

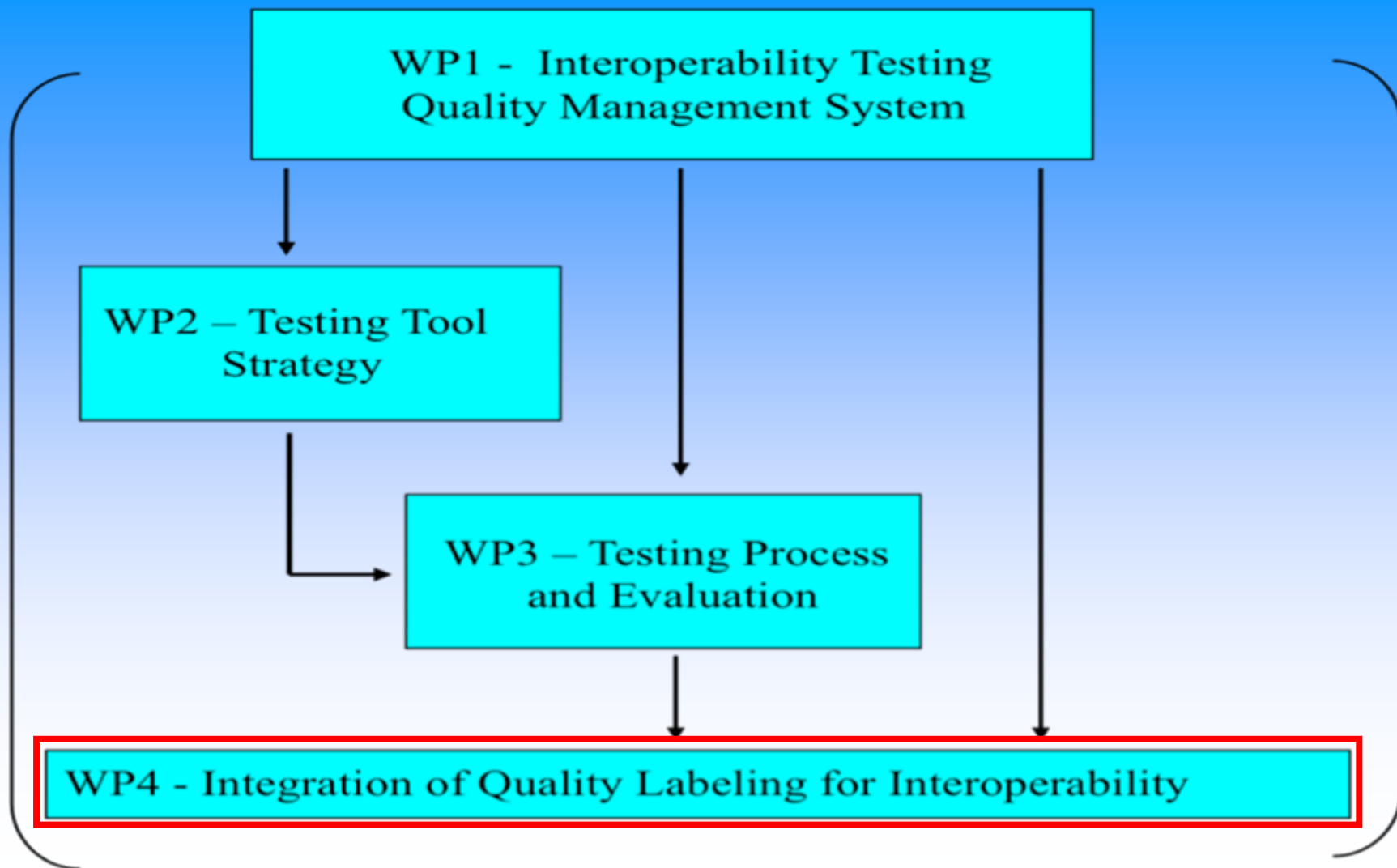
# HITCH

Healthcare Interoperability Testing  
and Conformance Harmonisation

Roadmap to Interoperability  
Certification and Quality labelling

[Charles Parisot, IHE-Europe Steering Committee](#)

## Where are we within HITCH ?



- ▶ What is Certification ?
- ▶ State of the Art of Certification
- ▶ Certification Scenarios
- ▶ Roadmap

# ▶ What is Certification

- ▶ State of the Art of Certification
- ▶ Scenarios for the certification
- ▶ Roadmap

## Definitions

### ▶ Quality Labelling

Quality Labelling can be defined as granting a Label after having performed a Quality Assessment. Quality Labelling can be done by the organisation that has performed the Quality Assessment.

### ▶ Certification :

Based on ISO 9001:2000 (and ISO 9001:2008) or ISO 14001:2004, “certification” could be defined as issuing the written assurance (the “certificate”) by an independent accredited external body that it has audited and verified that the product or software conforms to the specified requirements [2].

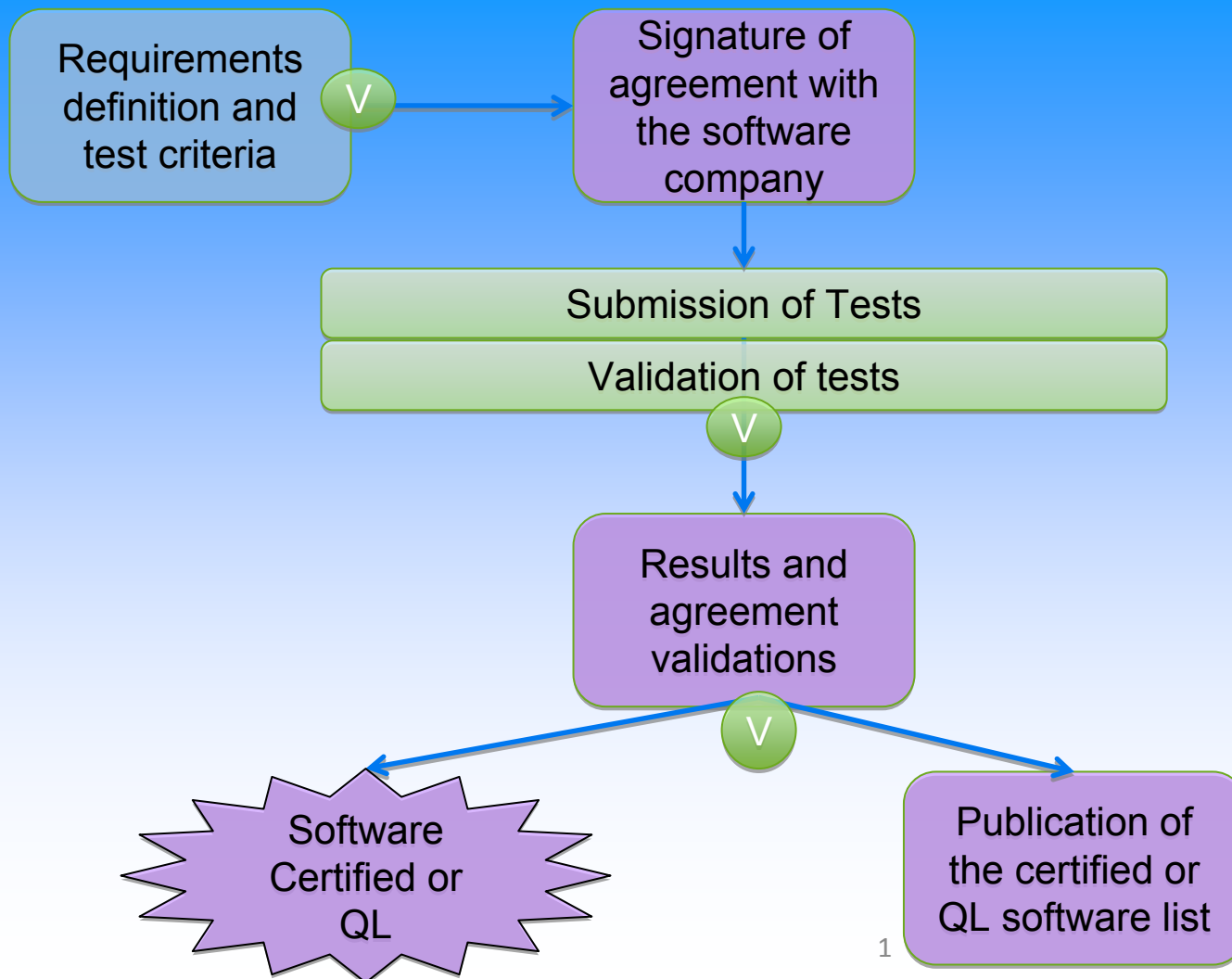
### ▶ Audit

Audit is an independent, objective assurance and consulting activity designed to add value and improve an organisation’s operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

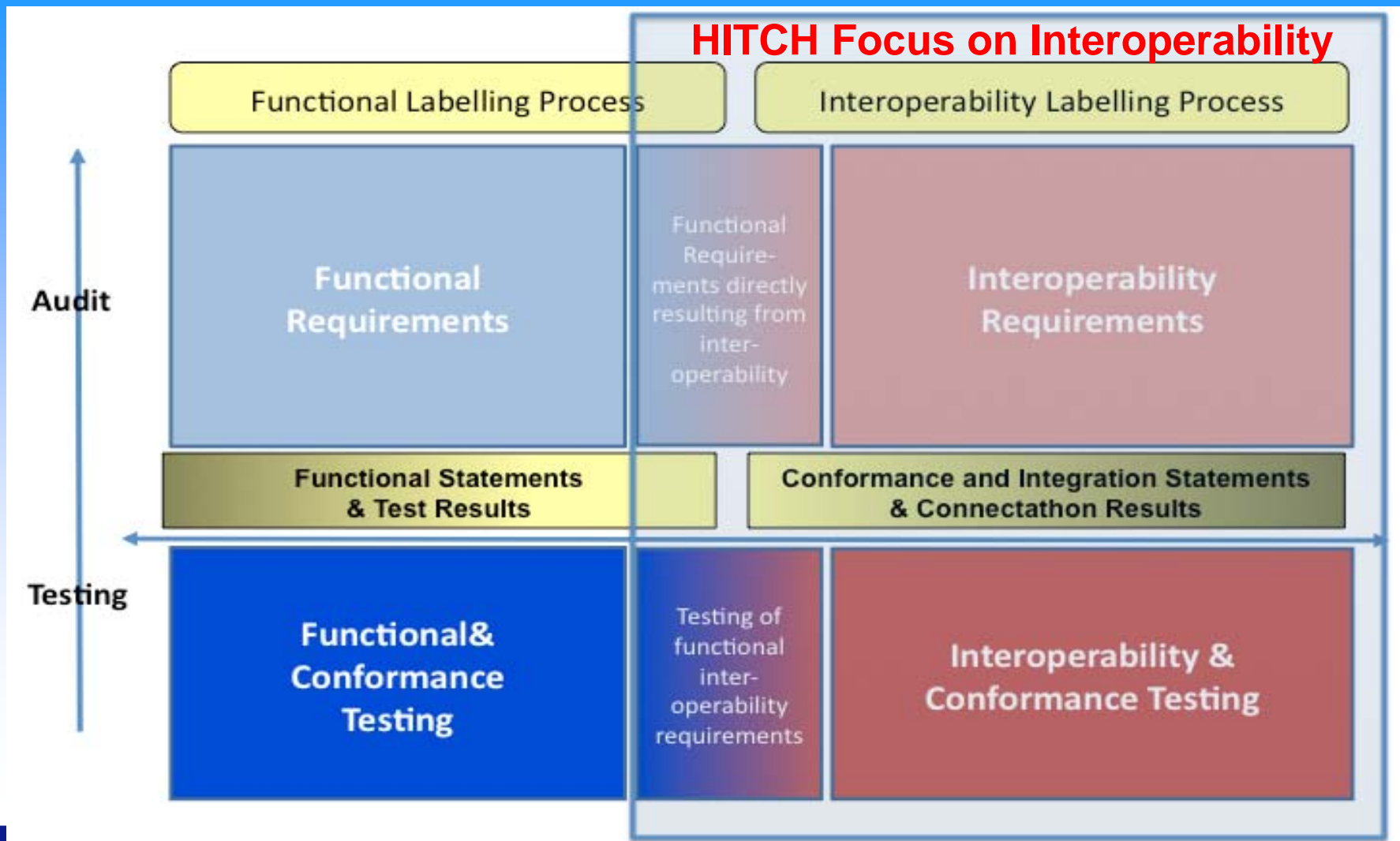
## Differences - Quality Labelling & Certification for Interoperability

- ▶ Quality Labelling and Certification require the same:
  - ▶ Quality Management System
  - ▶ Test Tools
  - ▶ Testing process
- ▶ They differ by the « level of trust » or type of « reference »

## The certification/ Quality labelling process

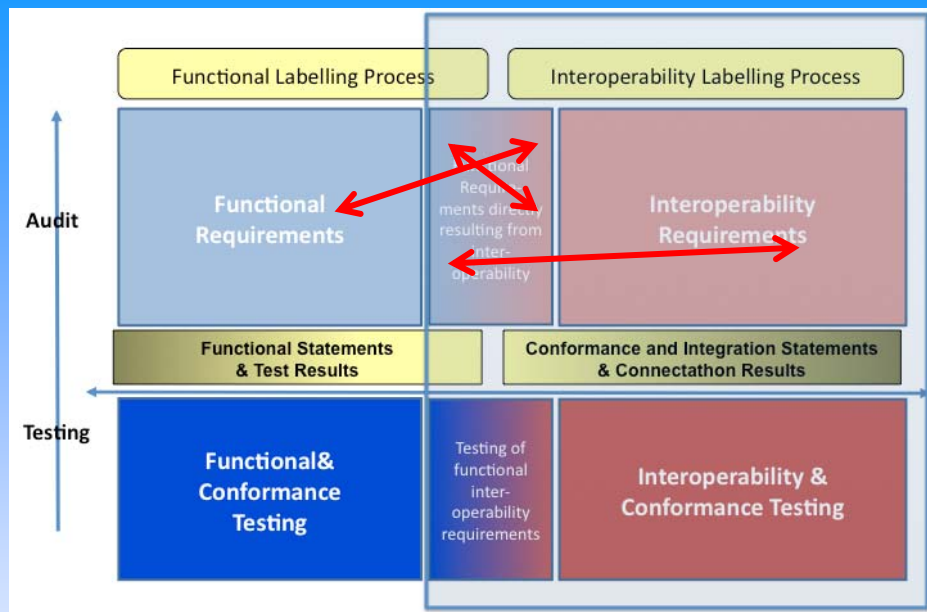


# Relationship between Test/Labelling Functional & Interoperability





## Relationship between Functional and Interoperability



- ▶ Interoperability testing and functional testing are two different but complementary aspects. They can be tested and labeled independently. Some relationships between them exist and have been identified by HITCH.

- ▶ What is Certification
- ▶ **State of the Art of Certification**
- ▶ Scenarios for the certification
- ▶ Roadmap

## Survey of State-of-the-Art on quality labelling & certification

- ▶ Austria
- ▶ Belgium
- ▶ Canada
- ▶ Denmark
- ▶ France
- ▶ Germany
- ▶ Greece
- ▶ Ireland
- ▶ Norway
- ▶ Serbia
- ▶ Slovenia
- ▶ UK
- ▶ USA

### Some takeaways/ discussion topics:

- Interoperability quality labelling & certification is emerging, but limited use of quality management systems
- Interoperability Quality Labelling in use (e.g. IHE)
- Interoperability Certification and Quality Labelling seems to be mostly used as a standards adoption acceleration scheme
- Interoperability efficiency (ROI) has limited evidence

## 12 Some Existing Testing, Certification & Quality Labelling

Country	Scope	Ref. Entity (National/ private)	Accredited entity	Test/Audit Entity	Certification /Quality labelling
<b>Austria</b>	<b>Claims/ Payments</b>	ASV Allgemeines Sozialversiche rungsgesetz,	HVB Hauptverband der Sozialver sicherungsträger	HVB Hauptverband der Sozialver sicherungsträger	Certification
<b>Belgium</b>	<b>EHRs functionality</b>	Ehealth Platform		Ramit Auditors	Certification
<b>Denmark</b>	<b>Interop.</b>		Medcom	Medcom	Certification
<b>England</b>	<b>GP, Pharmacy, Bookings, Social Care, Summary</b>		NHS-CFH	NHS-CFH	Certification
<b>USA</b>	<b>EHRs funct. &amp; Interop</b>	HHS-ONC	ATCBs: CCHIT, Drummond, etc	ATCBs: CCHIT, Drummond, etc	Certification
<b>France</b>	<b>Claim/ Payments</b>	CNAM	CNDA		Certification
<b>France</b>	<b>ePrescription</b>	HAS	COFRAC	AUditors	Certification

## 13 Impact/Benefit of Testing/Certification/Quality Labelling

<b>General</b>	<p>Improve the quality, safety, efficiency of health</p> <p>Reduce health disparities</p> <p>Ensure adequate privacy and security protections for personal health information</p> <p>Promote the conformity to the clinical regulation</p> <p>Decrease the treatment cost for the same level of quality</p>
<b>Functionality</b>	<p>Enhanced functionalities, harmonisation of systems</p> <p>Improve vendor reliability</p> <p>Support the end-user (prescriber)</p> <p>Improve quality of “content” and “output”</p>
<b>Interoperability</b>	<p>Improves interoperability (implementation of standards)</p> <p>Conformity with regulation</p> <p>Zero paper (electronic claim document/ Healthcare information )</p> <p>Reduces delay of reimbursement/ Healthcare information available to the right person</p>
<b>Financial</b>	<p>Receive financial incentives (users)</p>

## 14 Profiles of Some Known Actors

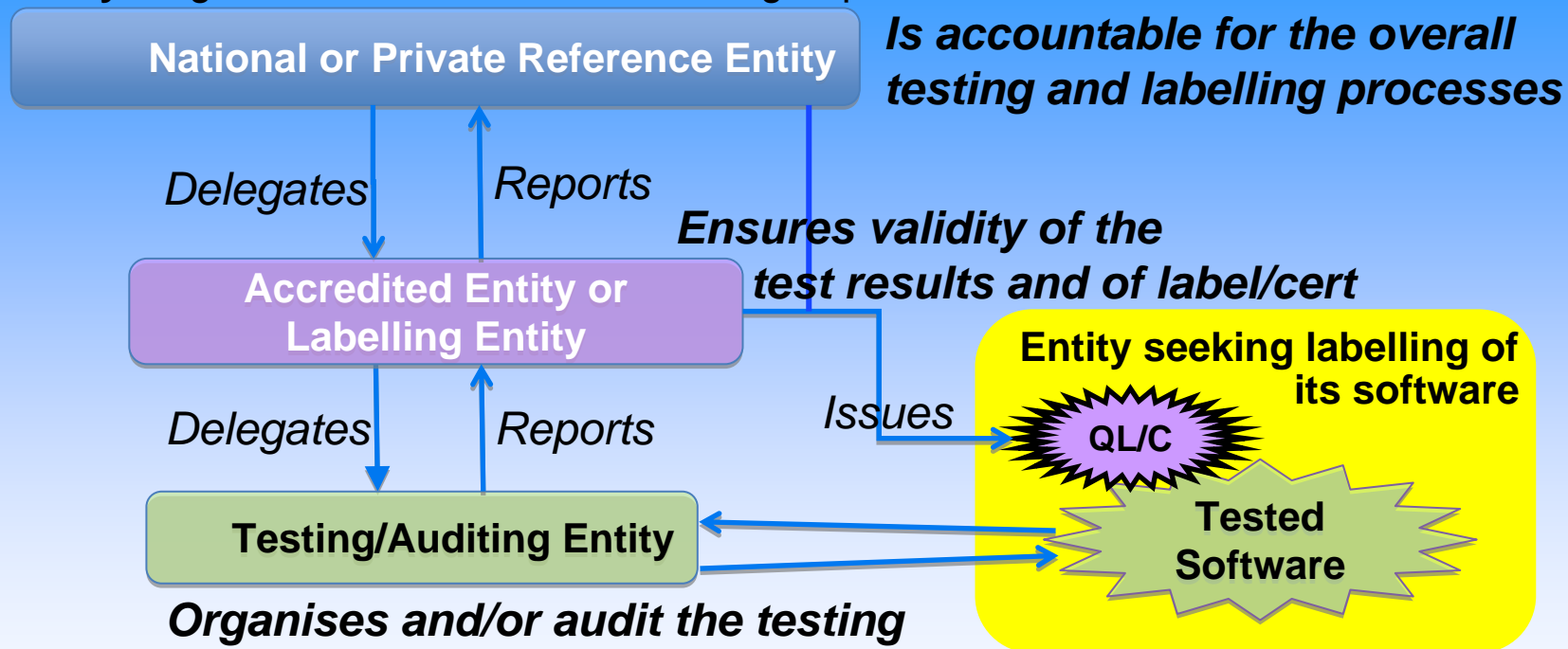
	<b>EuroRec</b>	<b>NIST</b>	<b>IHE</b>	<b>ETSI</b>	<b>Continua</b>
<b>Scope</b>	EHR content & functionality	Functionality & Interop	eHealth Interop	Communication Interop	Personal & fitness devices Interop
<b>SDO</b>				✓	
<b>Requirements</b>	✓		✓	✓	✓
<b>Tools</b>	✓	✓	✓	✓	✓
<b>Testing/Audit</b>	✓		✓		✓
<b>Testing Service</b>	Quality labelling/ certification	None/ Support	Quality labelling/ Certification	None	Quality Labelling/ Certification
<b>Deliverables (requirements)</b>	Requirement repository		Technical Framework	Standards	Impl. Guidelines
<b>Deliverables (tests tools and test results)</b>	Management tool	Test Tools, support	Management tool, test tools, test results, support	Test scripts, support	test tools, test results
<b>Other</b>	Seal Level 1 and Level 2		vendor Integration st'm'ts Repository		Logo

- ▶ Definition
- ▶ What is Certification
- ▶ **Certification Scenarios**
- ▶ Roadmap

## Certification and testing to be organized around different key roles

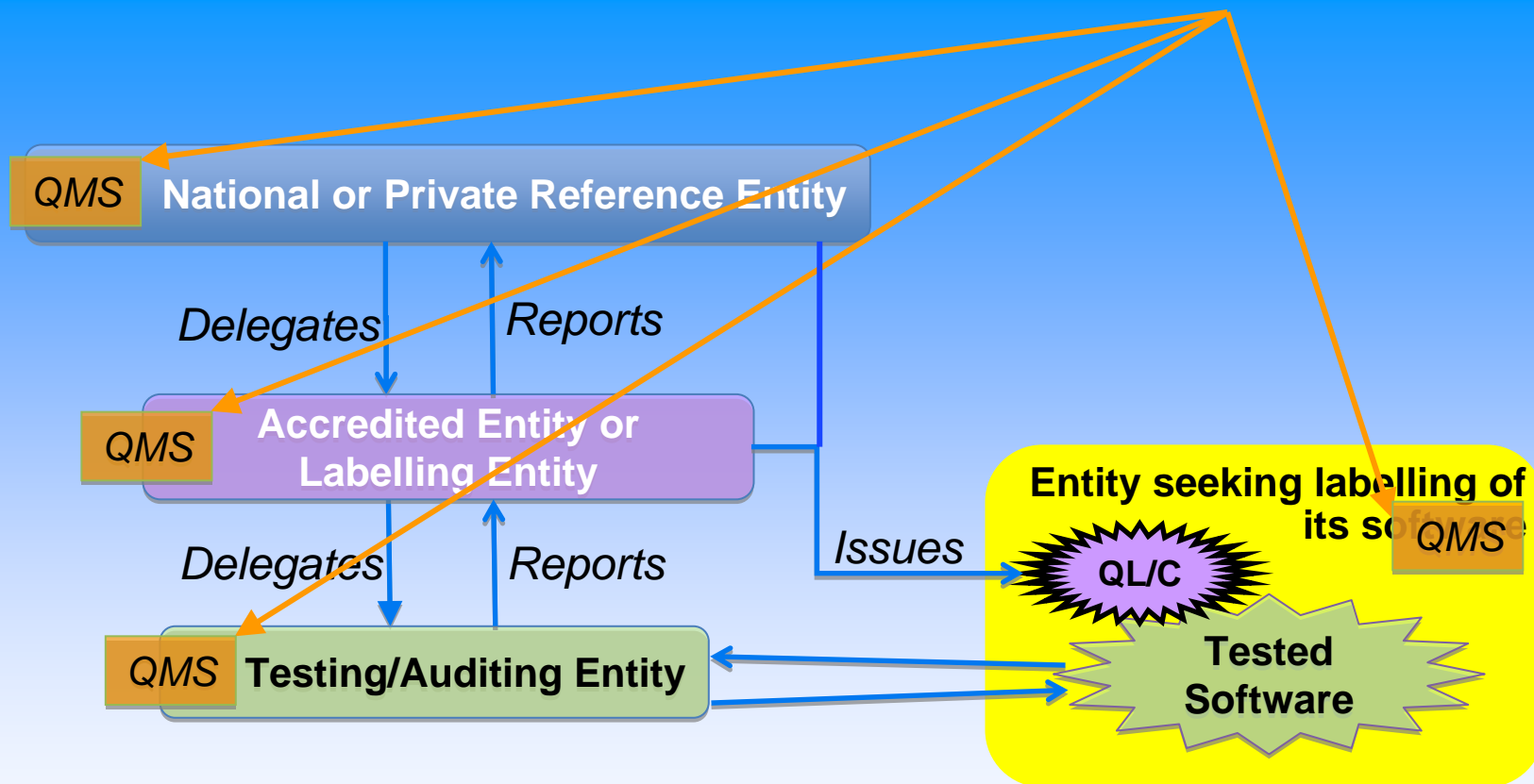
**National Agency** Entity created by the law or,


**Private Entity** :Organisation, association or other group of stakeholders






# Certification and testing organized based on consistent QMSs

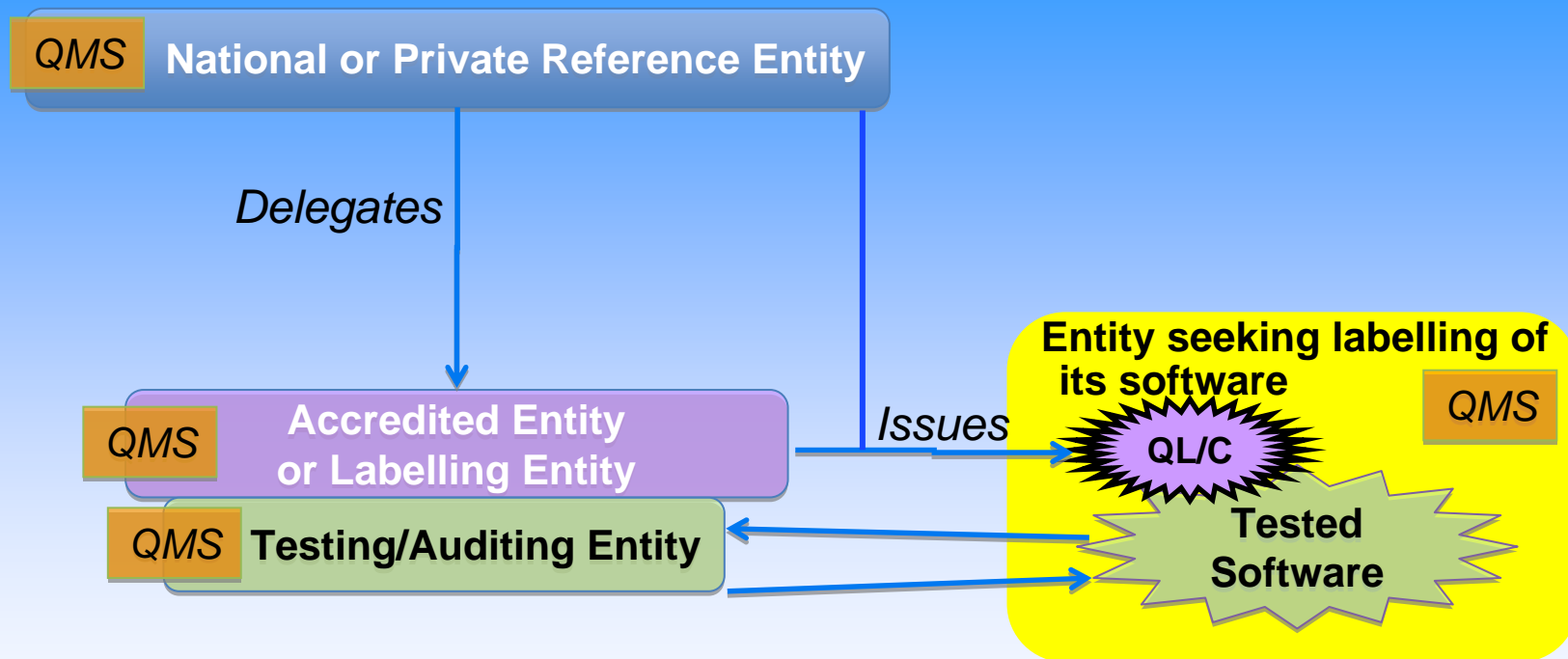



 The entity organises the tests


 The entity validates the results and issues label

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## Labelling and testing can be **combined** in one entity

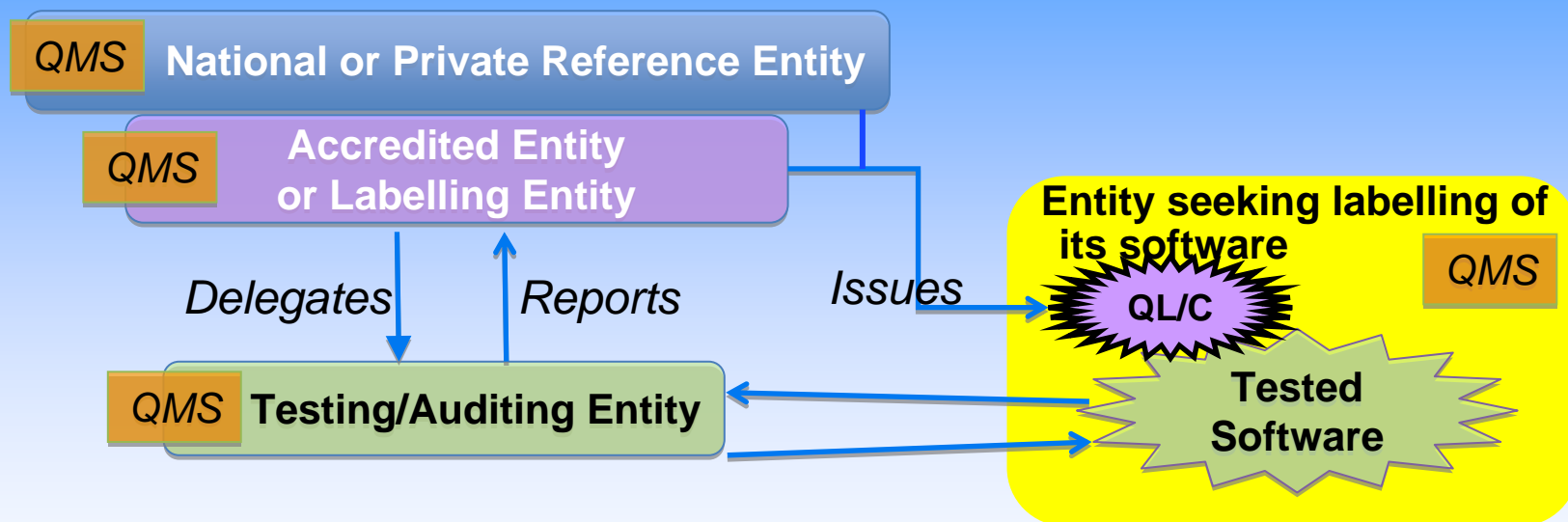



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
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## Reference and Labelling can be **combined** in one entity

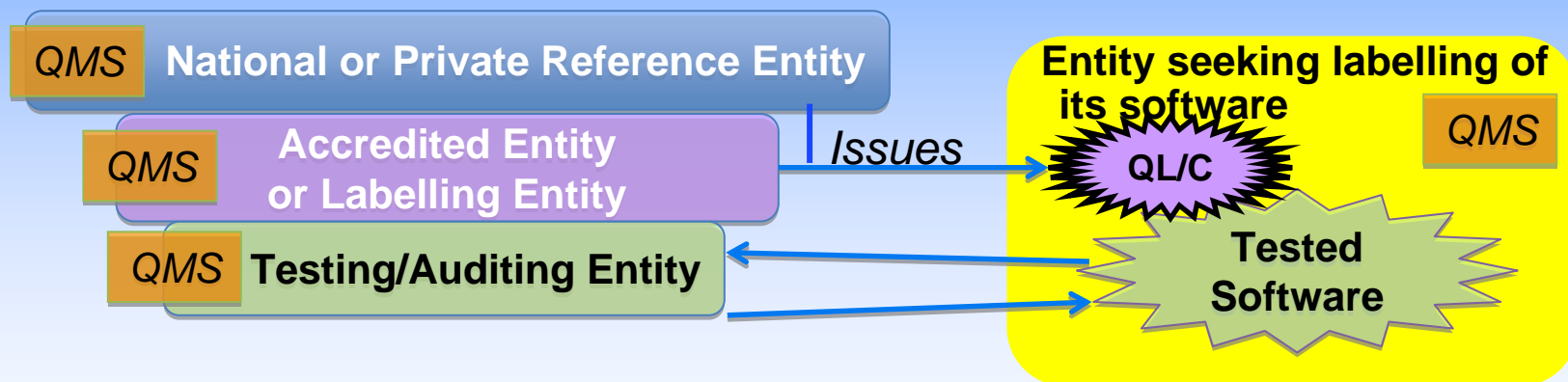



 The entity organises the tests


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## Reference, Labelling and Testing can be **combined** in one entity



 The entity organises the tests

 The entity validates the results and issues label

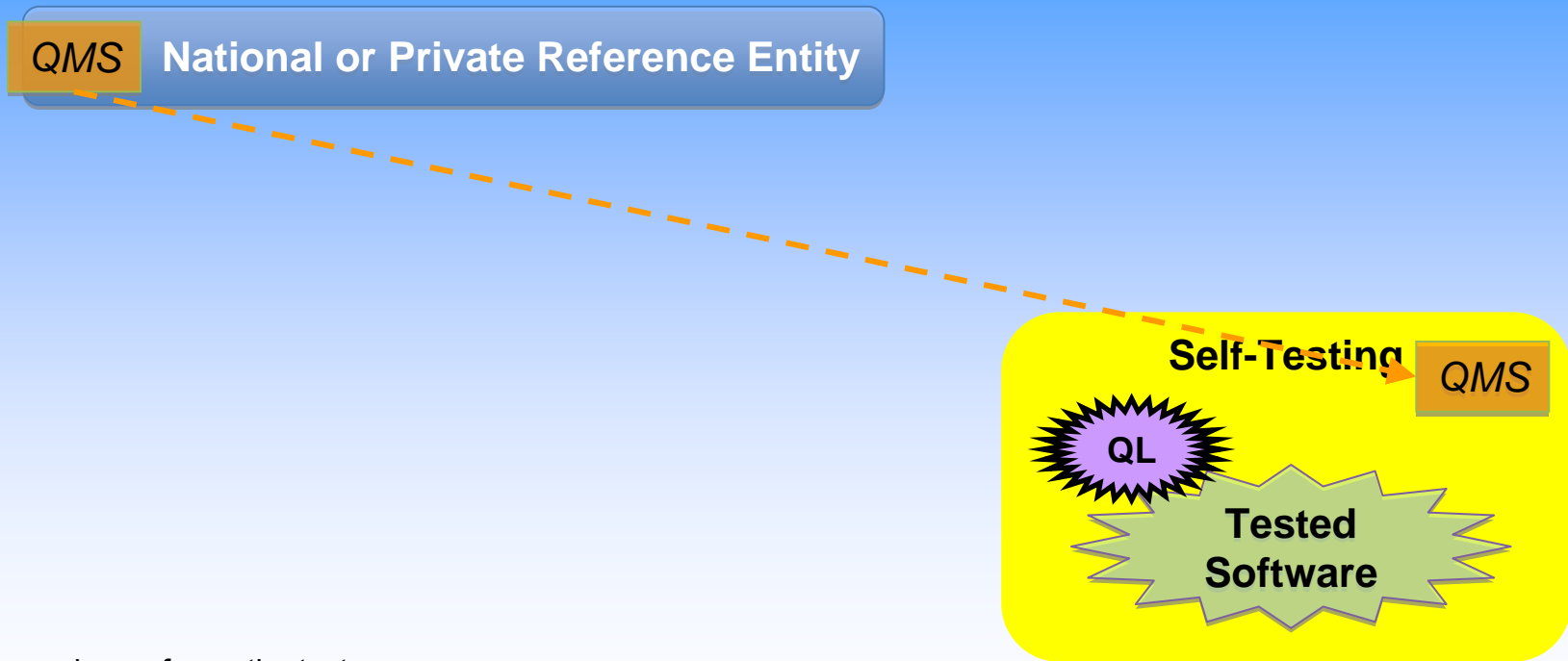
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## Certification scenarios


- ▶ **Self-labelling:**
- ▶ **Self-certification with external reference:**
- ▶ **Third party certification:**

## Self-Labeling:

*The testing process is performed by the vendor according to the testing specifications and an agreed interoperability quality assurance framework.*



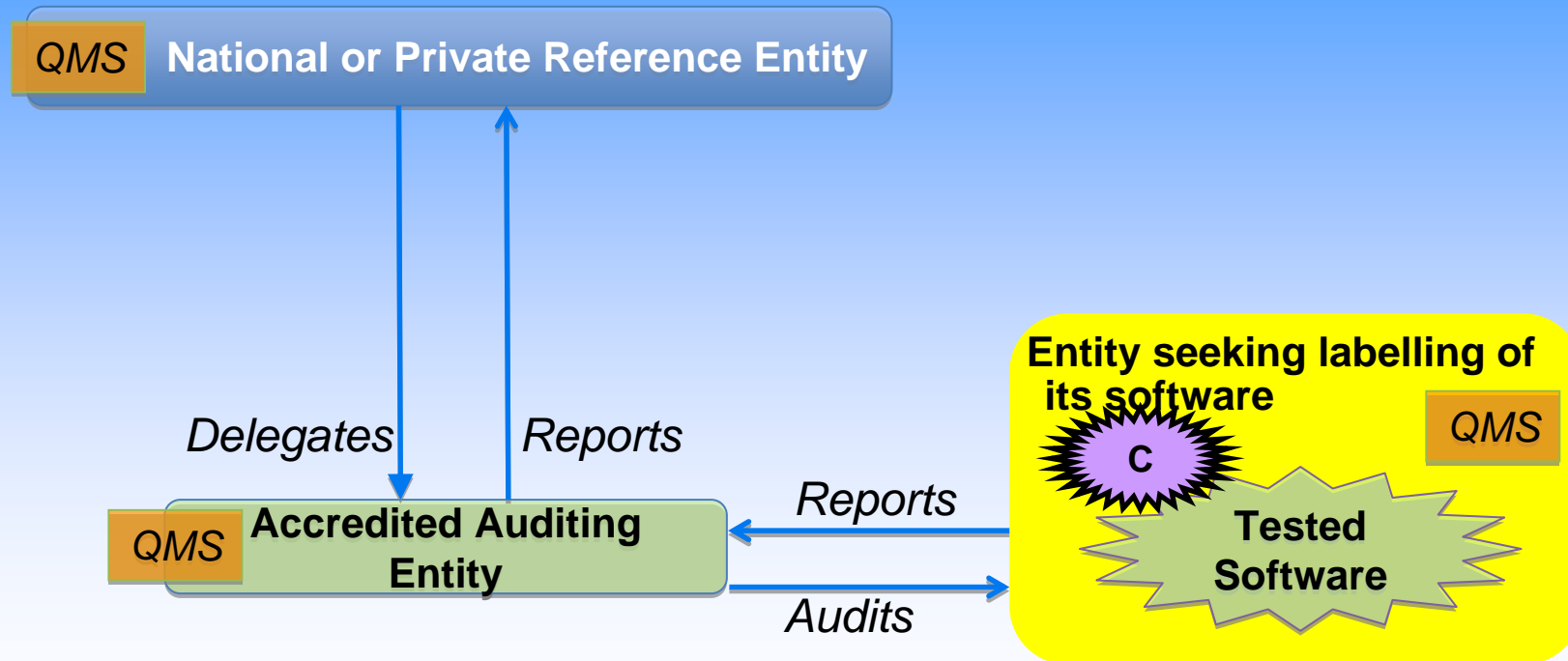
 The vendor performs the tests

 The vendor registers its labels

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
## Self-Certification with External Reference:

*The testing process is performed by the vendor (like self-certification) according to the testing specifications but the vendor is subject to an external audit process performed by an accredited third party.*



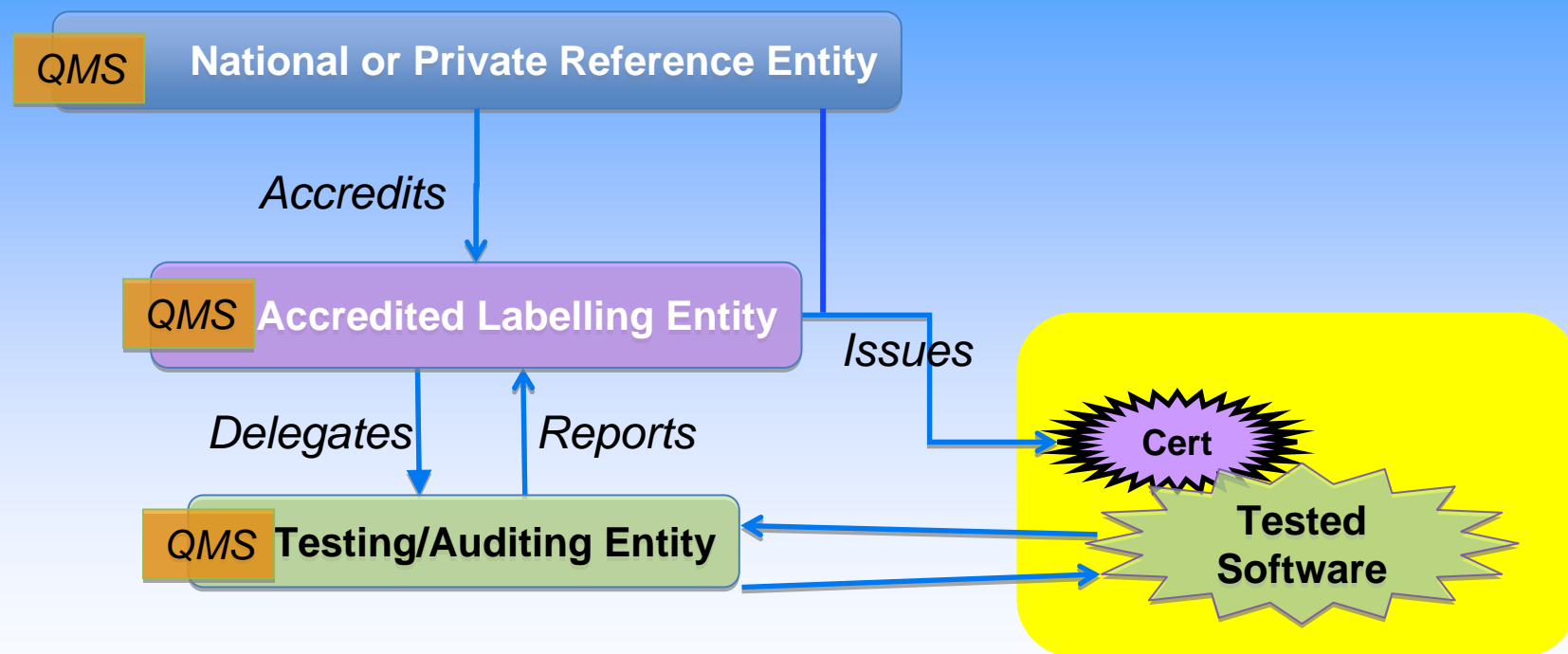
 The entity organises the audits of the vendor performing the tests


 The entity registers its labels that are valid if audit is passed

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## Third Party Certification:

*The testing process is performed by an accredited third party according to the testing specifications under an agreed interoperability quality assurance framework. The trust of certification decreases if the testing process is performed by a third party without accreditation.*



 The entity organises the tests

 The entity validates the results

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## Certification scenarios

### ▶ **Self-labelling**

*The testing process is performed by the vendor according to the testing specifications and an agreed interoperability quality assurance framework.*

### ▶ **Self-certification with external reference:**

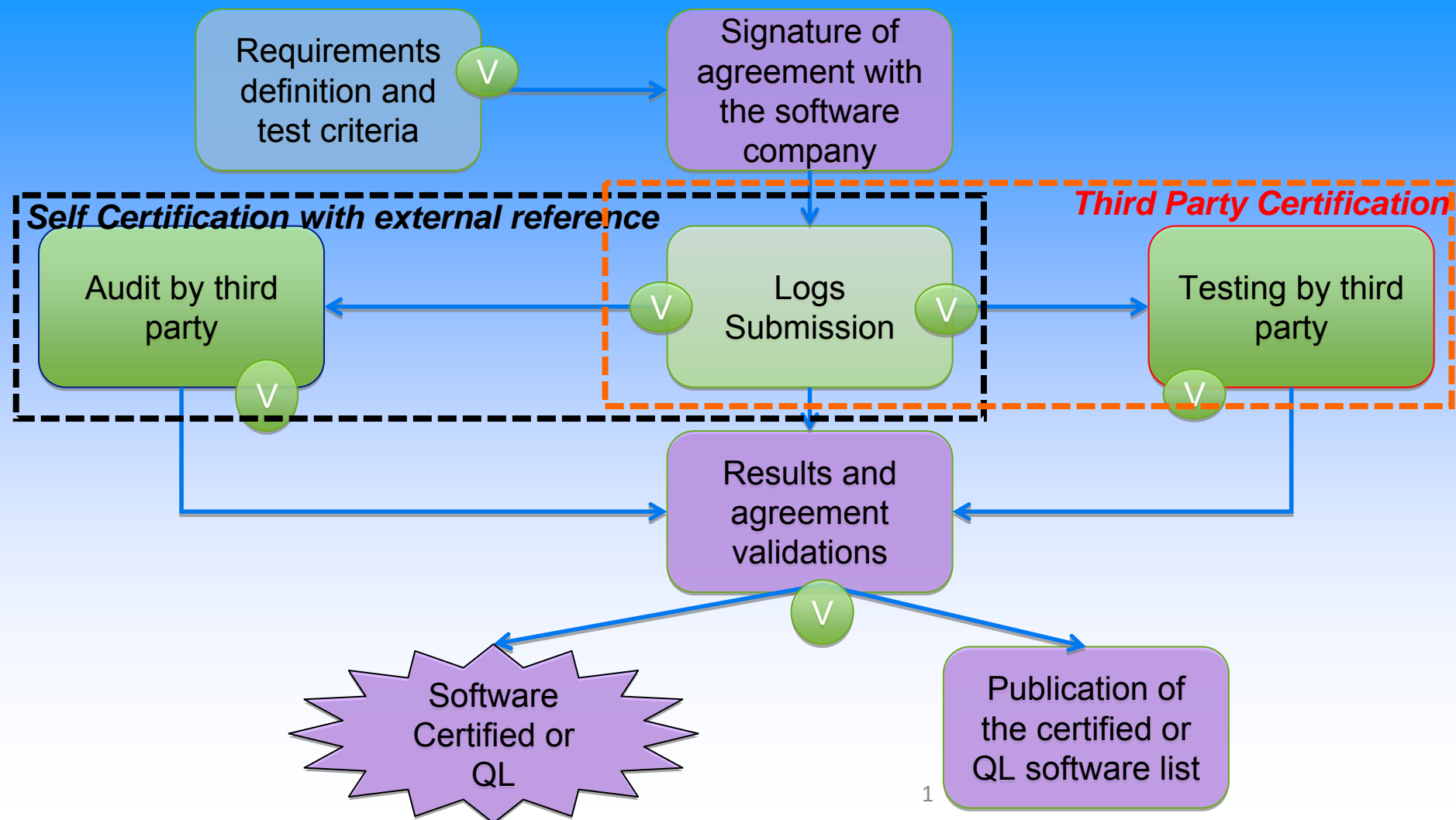
*The testing process is performed by the vendor (like self-certification) according to the testing specifications but the vendor is subject to an external audit process performed by an accredited third party.*

▶ *This process is intermediary between self-labelling and third party certification.*

### ▶ **Third party certification:**

*The testing process is performed by an accredited third party according to the testing specifications under an agreed interoperability quality assurance framework. The trust of certification decreases if the testing process is performed by a third party without accreditation.*

## The certification/ Quality labelling process



## Discussion: Market Maturity

### Third Party Certification

### Self Certification with External Reference

### Self Certification

- Accelerates the recognition of the specifications
- Depends on level of sanctions when audit fails e.g lose right to use certification in commercial activity

- Stable Environment

Low Maturity

High Maturity

- Dynamic domain (fast developing)
- Better with specification not yet widely adopted
- Easy with informal third party quality labelling

## Business Model and costs

### Third Party Certification

- Most expensive and trusted
- Clarification of the market
- Enables government incentives
- Trail implementation testing of new specifications

High Costs

### Self Certification with External Reference

- Medium costs and trusted
- Less expensive than third-party certification and more flexible

### Self Certification

- Less expensive but needs to build trustworthiness
- Easier on large market
- Needs experienced consultants

Low Costs

- ▶ Definition
- ▶ What is Certification
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## To move forward in Quality management for eHealth interoperability:

1. **Drive adoption of HITCH proposed interoperability QMS and guidelines to interoperability testing processes.** Improve with usage.
2. **Drive closure of key gaps in interoperability testing tools building consistent test tools upon a shared management platform tool and methodology.** This requires that most EU countries recognize and adopt consistent profiles (tools reuse).
3. **Further encourage collaboration between the functionality-focused and the interoperability-focused testing/labelling initiatives to document “relationship between criteria”.**
4. **Keep flexibility across the three proposed labelling/certification schemes to facilitate evolution** (reduce costs as different segments of eHealth market mature and avoid to legislate or regulate specific schemes).

**Are those the core elements of  
a European Roadmap on Interoperability Quality ?**

**Testing and labeling/certification are two very different concepts.**

**Any approach to interoperability quality labeling and/or certification without solid interoperability testing tools and processes is not possible.**

**Thank You**