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Saudi Food & Drug Authority

Saudi Food and Drug Authority track and trace: why, when, and how

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Track and Trace Project

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Drug Sector

Agenda

- Why

- What

- How

- When

Current Challenges

Counterfeit

Drug 's market flow

Track and Trace

Drug availability

Patient safety

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Counterfeit

Track

Patient safety

Year	Number of Samples	Number of Pharmacies	Number of Cites	Manpower	Project Budget	Time Limit	Counterfeit Percentage
2010	1654	140	61	13	202000 SR	45days	0.36%
2011	3680	1155	61	25	700000 SR	60days	0.23%
2012	6000	1400	61	30	700000 SR	90days	0.20%

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Current problem

3-6 days

Counterfeit

Inquiry from public or hospital to SDFA

Inquiry from SFDA to agent

Inquiry from agent to pharmacies

Track and Trace

Drug 's market flow

Drug availability

Patient safety

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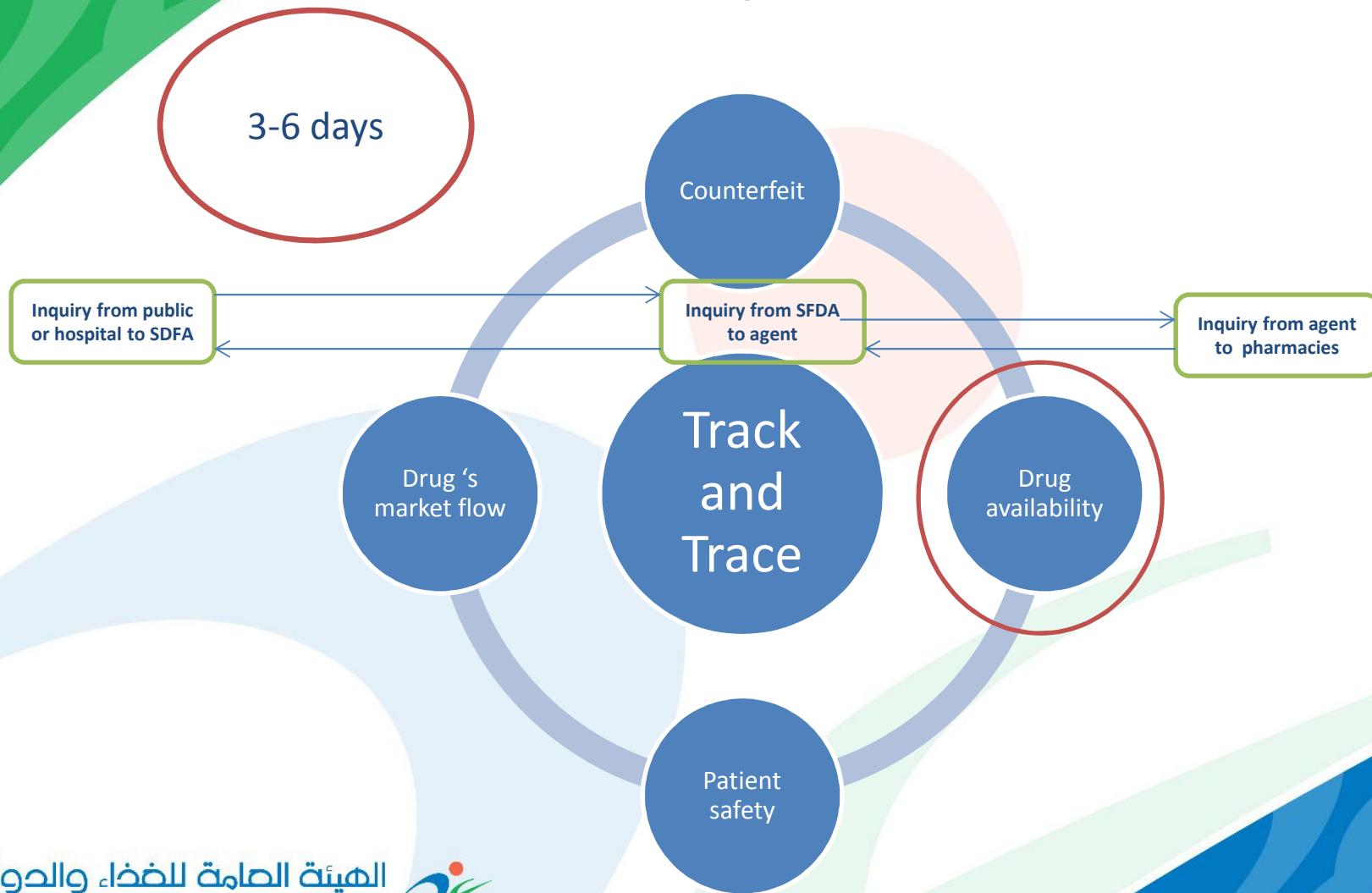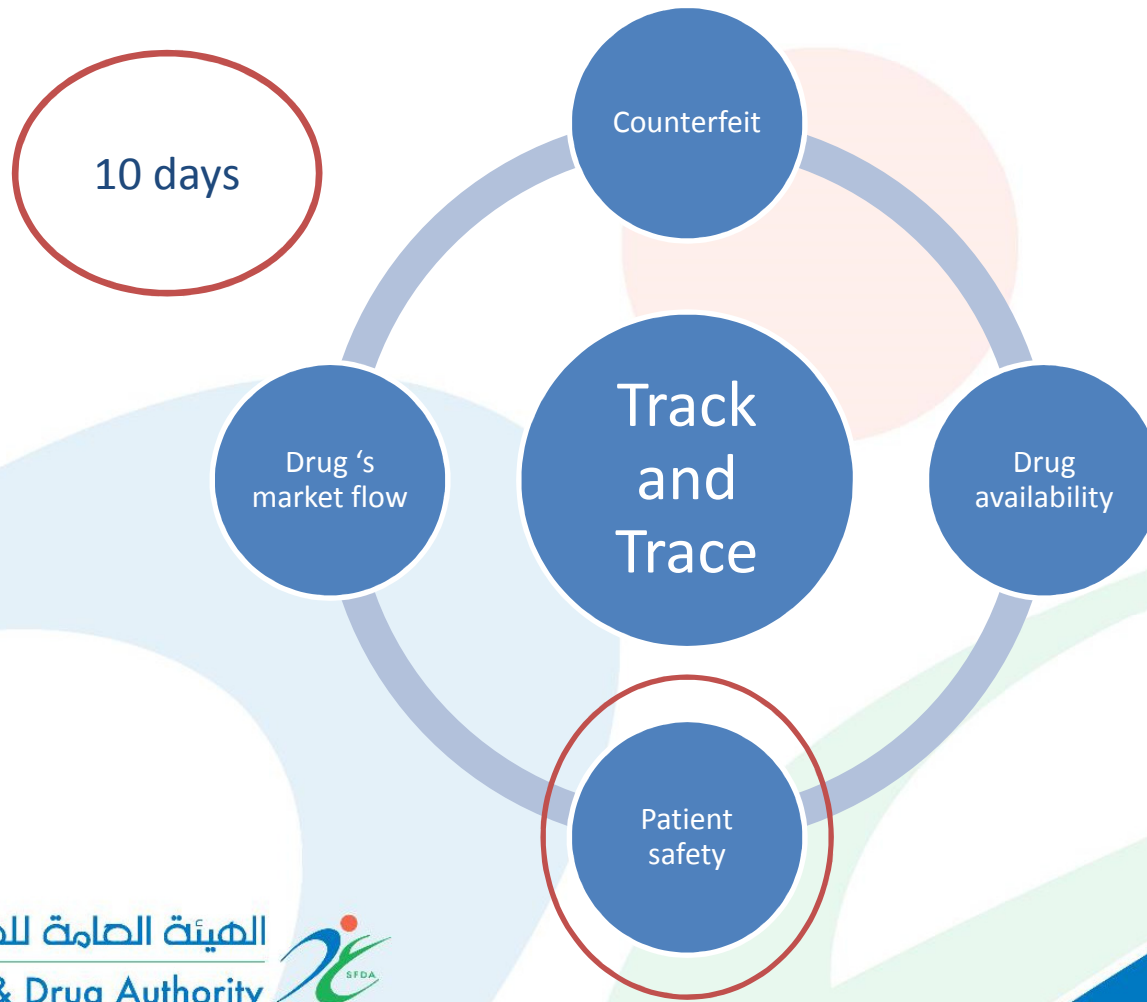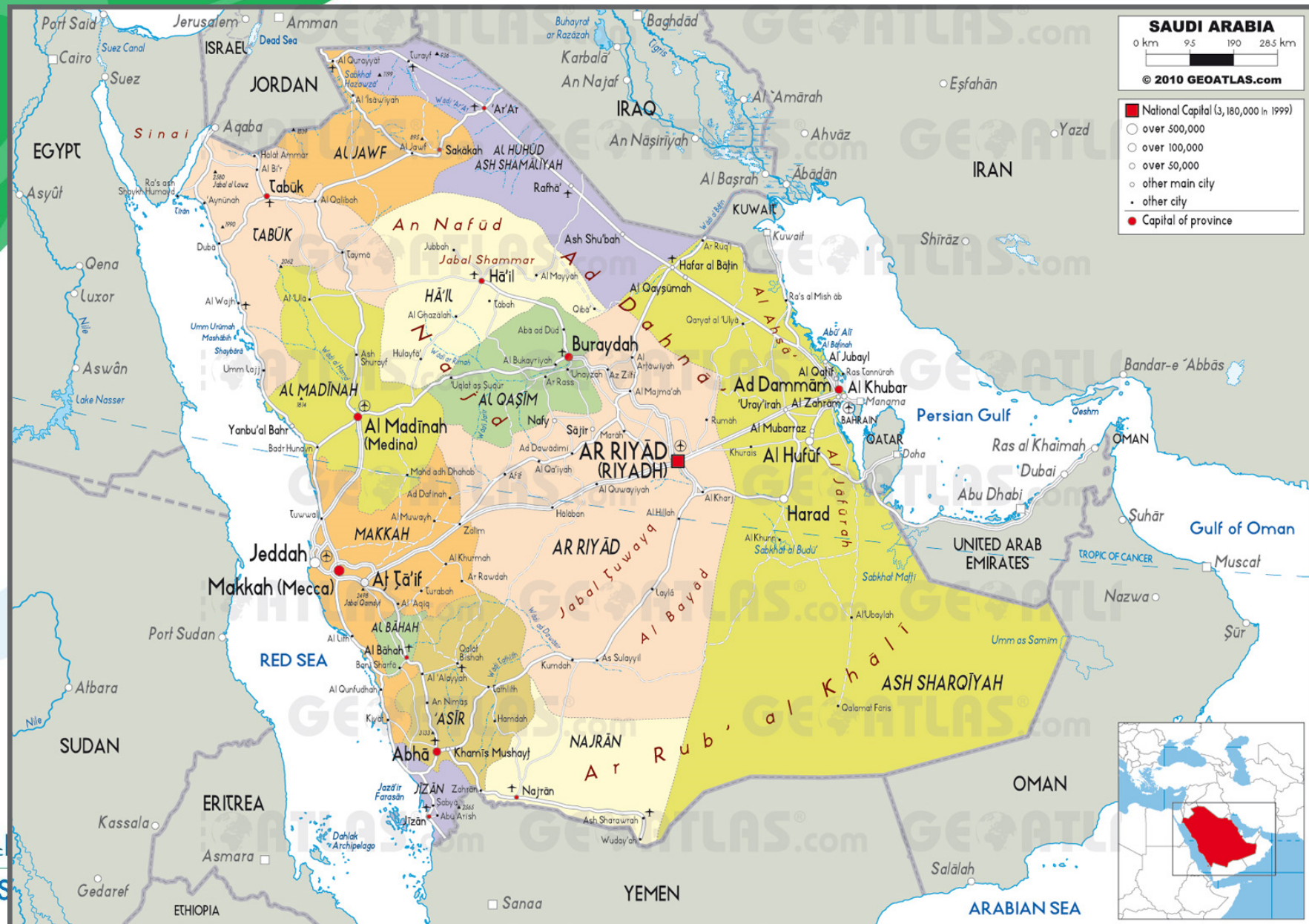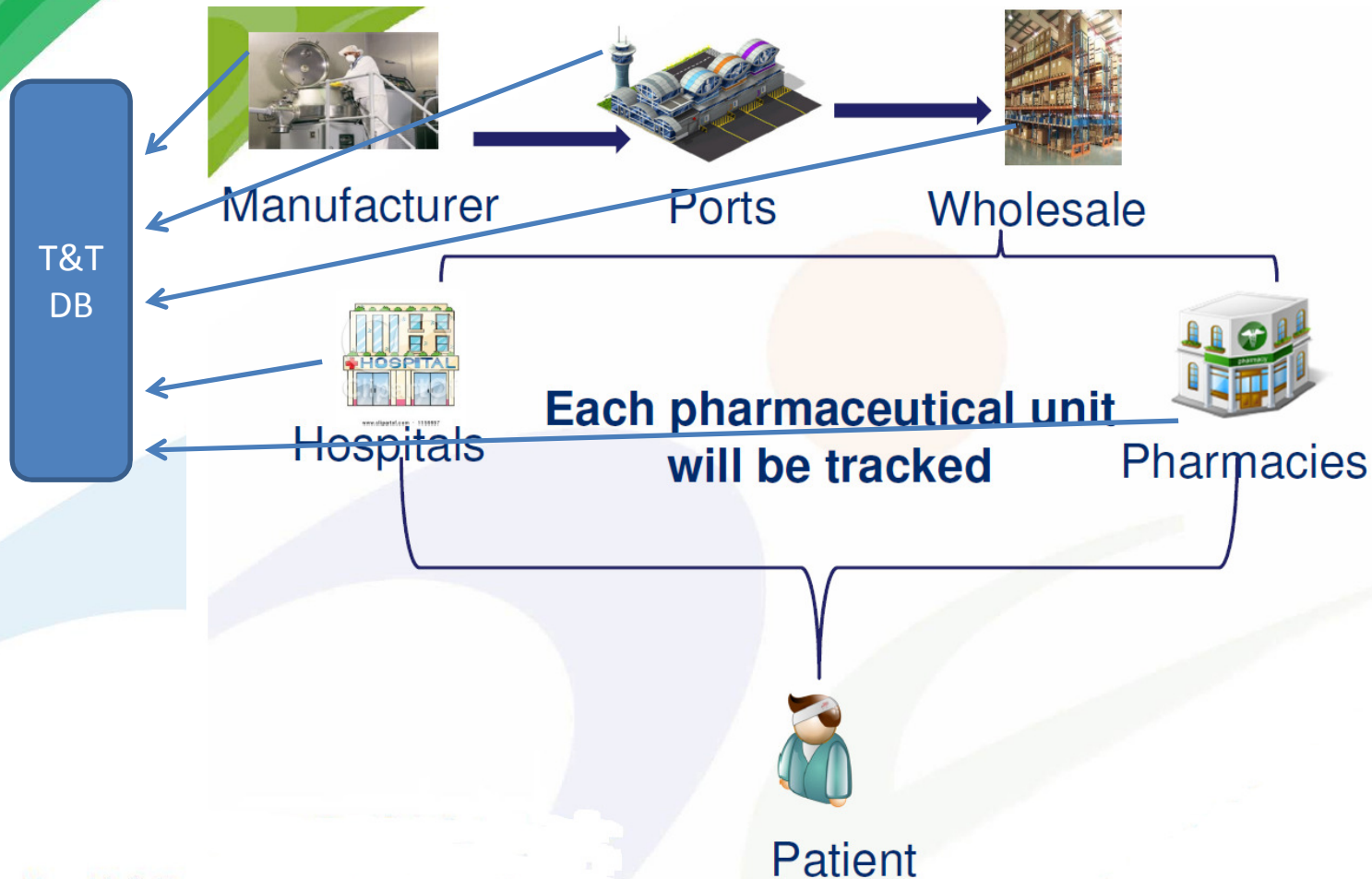
Current problem

Definition

- Track and trace all units belonging to each pharmaceutical product marketing in Saudi Arabia.

How dose the system work

T&T DB

Manufacturer → Ports → Wholesale

Hospitals

Each pharmaceutical unit will be tracked

Pharmacies

Patient

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❖ 2 D data matrix and GS1 standards

❖ Circular(s)

❖ Guidelines

❖ workshop

Implementation Plan

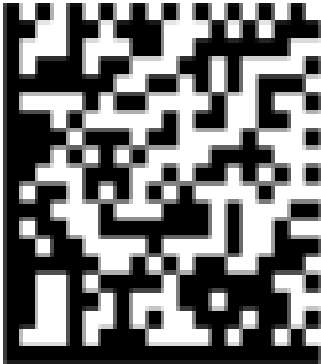27/4/2013   21/3/2017

Track and Trace project time frame

Start27/4/2013   End:21/3/2015   Start:21/3/2015   End: 12/3/2017

GTIN: 62800000000000   GTIN: 62800000000000

EXPIRY: YYMMDD   EXPIRY: YYMMDD

BATCH/LOT: ABCD1234   BATCH/LOT: ABCD1234

                                             SN : A21003652CF114

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Products included

- All Human drugs that are finally packaged and ready to be marketing are required to have 2 D barcode

- For inquiries please visit
  www.sfda.gov.sa
(Drug section / 2 D barcode data matrix guidelines)

Email: informatics.drug@sfda.gov.sa

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THANK YOU

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