

# Ömer Özkan

TÜBİTAK BİLGEM Software Technologies Research Institute, Turkey



# Medical Device Track and Trace System in Turkey Cooperated by

Turkish Medicines and Medical Devices Agency and The Scientific and Technological Research Council of Turkey

Ömer Özkan, Institute deputy manager, TÜBİTAK BİLGEM Software Technologies Research Institute, Turkey

26 October 2016

# **Presentation Topics**



- Overview
  - Project Purpose
  - Achievements
  - Scope
- Dissemination Activities



# **Presentation Topics**



- Overview
  - Project Purpose
  - Achievements
  - Scope
- Dissemination Activities



## Project Purpose



- To keep record of medical devices and cosmetic products
- To establish a National and Original infrastructure which meets performance requirements to keep track of products
- To contribute to ensuring patient safety and protection of public health
- To provide an infrastructure to ensure healthy and efficient execution of inspection services
- To ensure rapid measures are taken against possible risks to occur during use of the products

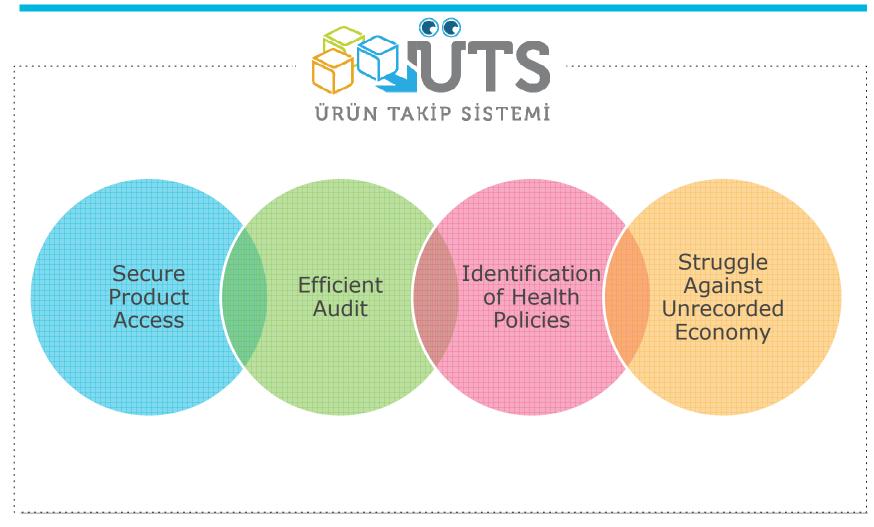


provides an infrastructure to track medical devices and cosmetic products manufactured in our country or imported from the production band to the place where they are sold and used.



## **Achievements**







# Scope



#### **Tracking and Monitoring**

Product Movements Module
Product Withdrawal Module



#### Citizen Oriented Services

Product Inquiry Module Registered-On-Person Product Inquiry Module Complaint Reporting Module





#### **Product Management**

Product Tree Management Module Product Management Module



Document and Certificate
Management Module
Reference Areas Management
Log Management Module
Announcement Module
Scheduled Tasks Module



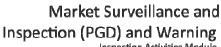
25 Modules

(8 Module Groups)



## User, Organization and Authority Management

User Management Module Organization Management Module Authority Management Module



Inspection Activities Module
Warning Module





#### Clinical Engineering

Mainterance and Repair Management Module Calibration Management Module Technical Personnel Certification Module Technical Service Management Module Calibration Organization Management Module

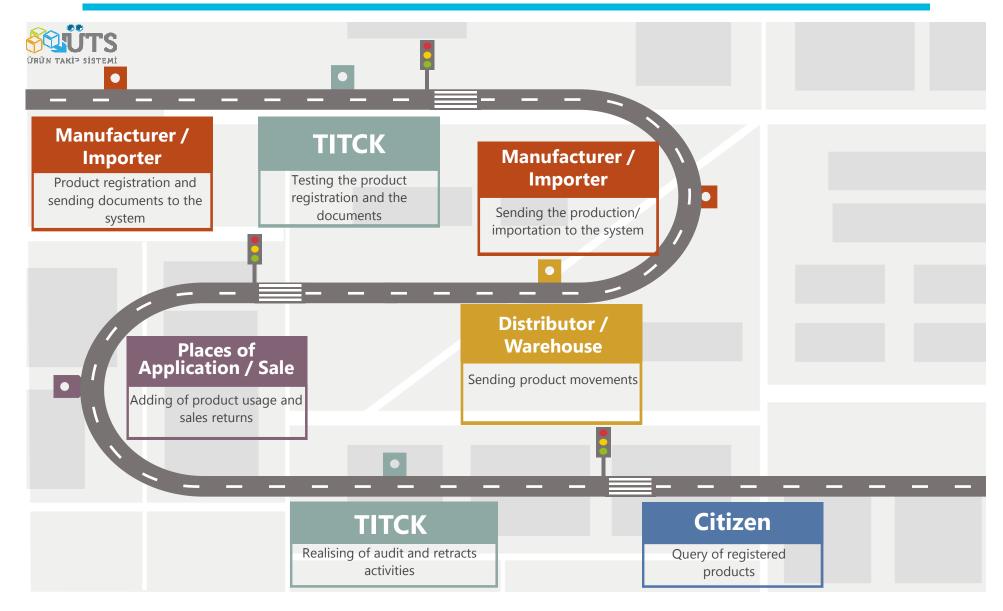


Precefined Reporting Module
Map Assisted Reporting Module



# Product Tracking System (ÜTS) Overview



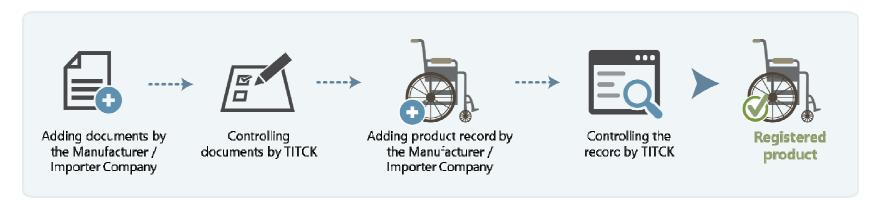


# **Product Management**



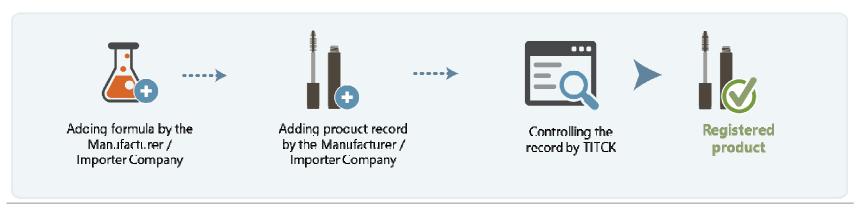


#### **Medical Device**





#### Cosmetic





# Single and Lot Based Tracking

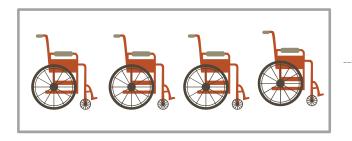




## **Single Tracking**







## **Lot Based Tracking**



**Single Product Group** 

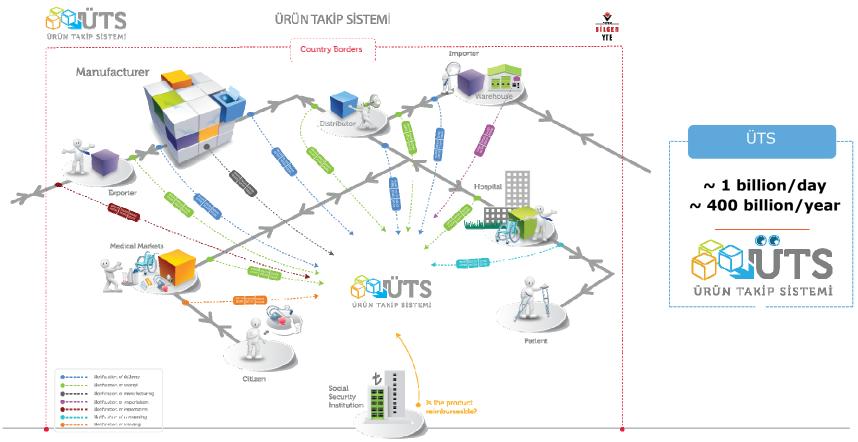


# Single Product Traceability



- 7/24 end-to-end single product tracking and monitoring
- Varying routes in product movements

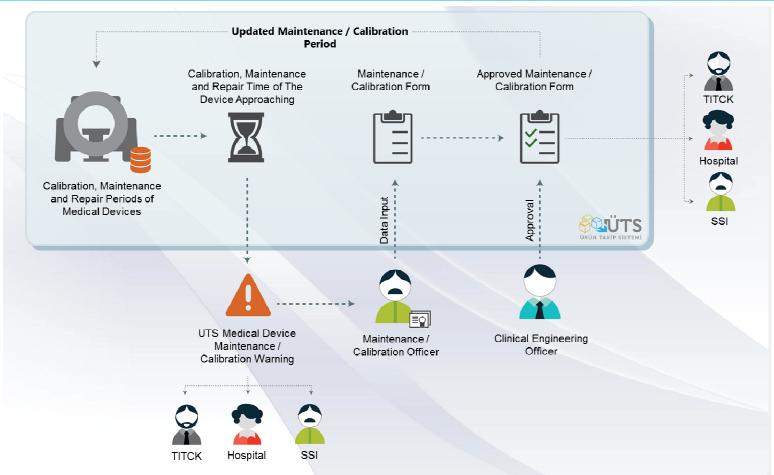
- Different movement types and codes of conduct
- Partner system diversity and number





# Clinical Engineering Processes



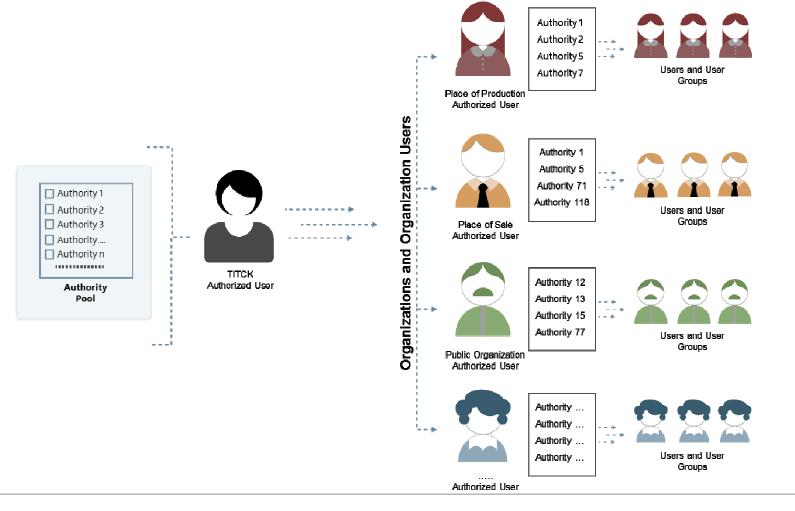


•Scenarios will be developed according to the Clinical Engineering Legislation to be issued.



# Organization, User and (Dynamic) Authority Management







# **Business Intelligence**



#### **SECTOR**

To access comprehensive information on single products

#### T.R. MINISTRY OF HEALTH

To contribute to determination of efficient health policies



#### **CITIZEN**

To access information on safe products

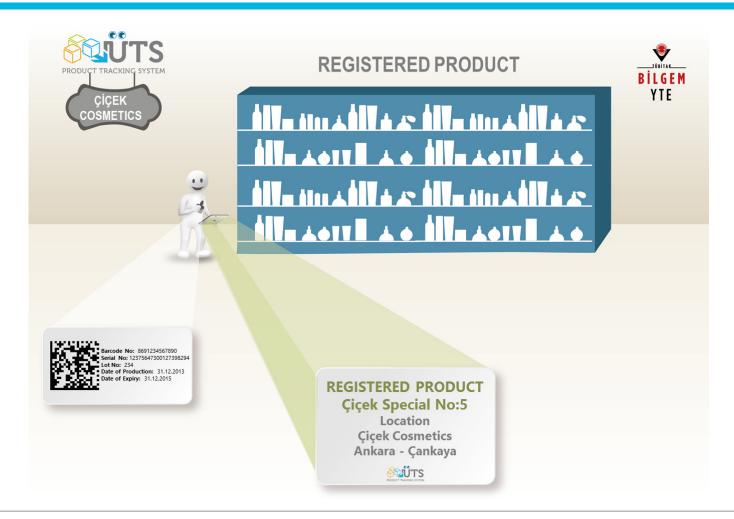
#### **INSPECTION TEAMS**

To actively contribute to risk based inspection and withdrawal



## Citizen Oriented Services

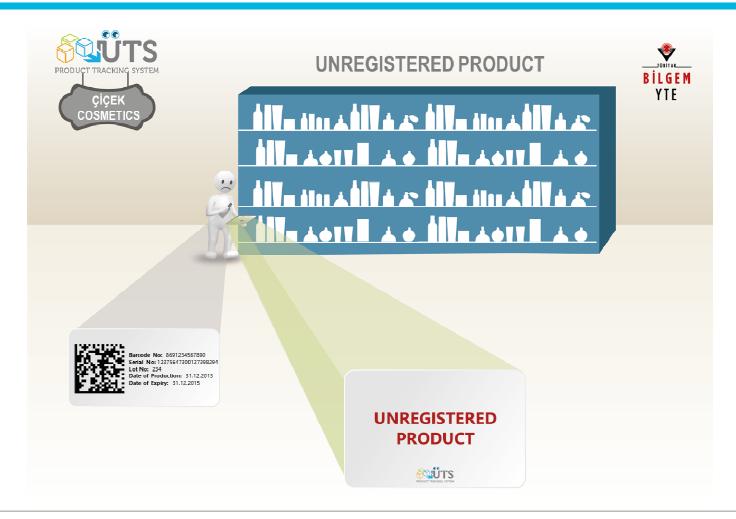






## Citizen Oriented Services

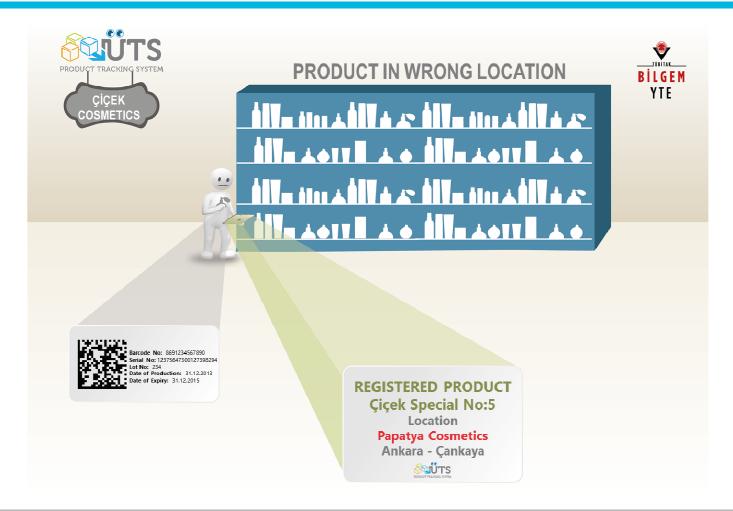






## Citizen Oriented Services







## **ÜTS Users**



#### **PRODUCT MANAGEMENT**

- Manufacturer and Importer Companies
  - Medical Device Manufacturers / Importers
  - Cosmetic Manufacturers / Importers
- Public Organizations
  - · Turkish Drug and Medical Device Institution (TİTCK)
  - Social Security Institution (SGK)
  - National Poison Information Center (UZEM)

#### **CLINICAL ENGINEERING**

- Maintenance and Calibration Companies
- Public Organizations
  - Turkish Drug and Medical Device Institution (TİTCK)
  - · Social Security Institution (SGK)
  - Turkish Public Hospitals Authority (TKHK)
  - Turkish Public Health Authority (THSK)
  - Turkish Atomic Energy Authority (TAEK)

#### **PRODUCT MOVEMENTS**

- Manufacturer and Importer Companies
- · Distributors / Warehouses
- · Places of Use
- · Places of Sale
- Public Organizations
  - Turkish Drug and Medical Device Institution (TİTCK)
  - Social Security Institution (SGK)
  - Turkish Public Hospitals Authority (TKHK)
  - Turkish Public Health Authority (THSK)

#### MARKET SURVEILLANCE AND INSPECTION

- Public Organizations
  - Turkish Drug and Medical Device Institution (TİTCK)
  - Social Security Institution (SGK)
  - T.R. Ministry of Economy
  - T.R. Ministry of Customs and Trade



# **Integrations**

**Medical Devices** 



### **15** System Integration

VIUTS	MERSIS  Central  Registration  System	ESBIS Tradesmen and Craftsmen Information System	MERNIS  Central  Population  Administrati  on System	<b>ÇKYS</b> Core Resource  Management System	MKYS Material Resource Management System	HBYS e Hospital Information Management System	<b>e-Nabız</b> e-Pulse Portal
<b>*</b>	EUDAMED The European Databank on Medical Devices	National PGD Database Market Surveillance and Inspection	<b>GMDN</b> Global Medical Device Nomenclature	<b>VEDOP</b> Tax Administration Automation Project	<b>e-Devlet</b> e-Government Gate	TITCK EBYS  Electronic Information  Management System	



and Inspection



# **Presentation Topics**

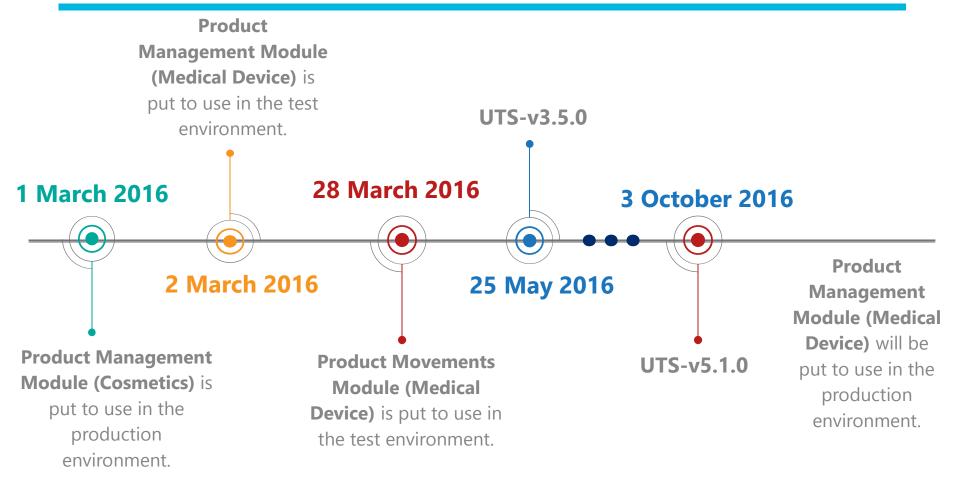


- Overview
  - Project Purpose
  - Achievements
  - Scope
- Dissemination Activities



## **ÜTS** Timeline







## **ÜTS Portal**



 Information about the new versions, training materials, news on workshops conducted and up to date information about the project are published in the portal.

# http://uts.saglik.gov.tr/





## **Contact Information**



## Ahmet DİKİCİ, Ph.D.

Chief Researcher and Project Manager





### **THANK YOU**











Çukurambar Mah. 1478. Cadde No:22 06100 Çankaya / ANKARA +90 (312) 289 9 222 yte.bilgem@tubitak.gov.tr http://yte.bilgem.tubitak.gov.tr/

