Reflections on Post Market Surveillance Harmonization Activities
Focus on UDI

AHC- AHWP- Seoul- Nov 2014

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Your expectations for my presentation today ?

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Isn't your biggest fear that a product problem can create a "serious public health threat" ?

P. Auclair 2014

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Key Facts-changing environment

Changes in the world economy:

- slower growth in US, EU, Japan and robust growth in developing countries, sustained and rapid growth in Asia with continuing high growth potential

- Rapid development of new technologies

- Patients / medical community awareness and demand increasing

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Key Facts (con't)—why UDI?

- Increasing regulatory pressures on government and industry – scarcity of resources, both human and financial

- Desire to ensure safety and performance of products brought to the markets

- Pressure for better control and traceability of product in the distribution chain.

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Regulatory Harmonization Initiatives in the Region

- Asia Harmonization Working Party (AHWP)

- Asia Pacific Economic Cooperation (APEC)

- Association of South East Asia Nations (ASEAN)

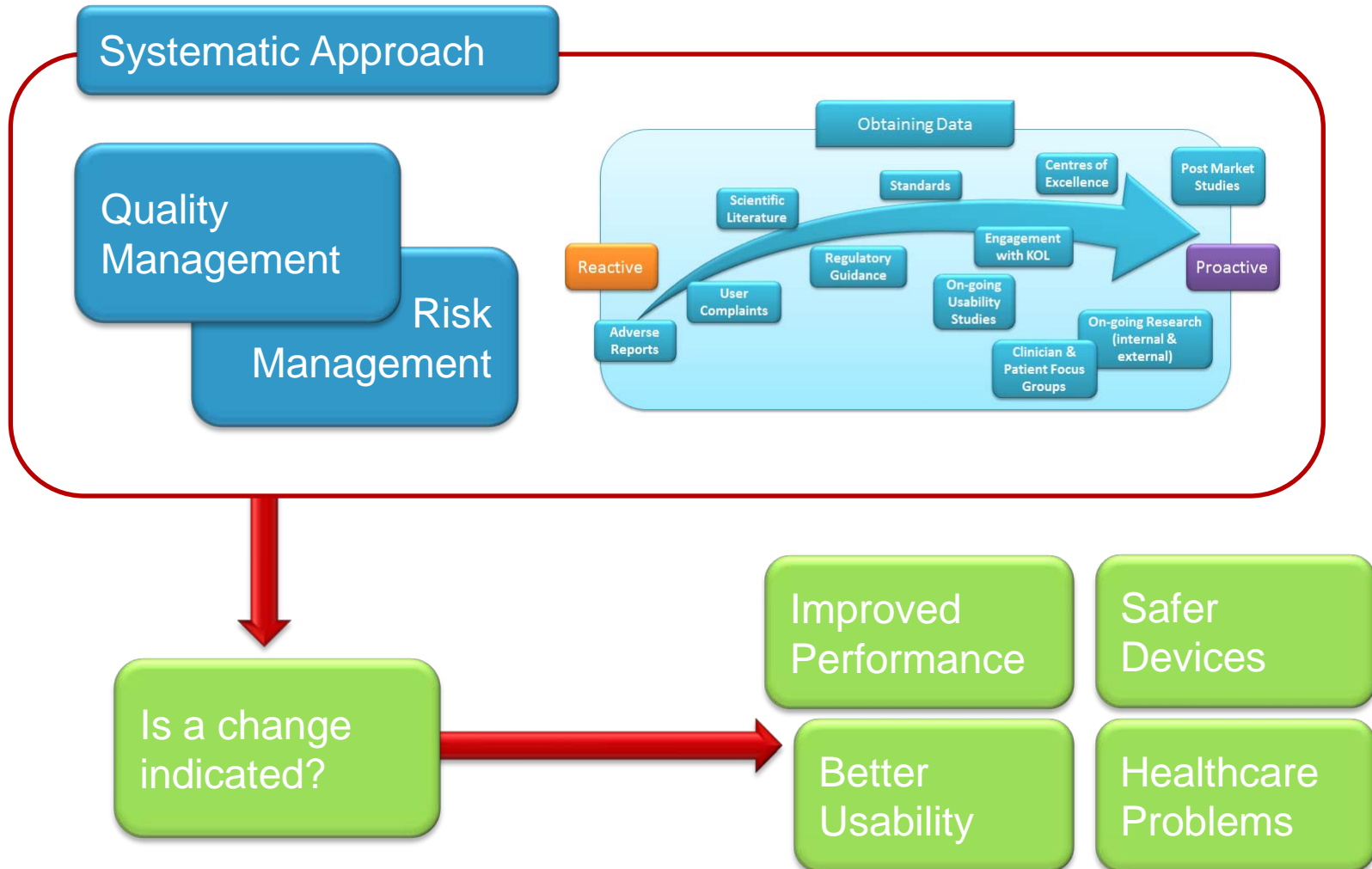- International medical device regulators Forum (IMDRF)

- …..

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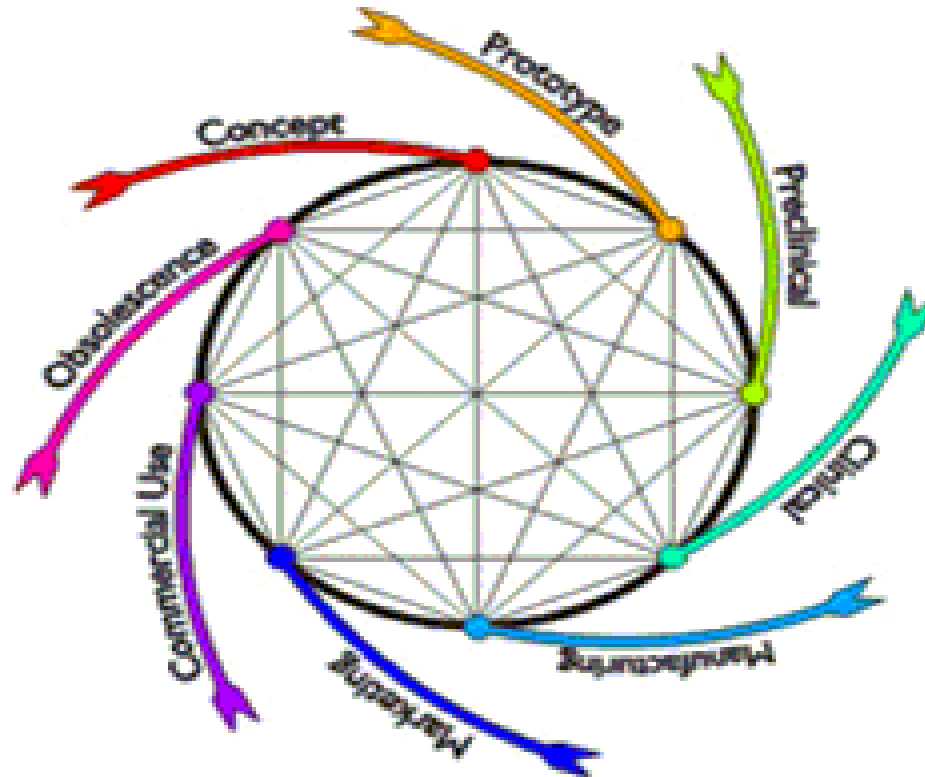
(*) picture fromMedical Device Innovation Initiative White Paper- CDRH Innovation Initiative- February 2011

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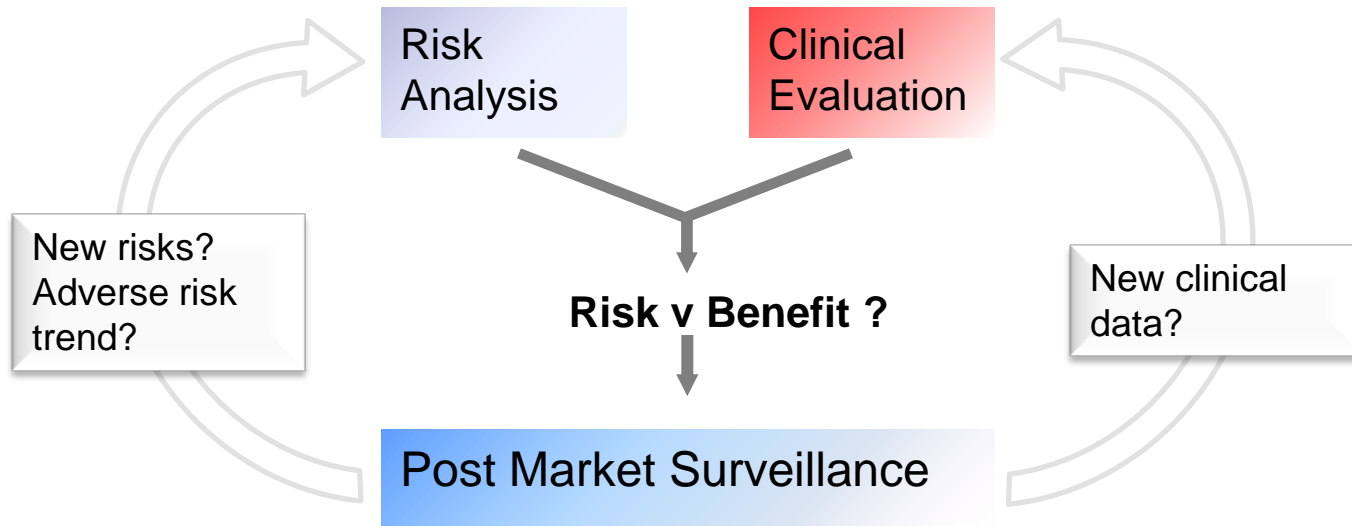# Safety and Performance of Medical Devices(*)

Systematic Approach

Quality Management

Risk Management

Obtaining Data

Reactive — Adverse Reports, User Complaints, Scientific Literature, Regulatory Guidance, Standards, On-going Usability Studies, Engagement with KOL, Clinician & Patient Focus Groups, Centres of Excellence, On-going Research (internal & external), Post Market Studies — Proactive

Is a change indicated?

Improved Performance

Safer Devices

Better Usability

Healthcare Problems

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Post Market Surveillance In Practice

Risk Analysis

Clinical Evaluation

Risk v Benefit ?

New risks?
Adverse risk trend?

New clinical data?

Post Market Surveillance

PMS Plan
> Post Market Clinical Follow Up Study
> Registry
> Published / Unpublished Literature
> Customer Surveys
> Advisory / Expert Meetings
> Complaints & Trending

PMS Outcomes
> Updated Risk Analysis & Clinical Evaluation
> Improved assessment of Risk v Benefit

Improvements:
> Instruction for Use
> Customer Trainings
> Indications
> Product Design

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Can UDI play a role in this picture ?

YES!

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是的

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UDI

What for?

The main roles of a UDI system (*)

(a) improving incident reporting;

(b) facilitating efficient recalls and other field safety corrective
actions (FSCA);

(c) facilitating efficient post market actions by national

competent authorities;

(d) enabling queries in numerous data systems;

(e) reducing the likelihood of medical errors linked to

misuse of the device.

(*) EU recommendation 2013/172/EU

Philippe Auclair, Nov. 2014 Abbott

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Example : Medical Error Reduction

Exposure to latex allergen alone is responsible for over 200 cases of anaphylaxis and 10 deaths each year due to severe reactions to latex allergy [reported US].

It is estimated that only 10% of MRI accidents and 50% of MRI deaths are reported. MRI-related deaths reported in the past have been attributed to mishaps from improperly screened patients with aneurysm clips, pacemakers and ferromagnetic objects accidentally brought into the magnet

Potential exposure to Creutzfeldt-Jakob disease (CJD) from reprocessed surgical instruments.

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Sherlock Holmes' lesson

"Danger! What danger do you foresee?"
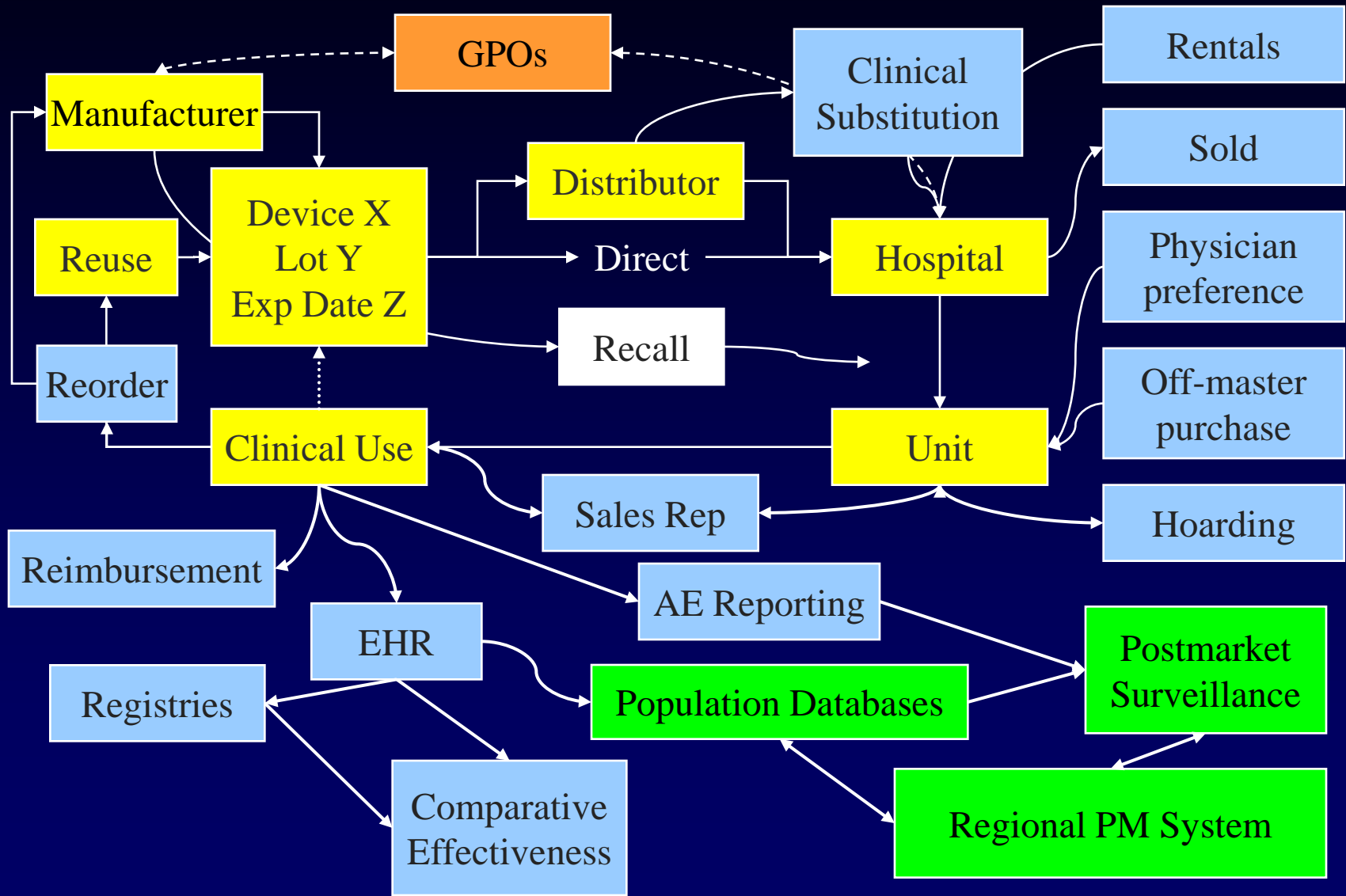
Holmes shook his head gravely

"It would cease to be a danger if we could identify it"

Sir Arthur Conan Doyle,

The Adventures of Sherlock Holmes: The Adventure of the Copper Beeches, 1891.

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Device Information Lifecycle

Capturing events throughout the distribution chain

Some of the EVENTS TRANSMITTED into a DATABASE (*)

Lab – PRODUCT STATE	Logistics movements	Other
• Quarantine • Export • Clinical Trial • Medical Sample • Stolen / lost • Retention counter sample	• Shipping to a next link • Reception from a previous link • Return / Recall • Dispensation to the patient	• Code damaged / destroyed • Destruction of medicine

- • How to ensure participation and adherence by all participants? (Warehouses, Distributors , hospitals, patients…)

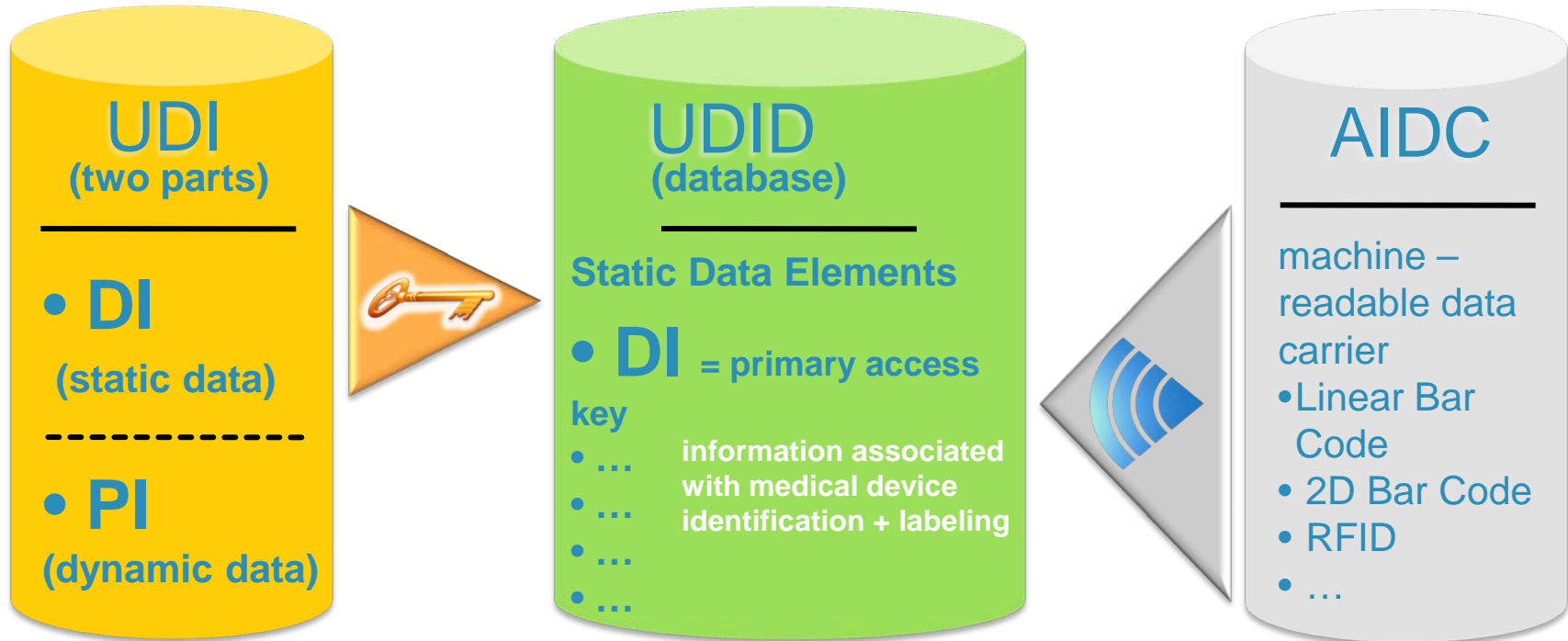(*) source ANMAT- Argentina

UDI

In Practice

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)

2. Place the UDI in human readable and/or AutoID on a device, its label, or both

3. Create and maintain the UDI Database

4. Adoption and Implementation

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UDI System – at a glance

UDI System

UDI
(two parts)
_____

- **DI**
  (static data)
- - - - - - - - - -
- **PI**
  (dynamic data)

UDID
(database)
_____

Static Data Elements

- **DI** = primary access key
- …
- … information associated with medical device identification + labeling
- …
- …

AIDC
_____

machine – readable data carrier
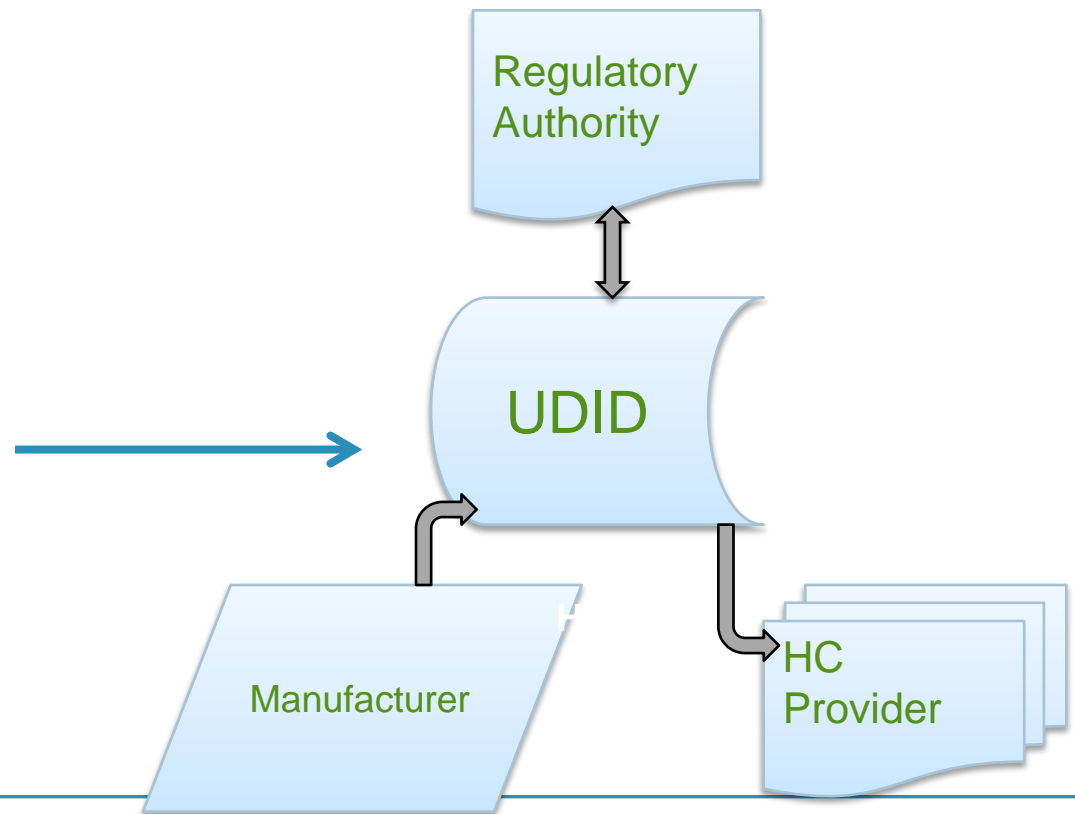- Linear Bar Code
- 2D Bar Code
- RFID
- …

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UDID – Global Core Data Elements

Collection of information with Med. Dev. identification and labelling global core elements (+ regional ‚add-ons')

List of core data e.g defined by IMDRF/UDI WG/N7FINAL:2013

Regulatory Authority

UDID

Manufacturer

HC Provider

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UDID – Global Core Data Elements IMDRF/UDI WG/N7FINAL:2013 (1)

1. For every device packaging level – the following shall be provided in a related way (for entire packaging hierarchy):

UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC),

Quantity per package configuration: (e.g., each, 10 each, 5 shelf packs),

Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128;

2. The Unit of Use UDI-DI (see section 7.6) code;

3. Manufacturer's name (if applicable);

4. Manufacturer's address (if applicable);

5. Manufacturer's customer service contact information (country/region specific, could be multiple);(If applicable)

6. Authorized Representative's name (regional representatives responsible for the medical device) (country/region specific, could be multiple) (if required by the local/regional regulatory authority) (see GHTF/SG1/N55:2009);

7. Authorized Representative's contact information (country specific, could be multiple);

8. Global Medical Device Nomenclature (GMDN) preferred code/term (valid at the time of the UDI submission);

9. Brand Name (if applicable);

10. SaMD version;

11. Device model or version; (see section 10.6)

12. Reference and/or catalogue number (if applicable);

13. How the device is controlled: serial, lot/batch number, and/or expiration date (or manufacturing date) or software version or software released date or ISBT-128 – check boxes (if applicable);
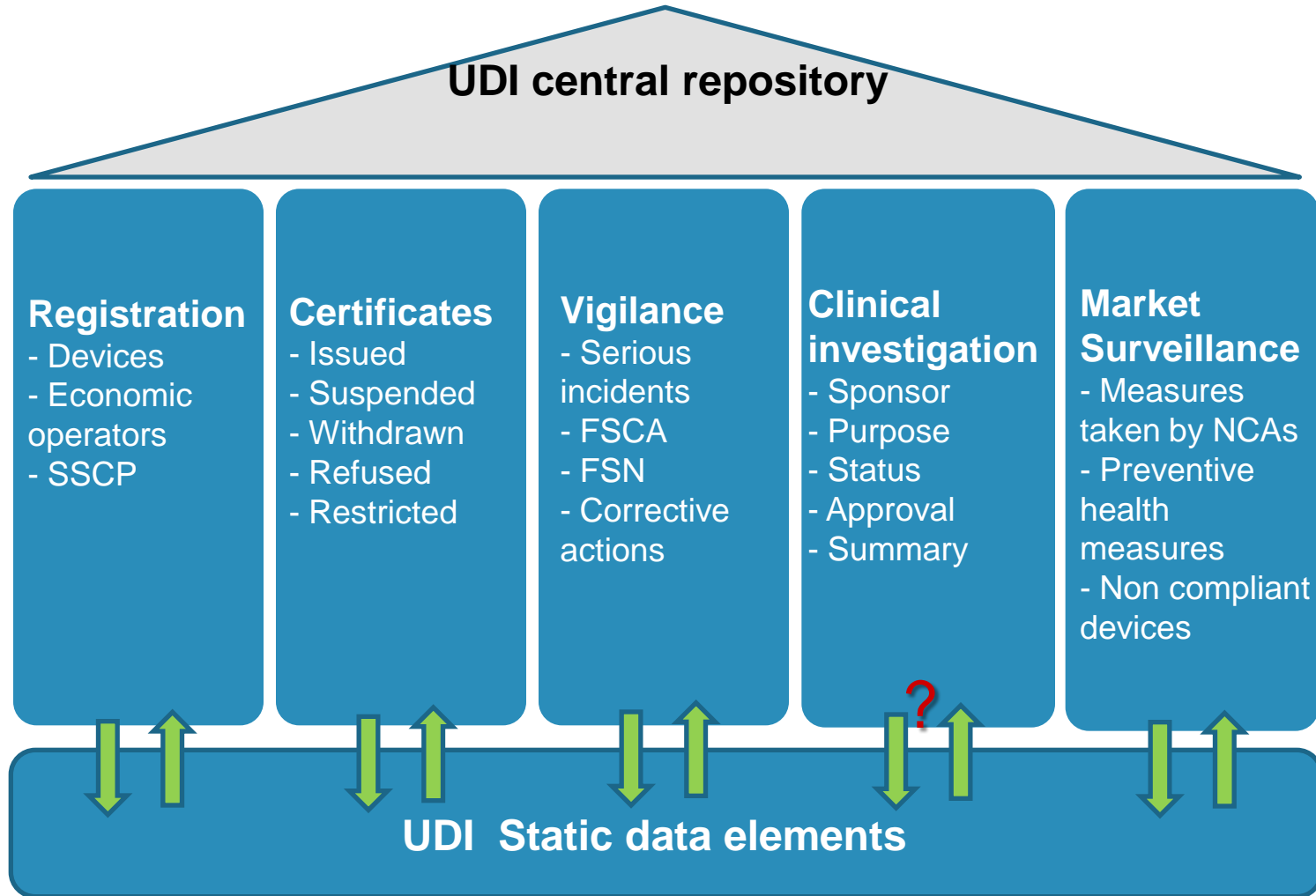
14. Clinical Size (including Volume, Length, Gauge, Diameter) (if applicable) (e.g. 8F catheter);

15. Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque;

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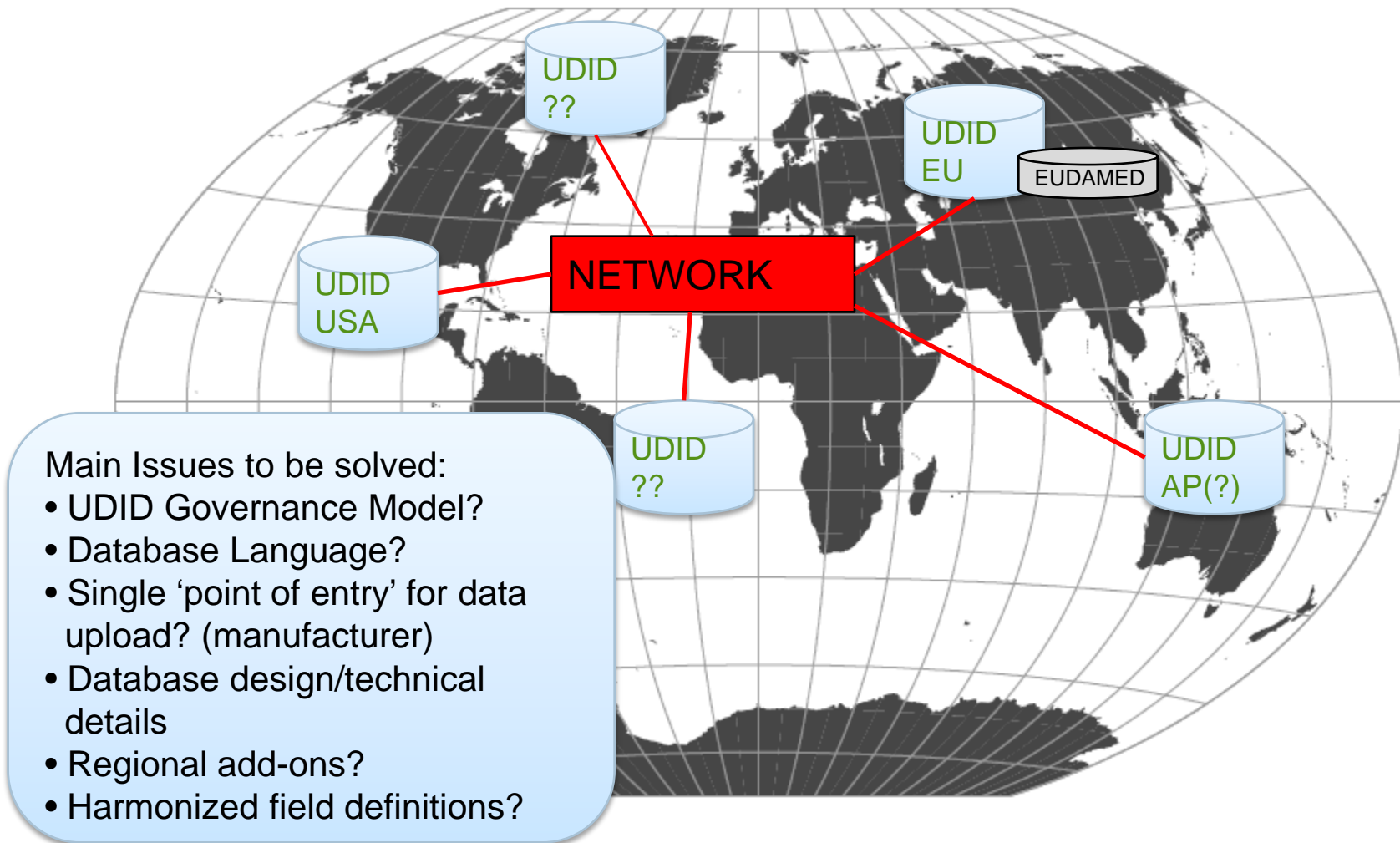# UDID – Global Core Data Elements IMDRF/UDI WG/N7FINAL:2013 (2)

16. Storage conditions, as labeled or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;

17. Handling conditions (if different than storage conditions), on the label or in the IFU (if applicable) – to include temperature range, needs to be refrigerated, relative humidity range, pressure range, avoid direct sunlight;

18. Labeled as single use? (Yes/No);

19. Packaged sterile? (Yes/No);

20. Need for sterilization before use? (Yes/No) – *if yes, then the method of sterilization should be indicated*;

21. Restricted number of reuses (if applicable);

22. License and/or marketing authorization or registration number (if required by the relevant regulatory authority)

23. URL for additional information, e.g. electronic IFU (optional);

24. Critical warnings or contraindications (as labeled) – if a particular regulation requires that the label of the device contains a critical warning or contraindication associated with the use of the device [e.g.: Labeled as containing latex? (Yes/No),

Labeled as containing DEHP? (Yes/No)

Labeled as MRI compatible? (Yes/No).]

25 . Date of discontinuance (referring to devices no longer placed on the market).

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UDI- possible database entries (*)

UDI central repository

Registration	**Certificates**	**Vigilance**	**Clinical investigation**	**Market Surveillance**
- Devices - Economic operators - SSCP	- Issued - Suspended - Withdrawn - Refused - Restricted	- Serious incidents - FSCA - FSN - Corrective actions	- Sponsor - Purpose - Status - Approval - Summary	- Measures taken by NCAs - Preventive health measures - Non compliant devices

UDI Static data elements

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UDI Database – open issues

Main Issues to be solved:
- UDID Governance Model?
- Database Language?
- Single 'point of entry' for data upload? (manufacturer)
- Database design/technical details
- Regional add-ons?
- Harmonized field definitions?

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Points to be carefully considered (1)

o Clear definition for level of access / category of stakeholders needed: *What to whom?*

o Need to further work on level of information to be included in database *What level of details ?*

o Potential to IP/confidentiality issues

o Reasonable, risk based implemetnation timeframe (eg 12mos for highest risk devices)

o Establish a preriod for clearing / exhausting inventory. 3-5 years? Depend on devices ?

# Points to be carefully considered (2)

- Technical

    o Duplication of economic operators

    o Duplicate/misidentification of products

    o Unability of extract reliable information

- Development of National databases

    o Burden in term of registration, maintenance

    o Cost?

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Network of National databases

- Different level of requirements/information

- Different languages

- Different methods for uploading data/format of data

- Different rules around changes etc.

- Different intended use/claims

- Compatibility issues between databases but also at global level

- Compatibility with UDI database

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In Summary
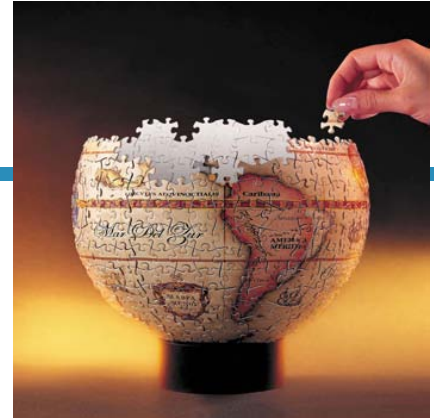
UDI will bring great benefits for:

- ✓ PATIENT SAFETY

- ✓ IMPROVED VIGILANCE & MARKET SURVEILLANCE

- ✓ GLOBAL TRADE

BUT it is essential that

- ✓ A pragmatic (risk-based) approach is adopted

- ✓ Healthcare providers are fully resourced to respond

- ✓ Regional authorities co-operate to ensure a truly GLOBAL and HARMONIZED Approach HARMONISED UDI approach enabling regional database compatibility

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Vision: harmonization for a better and safer use of medical devices