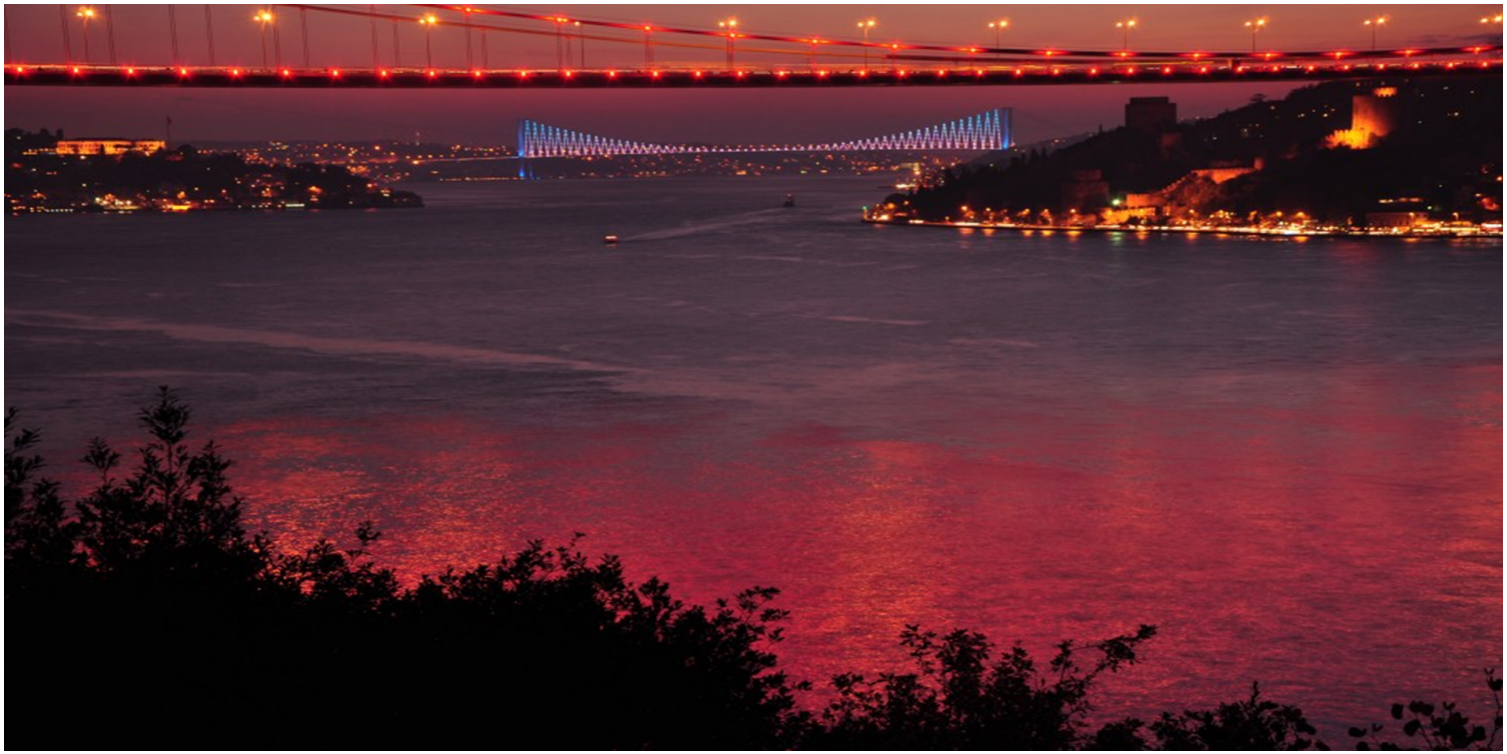

# CLINICAL RESEARCH IN TURKEY

Turkish Medicines and Medical Devices Agency
Director of Clinical Trials Department

HİLAL İLBARS,Pharm.,PhD.

# Potential of Turkey

# Bridge to Europe from Asia and Middle East



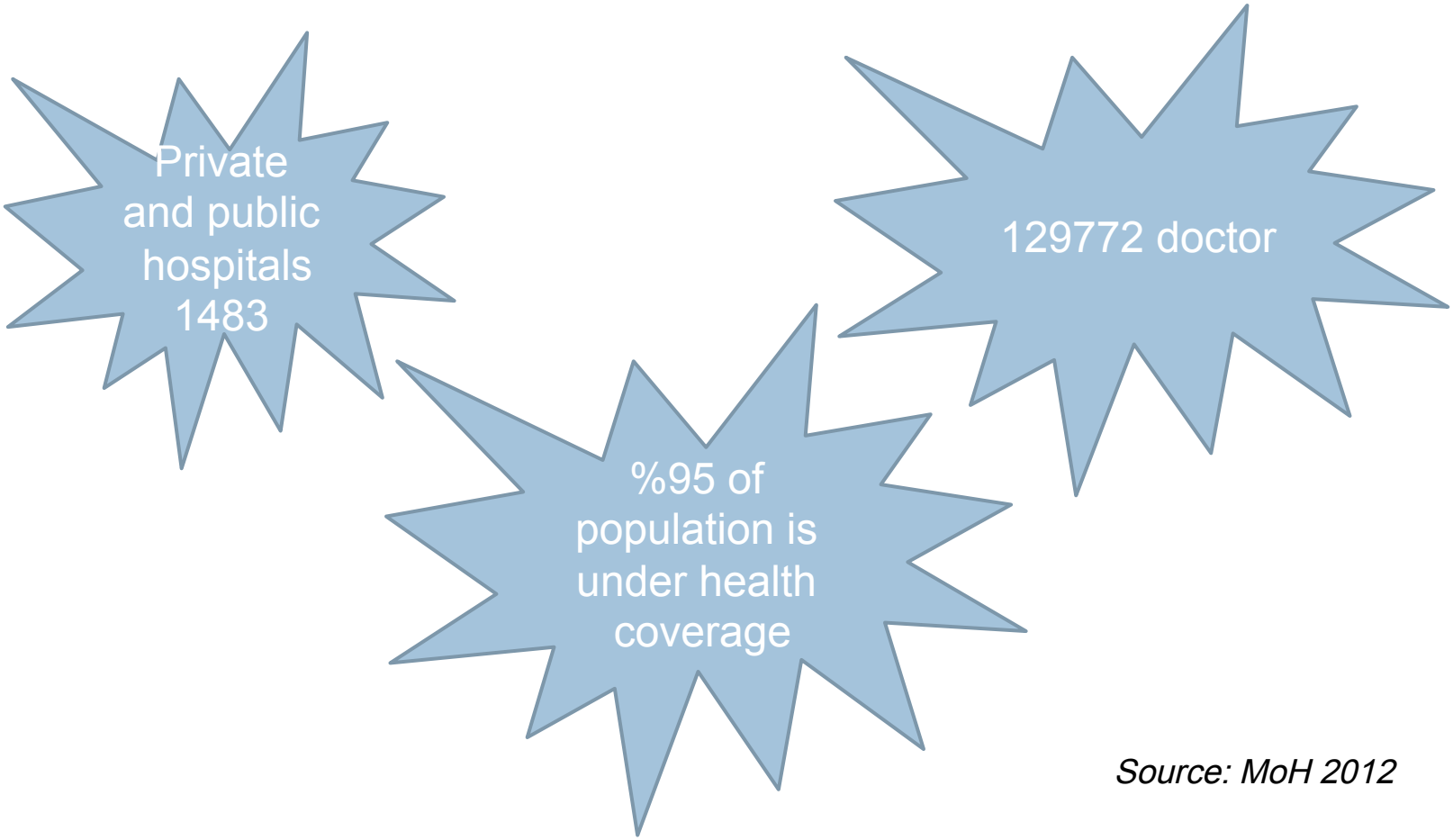
Turkey has been a developing and emerging country for almost all industries, especially for pharmaceuticals.

# Population
## 76.667.864
## with a annual growth rate of population % 13,7


% 24.6 under 14 years old,
% 67.7 is in the middle of 15 and 64 years,
only % 7.7 over 65 year,
with a median age of 30 years.

*Source: TÜİK, 2013*

# Potentials




*Source: MoH 2012*

# Attractiveness of Turkey in Clinical Research

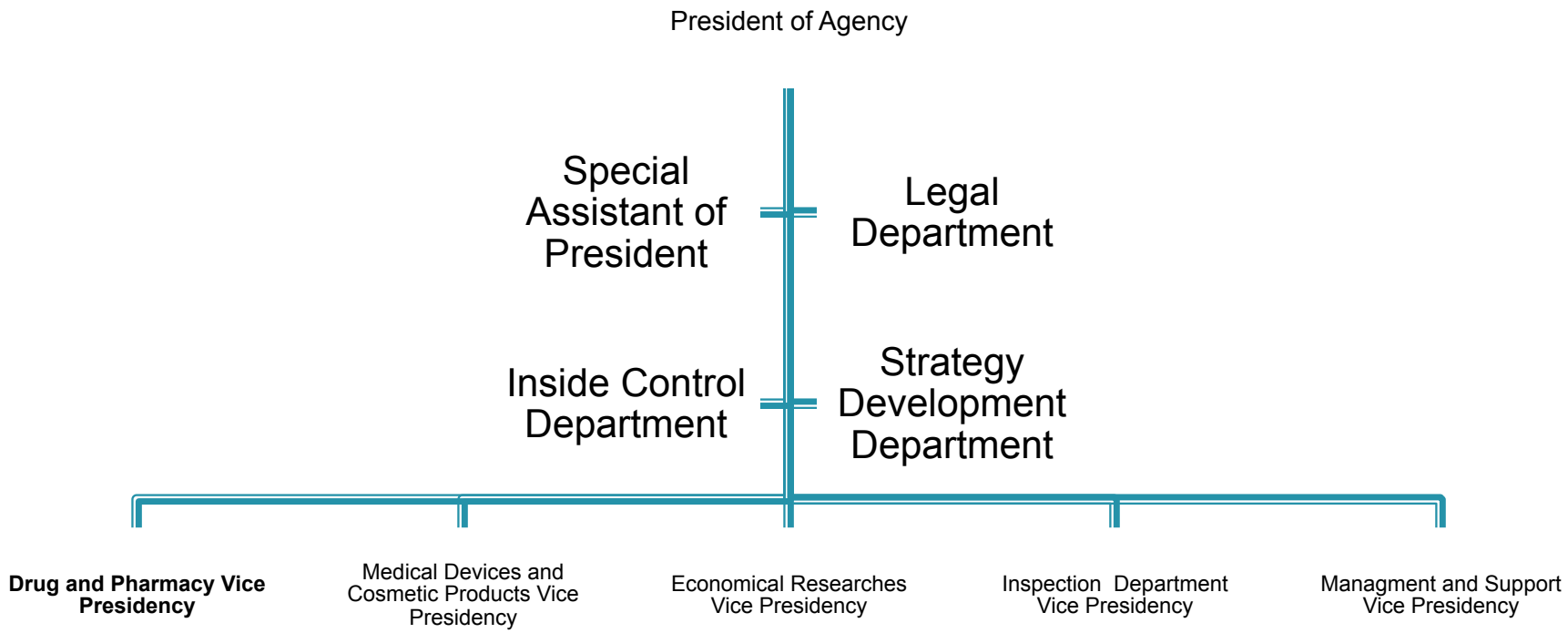
- Patient population
  - sufficient
  - naive patients
- Investigators
  - high number
  - trained on GCP
  - experienced in multi center trials (national/international)
- Research sites
  - qualified data
  - international reputation
  - technical infrastructure
- Ethics Committees
- Legislation is present for a long time

# Parties in Clinical Research

- Health Authority
- ECs
- Sponsors
- Investigators
- Universities
- Hospitals
- Foundations
- Associations
- CROs

# Competent  Authority in Turkey

# Turkish Medicines And Medical Devices Agency



# Clinical Trials Department

# Regulations in Turkey

# History of Regulations

- **1928** *In 1219 numbered act on **Medicine and Practicing of Medical Profession**, article 70th states that clinical trials can not be conducted without consent, and if clinical trials on children and persons under legal disability are planned obtaining consent of legal guardian is obligatory.*
- **1982** *In **Turkish Constitution** of 1982, in second part on fundamental rights and duties, article 17 of chapter 1 "Personal Inviolability, Material and Spiritual Entity of the individual" clearly states that clinical trials can not be conducted without consent of the subject.*
- *Article 10 and 11 of **Medical Deontology Regulation** highlights, that it should be declared that the performed procedure is a research and should be previously tested on experiment animals.*
- **1993** ***Clinical Drug Trials Regulation***
- **2004/2005** *Experiment on human titled 90th article of 5237 numbered **Turkish Penal Code**, in order to rule out penal responsibility of a consent-based scientific experiment on a human being.*


# Current Regulations

- Health Services Principal Act

  *1987 / 2011 / 2014*

- Turkish Penal Law

  *2004 / 2005*

- Regulation on Clinical Trials

  *2013 parallel to EC Directives*

- Guidelines

# Regulation on Clinical Trials

- Drug
- Non-Drug
  - New surgical methods; organ, tissue and stem cell transplantation clinical trials
- BA/BE
- Trial Site
- Investigator
- Sponsor

# Ethics Committees

- Structure of Ethics Committees
  - Clinical Trials - 93
  - BA/BE -2
- 7-15 member
- Sign the confidentiality document
- Duties and powers
  - Scientific and ethical viewpoint opinion
- 15 day- 7 day
- Standard

# Ethics Committees Members

- Specialist physicians
- Pharmacologist
- If applicable, medical ethics specialist or deontologist
- A biostatistician or public health expert
- A jurist
- Lay-member
- An engineer working in the biomedical field or biophysicist or physiologist

- BA/BE  EC members..

# Regulations for Medical Devices

- Parallel to
  - COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
  - COUNCIL DIRECTIVE 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
  - DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

# Guidelines

www.titck.gov.tr

# Guidelines

- Guideline for Good Clinical Practices
- Guideline Regarding Application Format and Documentation to be Submitted EC and MoH
- Guideline for Advanced Therapy Treatment
- Guideline for Studies on Pediatric Populations
- Guidance on the Collection, Verification and Presentation of Adverse Reaction Reports Occuring During Clinical Trials
- Guideline for GMP for IMP
- Guideline for Insurance of Volunteers
- Guideline for Inspections
- Guideline for Data Monitoring Commitees
- Guideline on Observational Studies Conducted with Drugs
- Guideline on Compassionate Use Programs
- Guideline on Archiving
- Guideline on Storage for IMPs
- SOP for Ethics Committee

# Application and Permit for the Trial

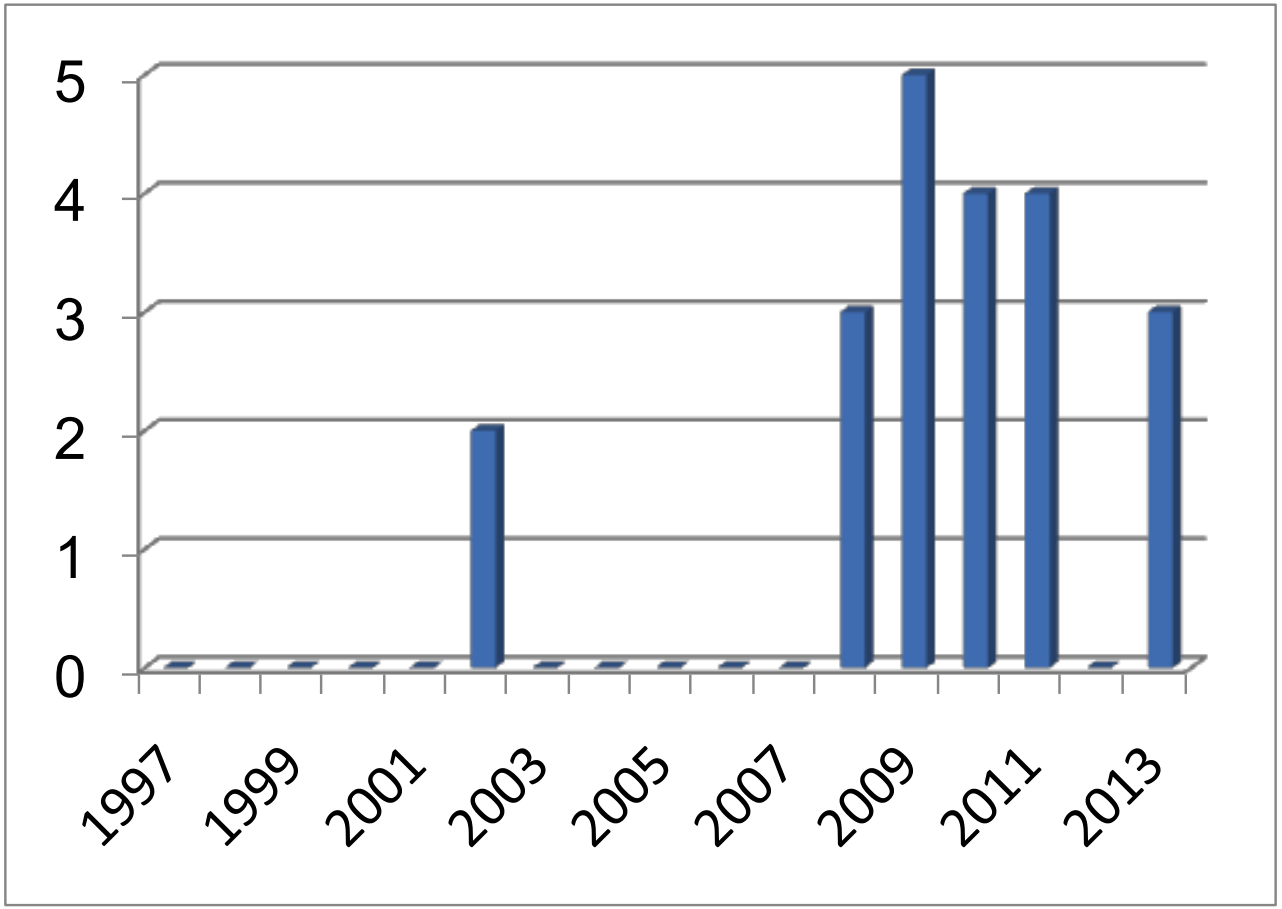
- Standard (Application forms)
- Sponsor (Submission)
- Parallel Submission
  - Ethics Committees
  - Turkish Medicines and Medical Devices Agency
- Application Forms
- Other Forms
- Submission Letters

# Audit/Inspection Experience

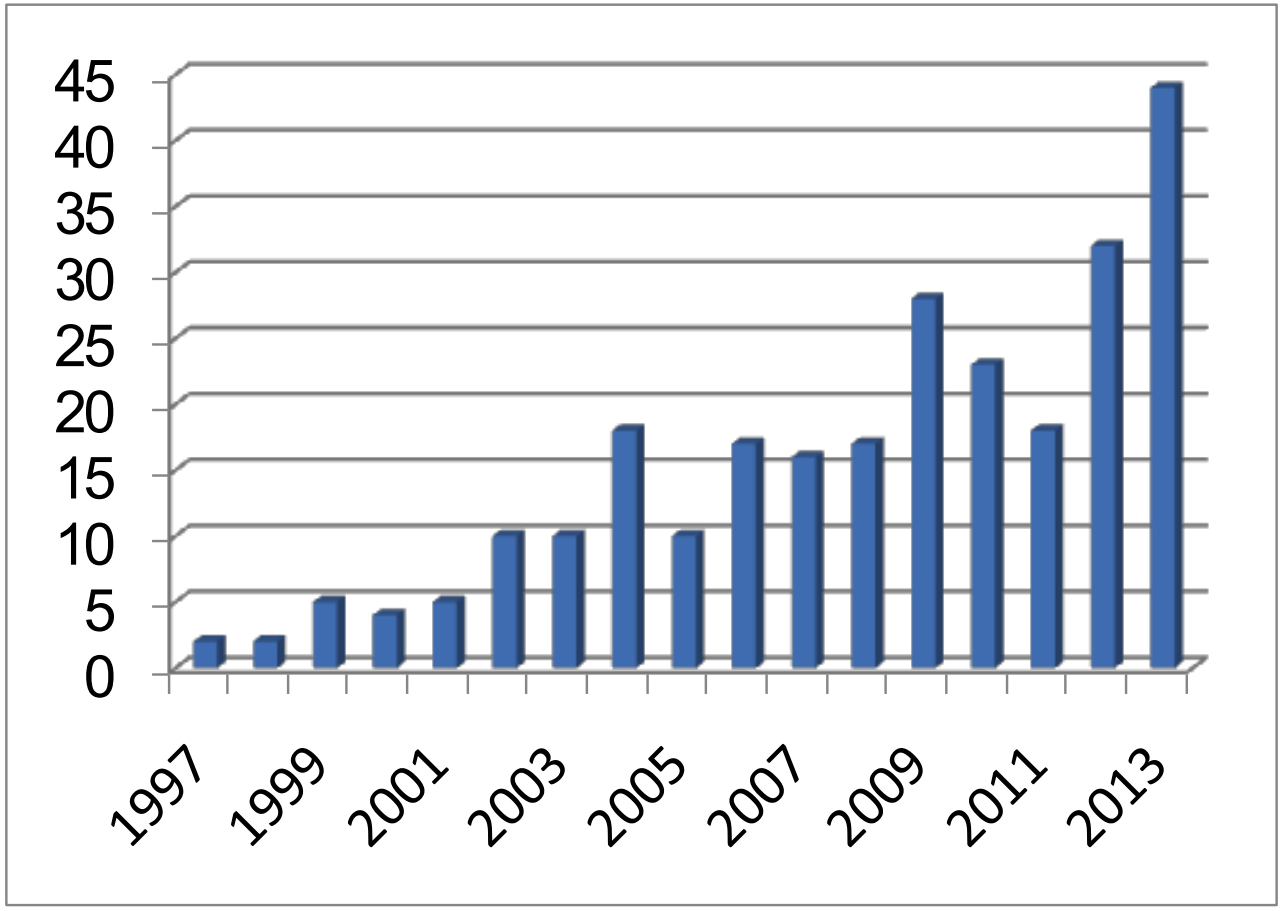
- FDA inspections / 9
- EMA inspection / 3
- Bfarm inspection for BE
- Ages inspection for BE
- Many sponsor audits
- Internal inspections; CROs, sponsors, investigators, sites.

# Statistics

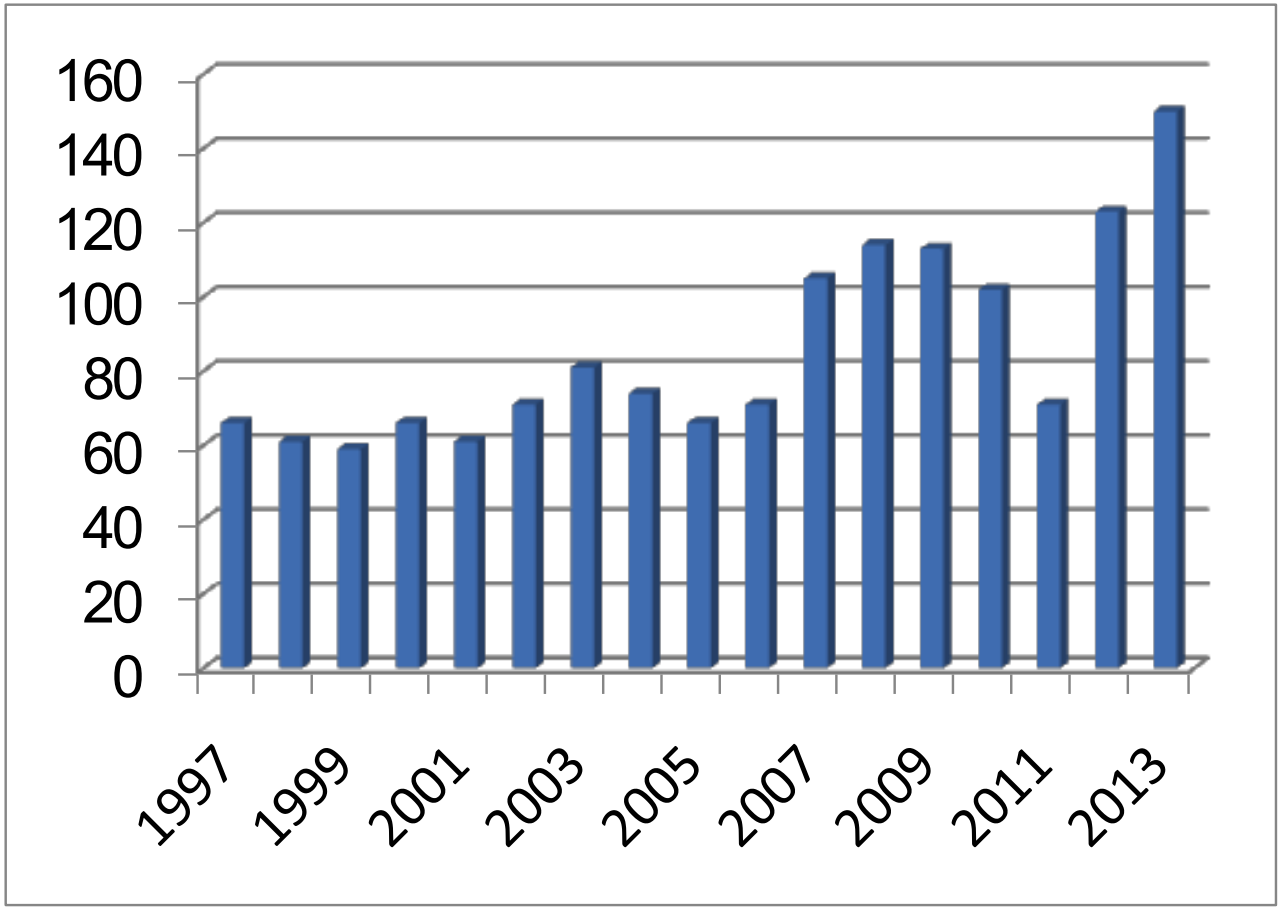
# Phase I



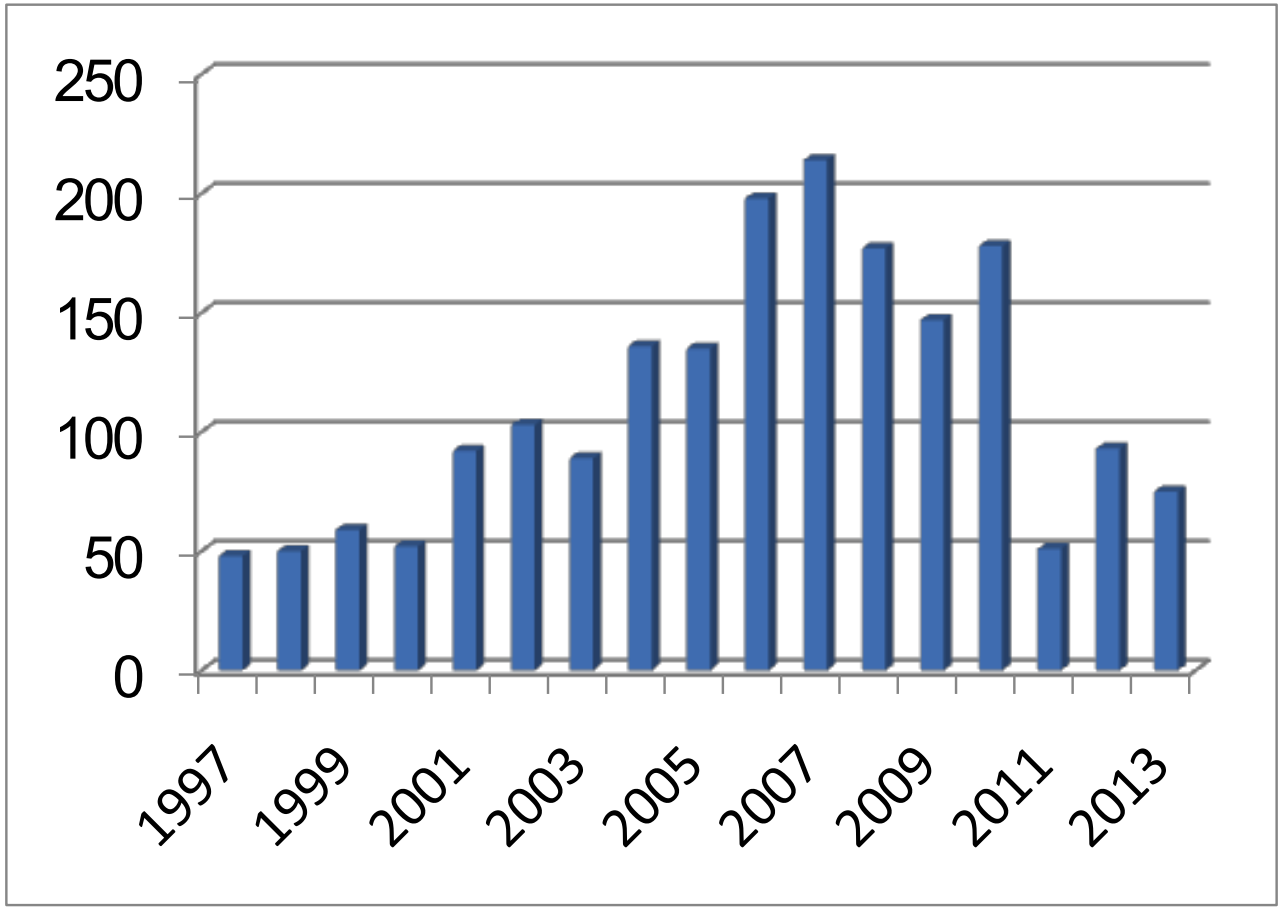
# Phase II


45
40
35
30
25
20
15
10
5
0
1997
1999
2001
2003
2005
2007
2009
2011
2013

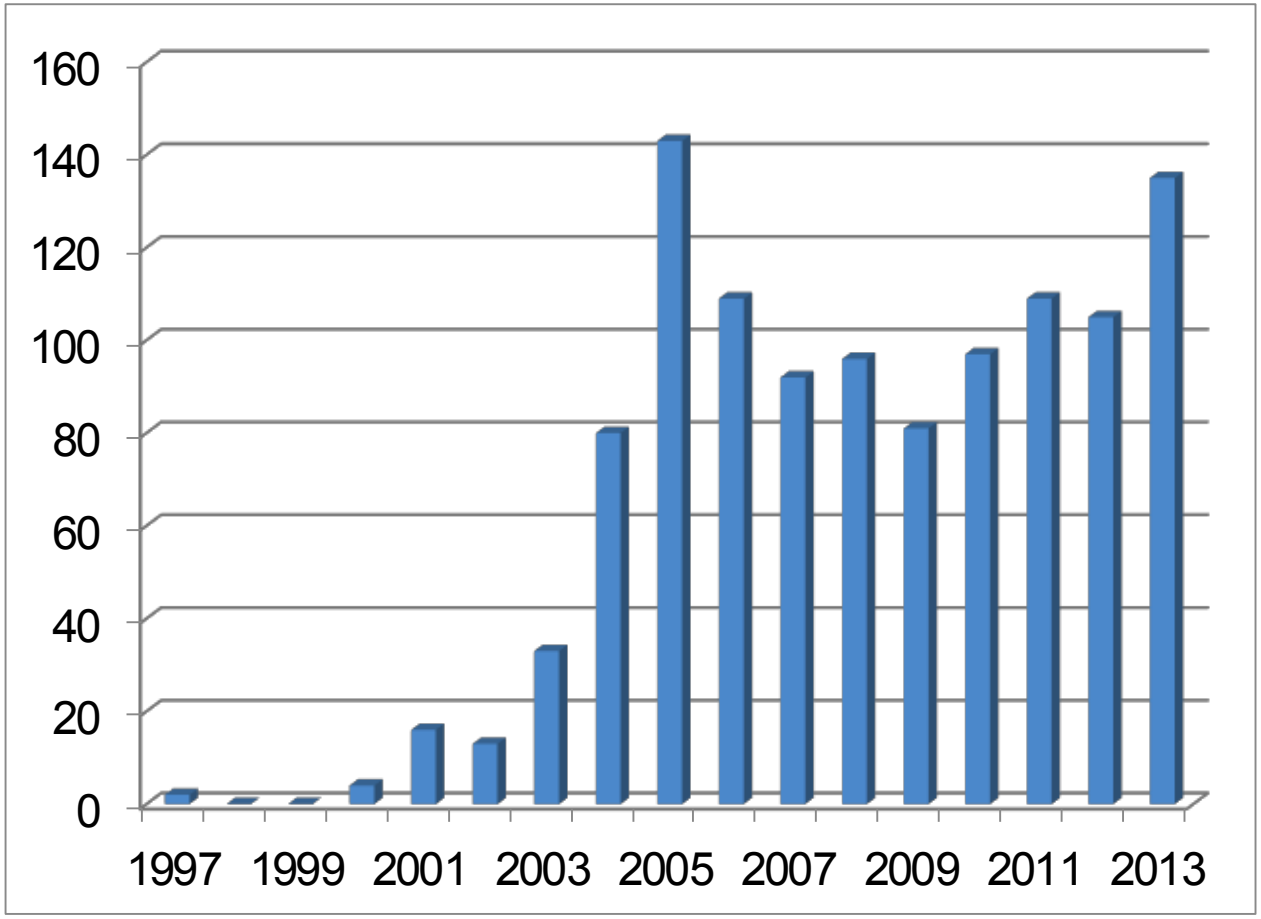
# Phase III


160
140
120
100
80
60
40
20
0
1997
1999
2001
2003
2005
2007
2009
2011
2013

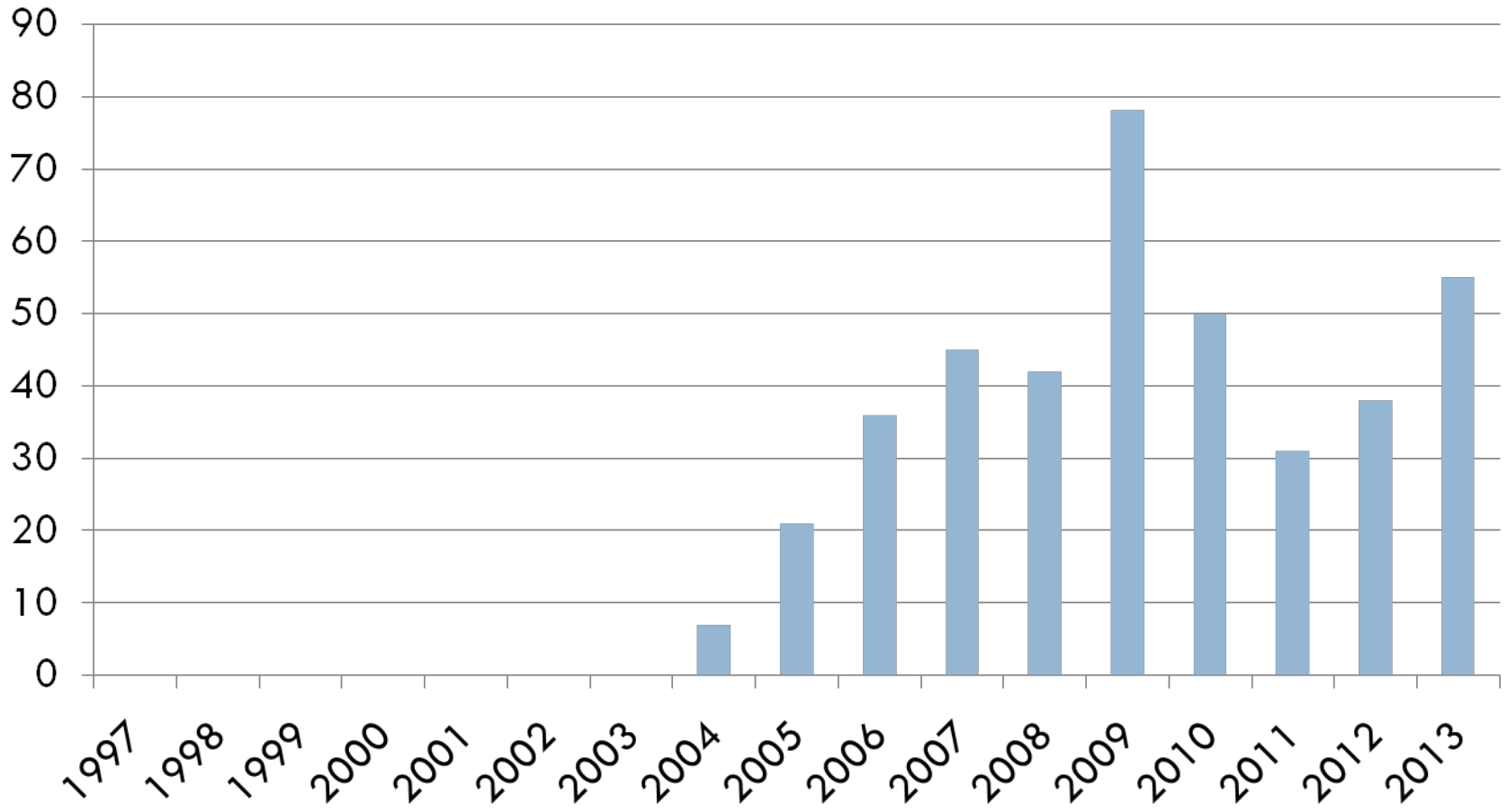
# Phase IV


250
200
150
100
50
0
1997
1999
2001
2003
2005
2007
2009
2011
2013

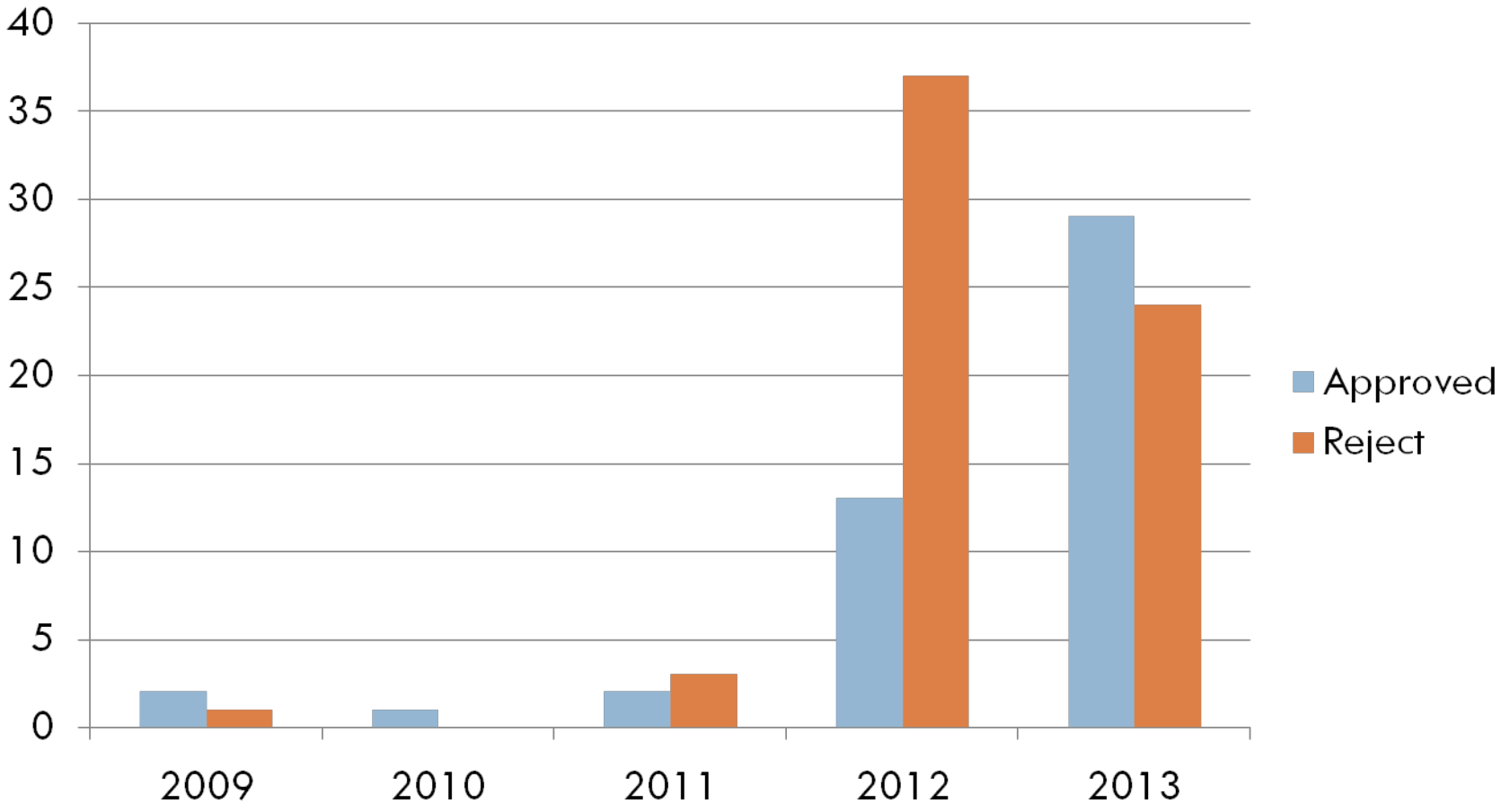
# BA/BE


160
140
120
100
80
60
40
20
0
1997
1999
2001
2003
2005
2007
2009
2011
2013

# PMS


90
80
70
60
50
40
30
20
10
0
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013

# Medical Device



# VISIONS AND NEEDS

# Country Potential

- Legislations are parallel to global requirements
- High number of patients and naive patient population
- High number of qualified and experienced investigators
- Internationally reputable research centers delivering qualified data

# What would it take to increase clinical trials in Turkey? –Short term actions

- A stable regulatory environment
- Shorten start up timelines
- Collaboration with university hospitals and other hospitals to create solutions for
  - payment issues
  - infrastructure
  - increase the interest of the investigators and hospitals for CTs
- Training programs to increase the interest and quality in clinical trials

# Center of Excellence in Clinical Trials in the future TURKEY

- Stable regulatory environment
- High quality data with high profile investigators and sites
- Being always a ‘reliable country’ for Global partners

# What would it take to increase clinical trials in Turkey? –Long term actions

- Continue collaboration with all related parties to shape the clinical trial environment
  - Ministry of Health
  - To change the mind set of ‘Hospital Managements’ to increase awareness, knowledge level and interest for CTs

- Continuous training programs to maintain the interest and quality in clinical trials.

- PR activities (eg: via Research Based Pharmaceutical Companies Associations) to increase the awareness and encouragement on clinical trials in patients, media and investigators.

# Goals

- Ensure grater accuracy and reliability of the data collected
- Training programs
- Speed up approval procedures
- Motivate investigators
- Increase the quality of research centers
- Patient recruitment procedures
- Track the whole procedure precisely
- Build up a national clinical research data base

# Turkey: Vision 2023 strategy

- Turkish government aims to make Turkey one of the world's top 10 economies in health services by 2023
  - by increasing R&D expenditures
- One on the main targets of the plan is development of basic and clinical research competencies

hilal.ilbars@titck.gov.tr

# Thank You