Time Issue

To fully complete a UDI project will take six months.

Companies who delay starting their UDI project are putting their export business at risk

Some of the Key Issues to consider

- Can my existing software systems be changed to accommodate UDI and GS1 coding?
- Can my software accommodate HL7 / SP7?
- How do I keep software them updated going forward?
- How do I deal with multiple locations?
- Can we handle any language or market specific add-ons
- What changes will I need to print hardware?
- Do I need to implement Direct Part Marking (DPM)?
- How do I get production data to DPM Machine?
- What changes do I need to make to business processes

UDI : Milestones and Timelines

FDA UDI Legislation (draft) published

US: FDA Legislation becomes a law

US: Implementation deadline for Class 3 products

US: Implementation deadline implants and life sustaining/ supporting MDs

US: Implementation deadline for Class 2 products

US: Implementation deadline for Class 1 products

Q1 2012 | Q3 2012 | Q2 2013 | Q2 2014 | Q2 2015 | Q2 2016 | 2017 | Q2 2018 | .....

IMDRF UDI work team to oversee, harmonize and support 'UDI Implementation / DB Governance / Promotion'

EU: UDI text for MDD revision available 'Traceability' → regulation

EU: MDD revision UDI legislation proposal

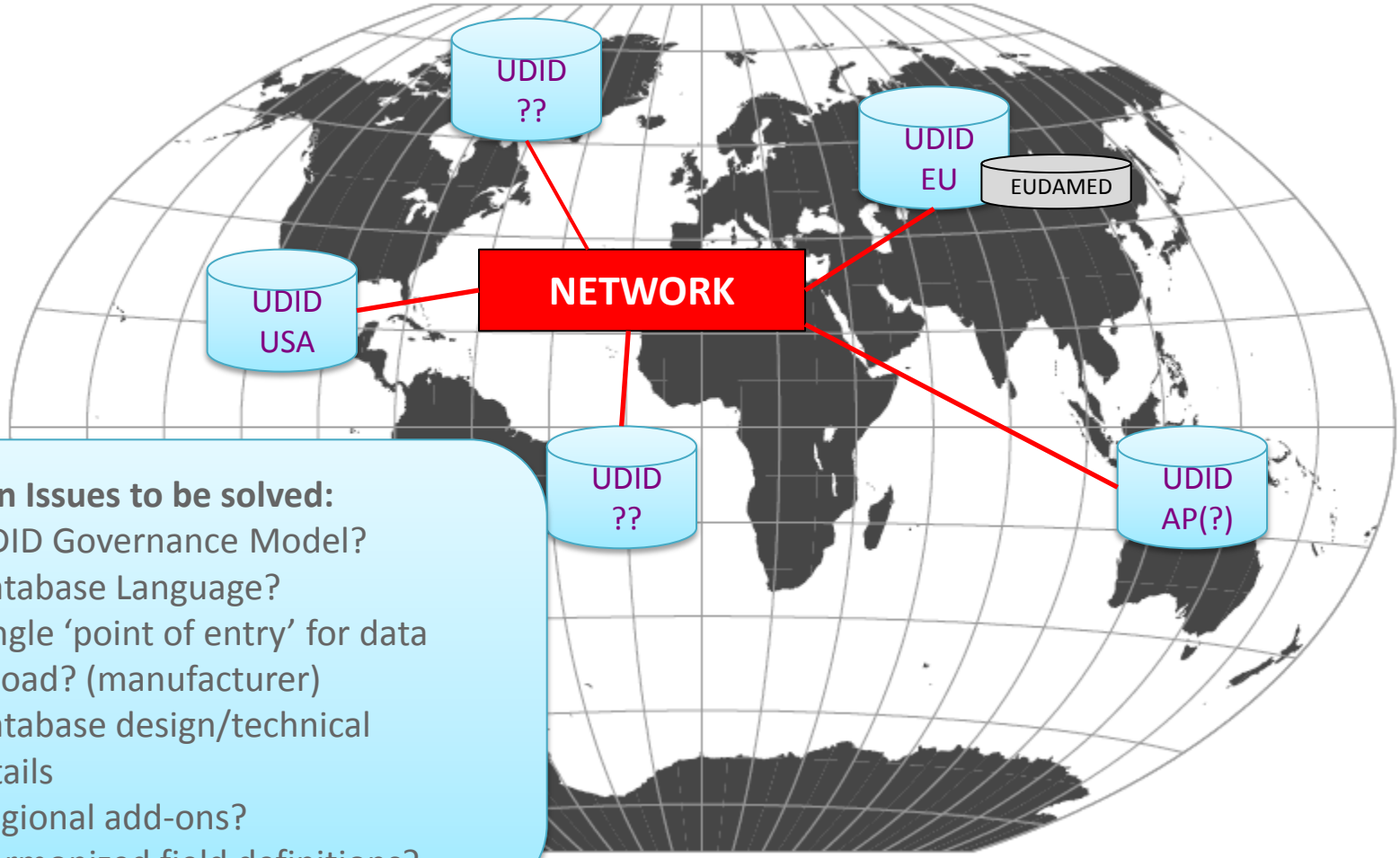
EU: 1 ½ - 2 years legislation process Parliament/Council (2012-2013)

EU: At least 3 years transition period for implementation on national level (2014-2016)

EU Delegated Act define technical details

Other regions??
Global??

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?

UDID – Global Core Data Elements

- Packaging Hierarchy (unlimited no.), per pack. level
- Device Identifier / Unit of Measure / Quantity
- Unit of Use (Identifier (if content of primary pack > 1)
- Manufacturer Name
- Manufacturer Contact Information
- Authorized Representatives (list of countries)
- Nomenclature (e.g. GMDN code)
- Nomenclature Term (e.g. GMDN term)
- Trade Name / Brand Name
- Device Model Number (REF No./catalogue no.)
- Controlled by (e.g. exp. date, lot no., serial no., …)
- Clinical Size (Size/Volume/Length/Gauge…)
- Additional Product Description (clinically relevant info)
- Special Storage Conditions
- Special Handling Conditions
- Labelled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use – Method of Sterilisation.
- Restricted number of reuses
- Labelled as containing Natural Rubber Latex
- Labelled as containing DEHP
- License / Marketing Authorization (e.g. registration no.)
- URL for additional information
- Critical warnings or contraindications as labelled

Collection of information with Med. Dev. identification and labelling

global core elements (+ regional ‚add-ons')