Global Medical Technology Alliance

Innovating for a Healthier World

GMTA

- Getting innovative medical technologies to patients –

- View on Work Items -

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Who Are We?

1990s Origins date s as informal network

2010 Formally established

2013 Became legally constituted in Switzerland as an "association"

2015 WHO approved as official NGO

- **Governed by Articles of Association, Governance Rules, Elected Board of Directors**

◆ **Membership open to medical technology associations (not companies)**

- willing to accept GMTA governance rules

- with functioning code of ethical business practices

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Countries Represented by GMTA

Select Work items

- NCAR
- SAMD
- MDSAP
- MD Adverse Event Terminology
- Registries
- RPS / UDI

View on NCAR

- Look forward to end of pilot
- Extension of NCAR welcomed
- Expect to see impact

Considerations on NCAR

- Notification to Manufacturers
- NCAR Beyond IMDRF?
- Outreach Industry

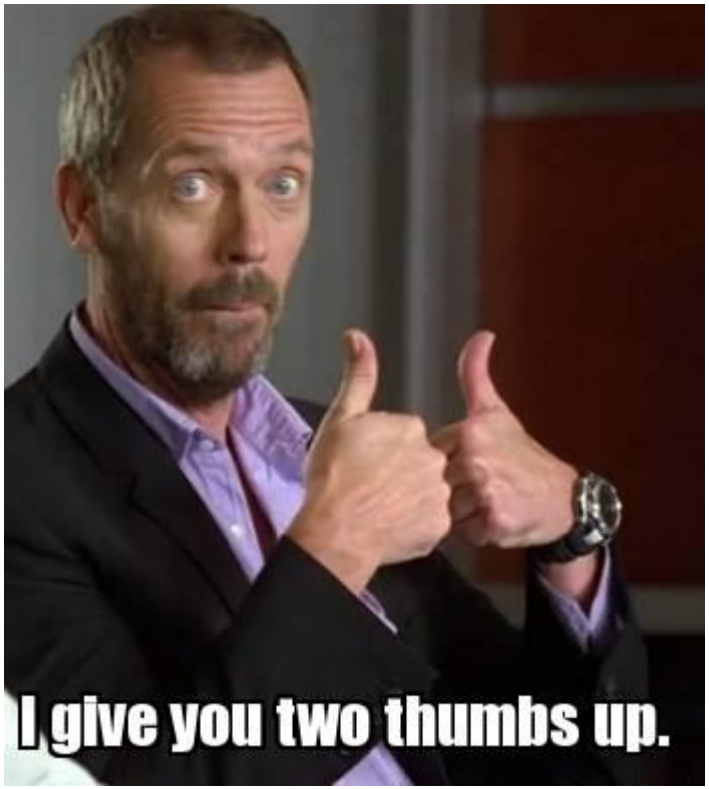
View on SAMD

There is an APP for THAT!

Considerations SAMD

- Regulatory impact of changes to SAMD
- Fuzzy logic – when is an APP a MD?
- Very welcomed key to harmonization
  Software distribution can be truly global

View on MDSAP



Considerations MDSAP

- Question of Capacity – Are there enough AUDITORS
- Extending MDSAP – more members on board?
- Reassuring Industry – accepting MDSAP audit reports

Adverse Event Terminology

- Welcome codification of reporting
- Development of terminology – where will it be used?
- Looking forward to consultations

View Registries

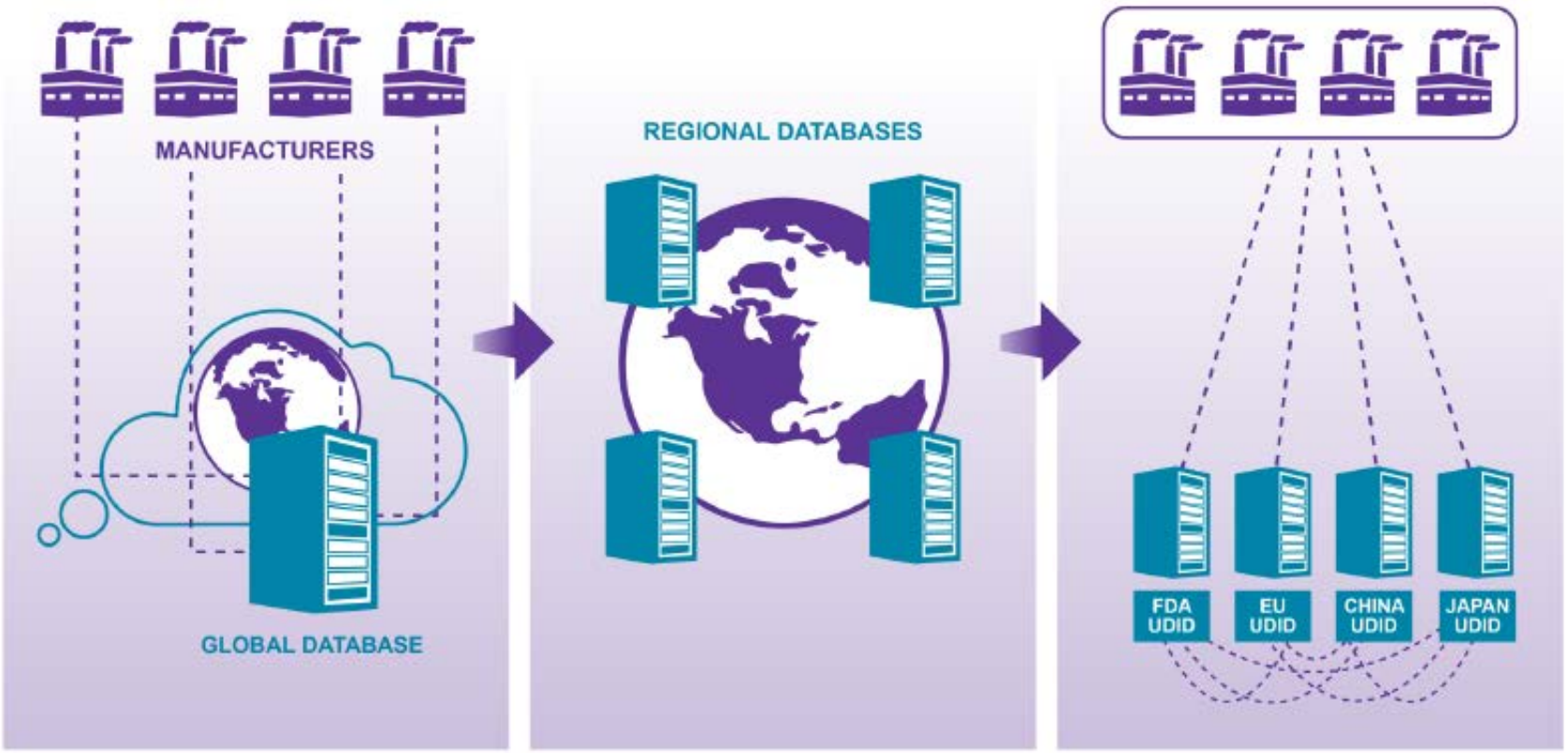
Considerations registries

- Generate lots and lots of data
- Who (and how) accesses the data?
- Confidentiality questions

Considerations RPS

- Welcome the ToC
- Represents a major investment
- Concerns about deployment

UDI



Original IMDRF/GHTF idea:
to develop a global UDI system

More realistic conclusion:
Deployment of a small number of regional UDI databases

The future:
Manufacturers' UDID will be feeding into regional databases which will ideally talk to each other

Essential Principles – Global UDI

- UDI gives each product a unique n… would enable full traceability if used by all stak… same UDI must be present on the label ar…

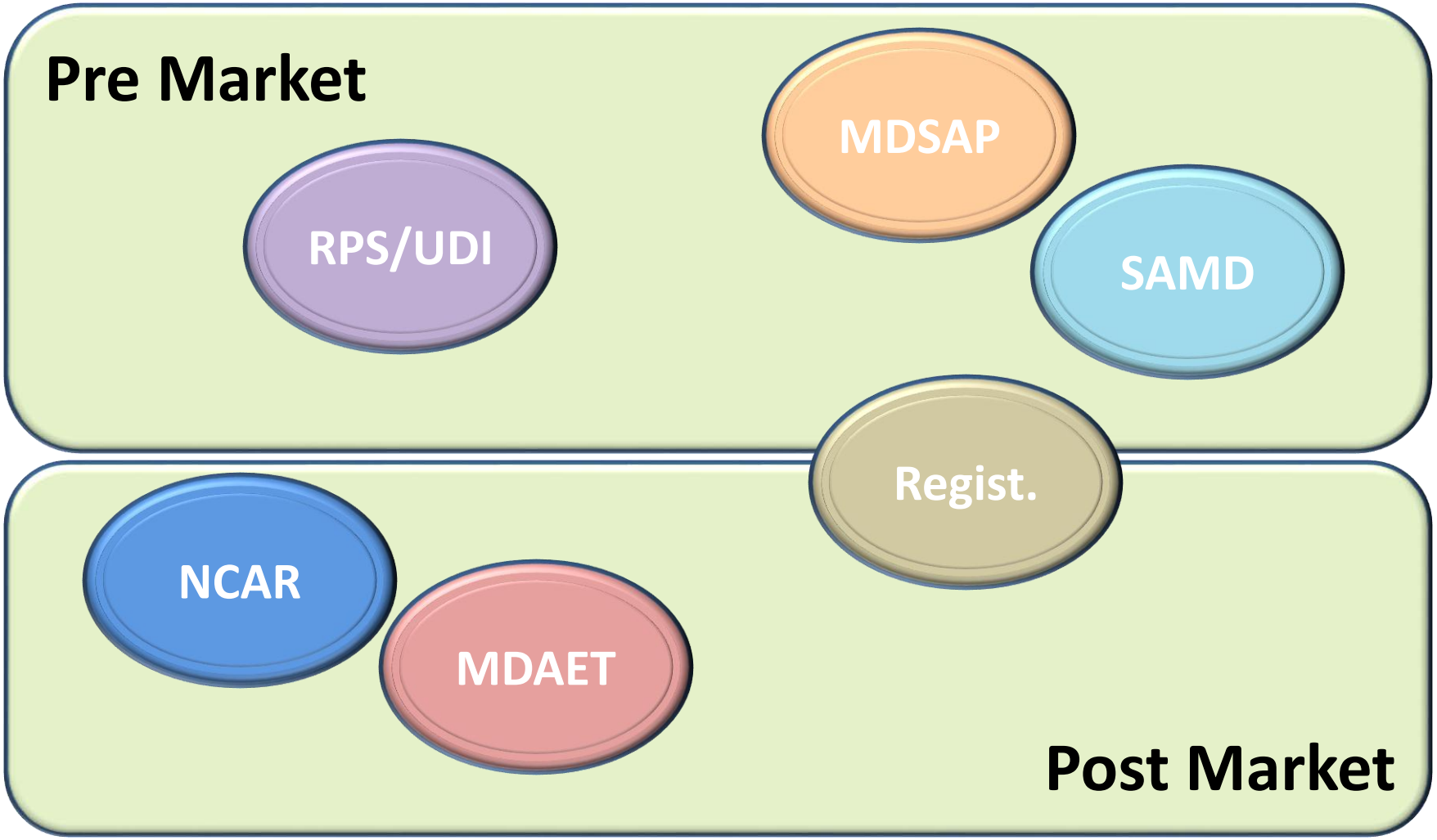
- Products ne… …acked throug… …hain using the same Ide… …er from point… …int of care – if a different UDI is used … includes hospitals using UDI… …d on patients (all the way to the … …rd)

- Databases should … built with interoperability in mind – core elements in particular should be compatible to enable the effective sharing of information.

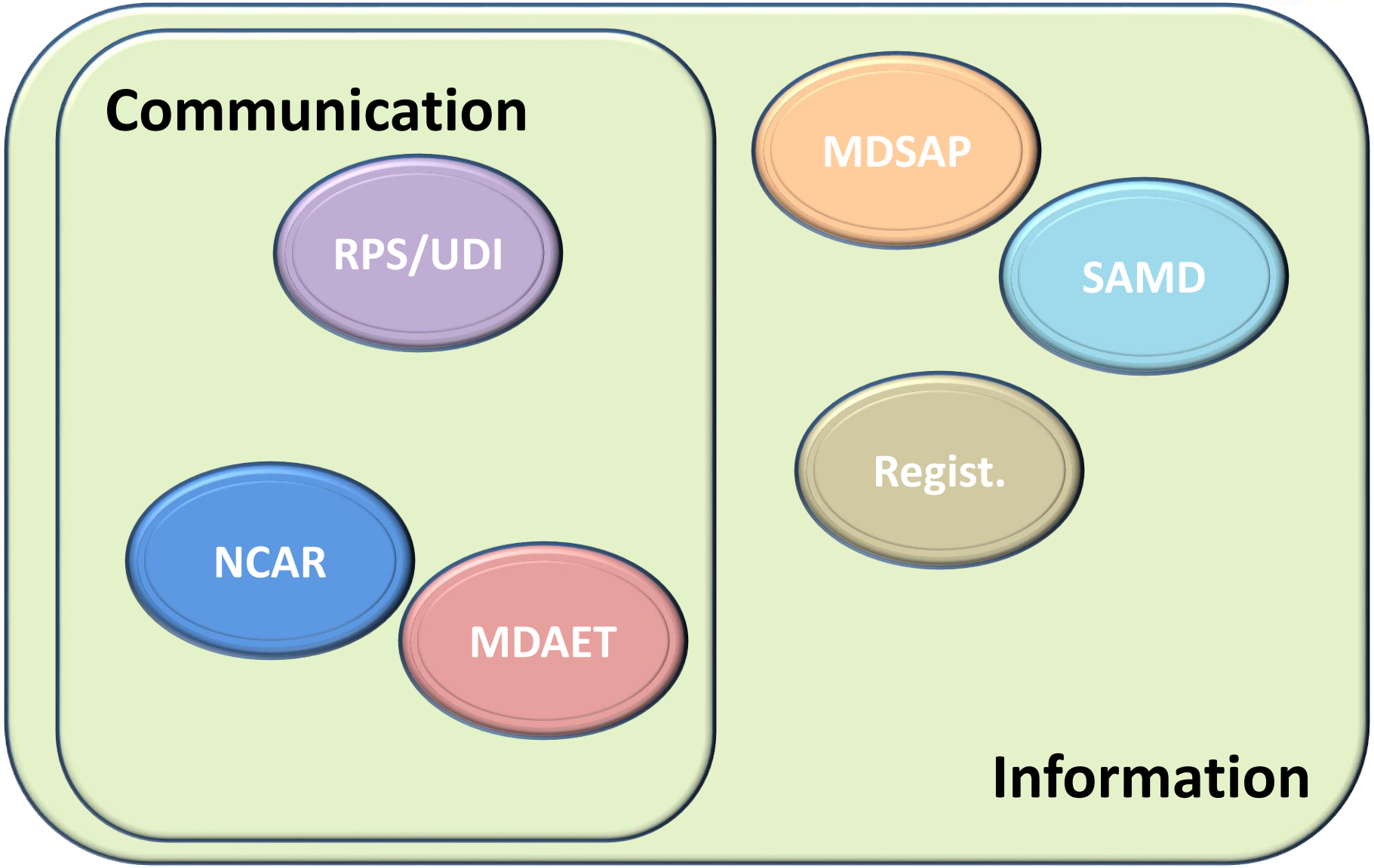
ONE LABEL

INTEROPERABLE DATABASES

Recapitulation…



Recapitulation…



Conclusion

- IMDRF has a strong focus on the key challenges facing the MedTech Sector
- GMTA Actively supports and engages with IMDRF
- IMDRF can enable access innovative medical technologies
- Communication and Information management are important regulatory trends

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Muito obrigado!

Thank you for your time!