

IHE and Conformity Assessment Scheme (CAS)

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Testing tools: the basis of certification

- Standard specifications are, as a rule, not tight enough and **differing interpretations and erroneous implementations** lead to interoperability problem.
- It has been proven many times that the only solution to that problem is the appropriate level of **testing**.
- In order for the testing to be precise, efficient and less dependent on human intervention **testing tools** are required.
- Quality of the data is expected by the Healthcare Professionals and for their secondary uses

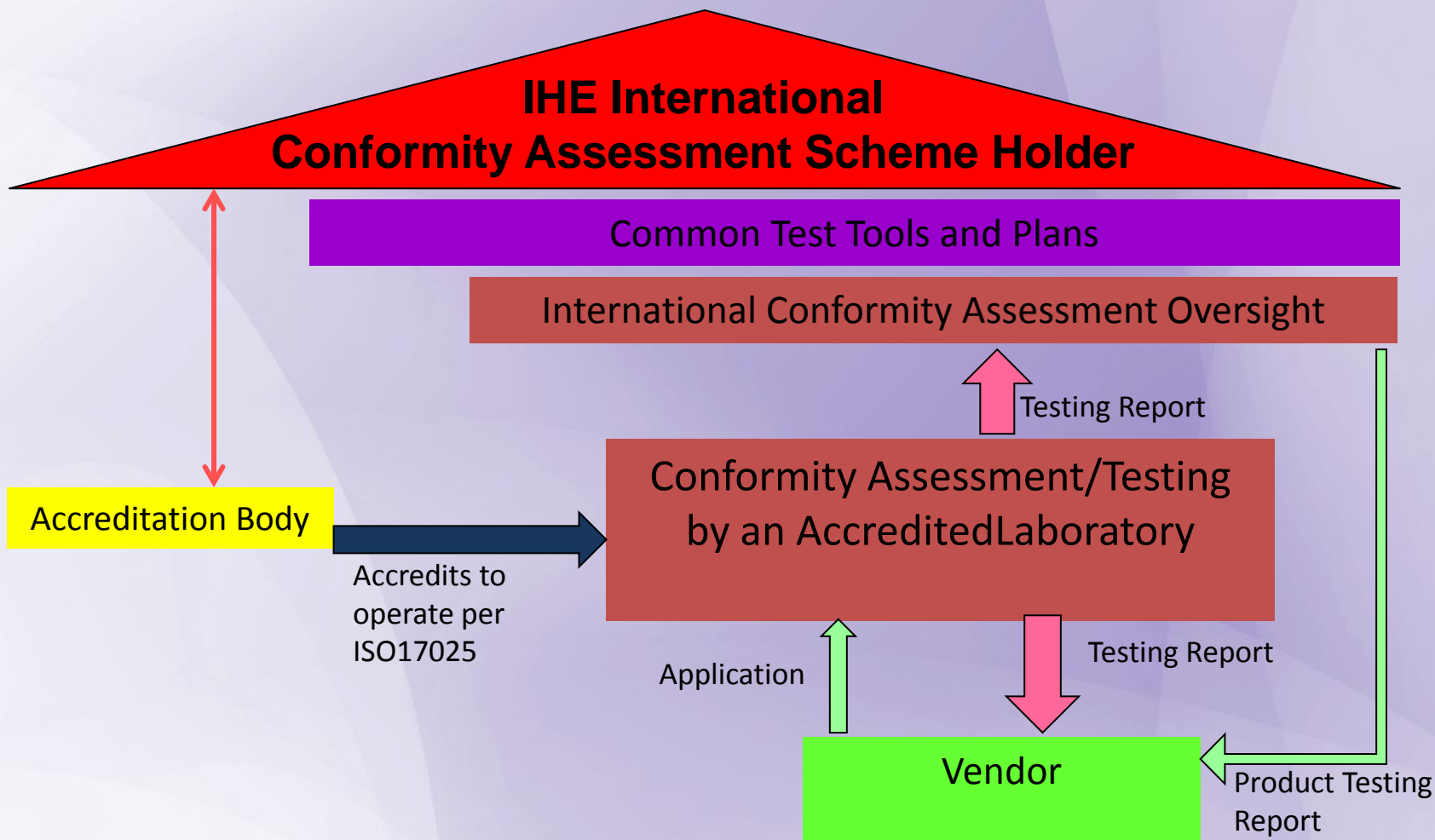
Objectives

- IHE develops a Conformity Assessment Scheme which forms the basis for IHE Conformity Assessment Programs and any official certification of conformance to IHE Profiles associated with such testing programs.
- The CAS Scheme consists of two volumes:
 - IHE CAS-1 Defines the necessary processes for establishing an IHE Conformity Assessment Program and for accrediting and operating testing laboratories
 - IHE CAS-2 defines the standardized test methods for assessing conformity to individual IHE Profiles. This document is currently under development.

What is meant by Conformity Assessment?

- Test Report provided by a trusted neutral organization that guarantees that an IHE profile implementation in a commercial products is positively tested against an IHE test plan/test tools
 - Specific version of a specific product (re-testing may be needed for every major version).
 - The process and rigor of “Conformity Assessment” to be defined in terms of a “conformity assessment scheme” (process, test plan and test tools) to ensure world-wide equivalence.
 - Expects a vendor to pass appropriate Connectathon tests as a prerequisite for seeking profile/actor accredited testing

Concepts of IHE Conformity Assessment



Elements shown above may be deployed in various ways

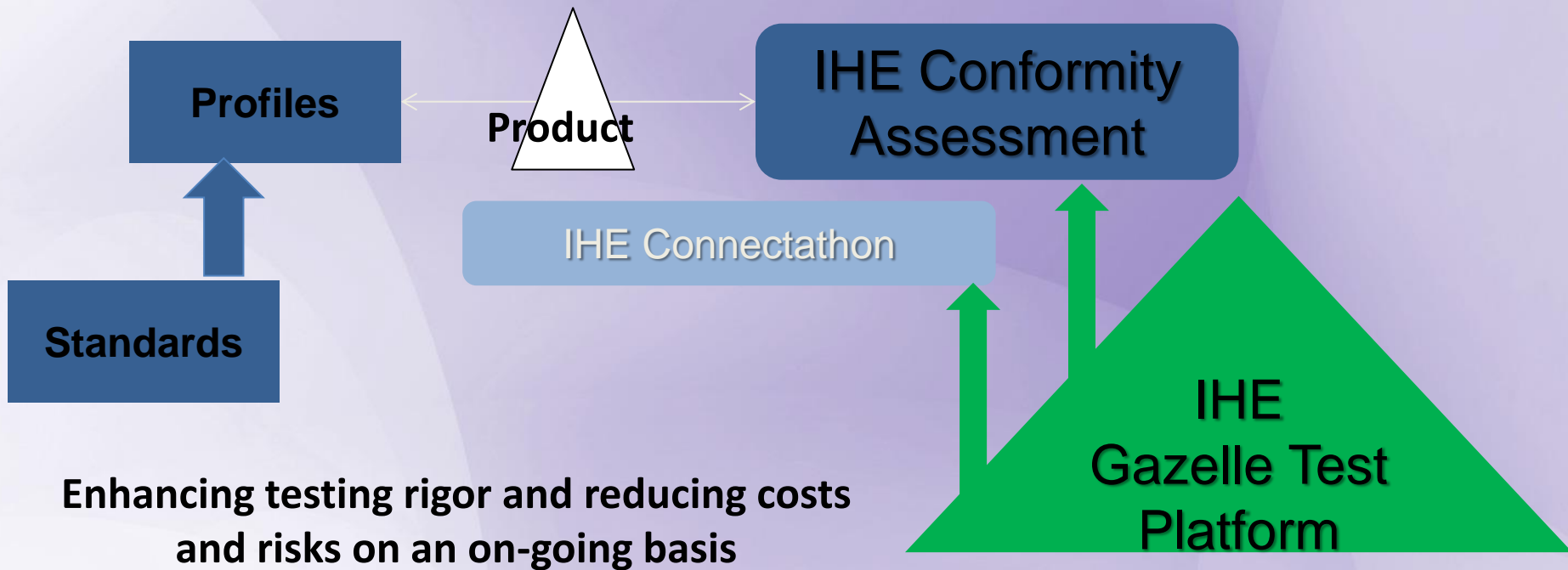
Elements of an IHE Conformity Assessment Scheme

- A single international scheme with delegation of accreditation operation testing at the national/regional level.
- Allows IHE National/Regional Deployment Committee to deliver a internationally recognized testing report based on transparency
- Testing of National extensions/combinations of IHE Profiles is to be addressed as a subsequent testing step (“projectathon” or ehealth project-specific interoperability specification).

IHE Conformity Assessment for who ?

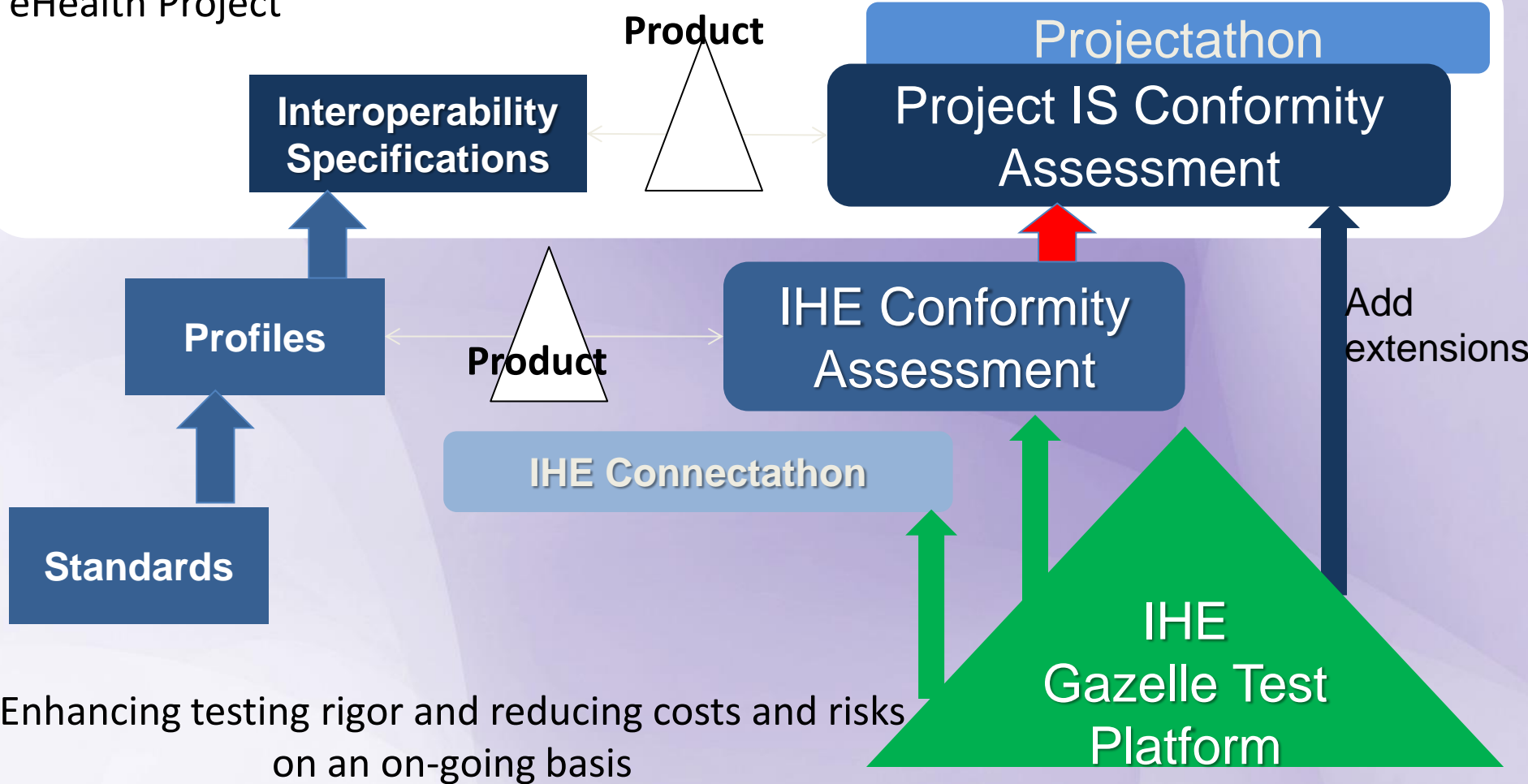
1. The larger eHealth Projects (national, regional, hospital network) that want to engage a broad number of vendors to supply products with IHE profile conformance. Use IHE Conformity Assessment as an entry criteria into procurement and project level lab testing (Projectathon).
2. The care delivery organization with simple interoperability projects (e.g. connecting devices to a Clinical System). Only a few profiles to be combined.
3. Vendors that want to avoid the overhead of retesting in each project at the profile level.

IHE overall Contribution (1)



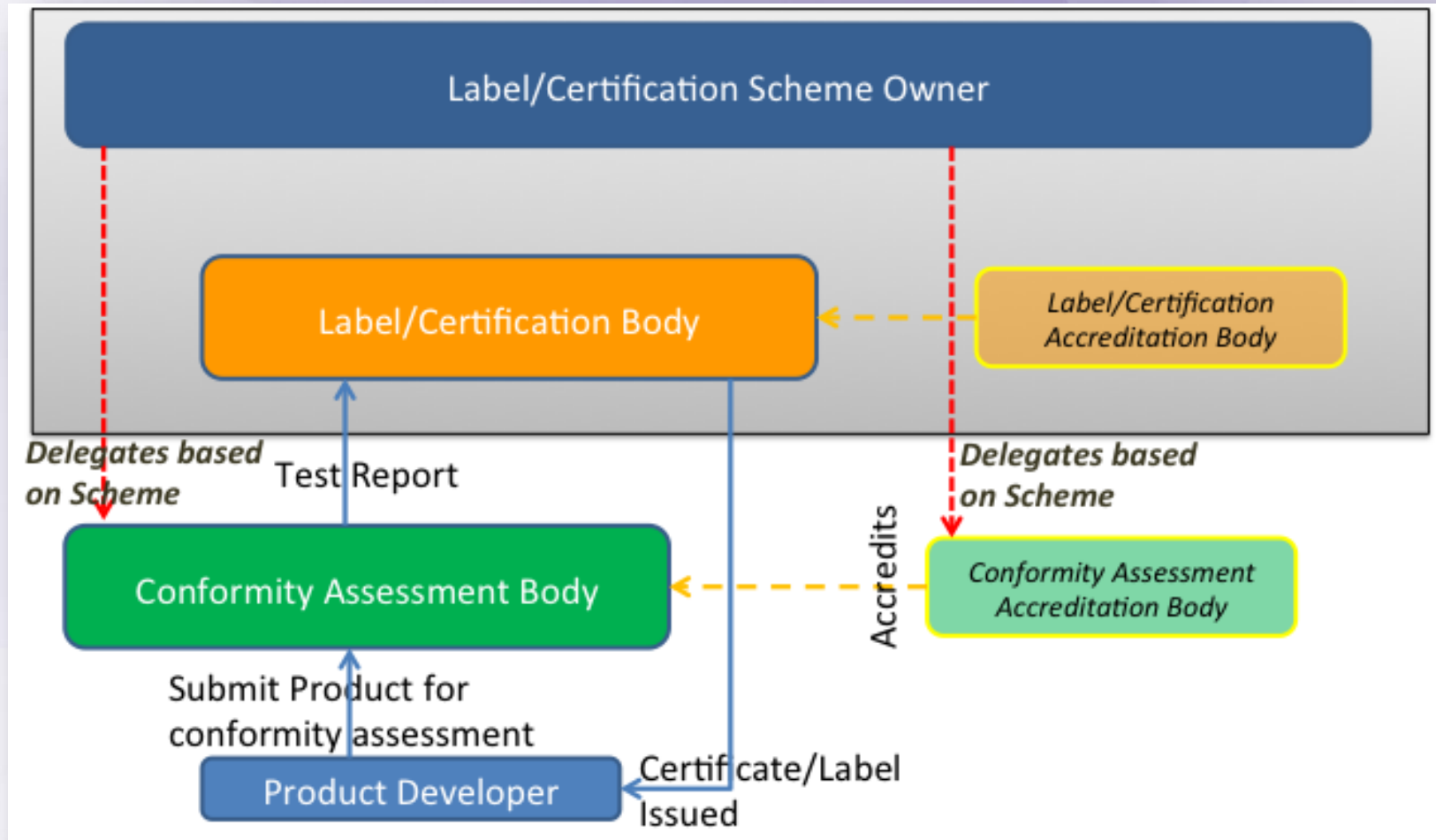
IHE overall Contribution (2)

eHealth Project



Implementation: Model 1

Labeling by eHealth project using accredited testing lab(s)





- Next Connectathon:
 - Companies can register their system for the first conformity assessment testing
 - Kereval, the testing laboratory is a ISO/IEC 17025 laboratory



Questions ?