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Genomic testing & personalized medicine

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myriad
WHEN DECISIONS MATTER

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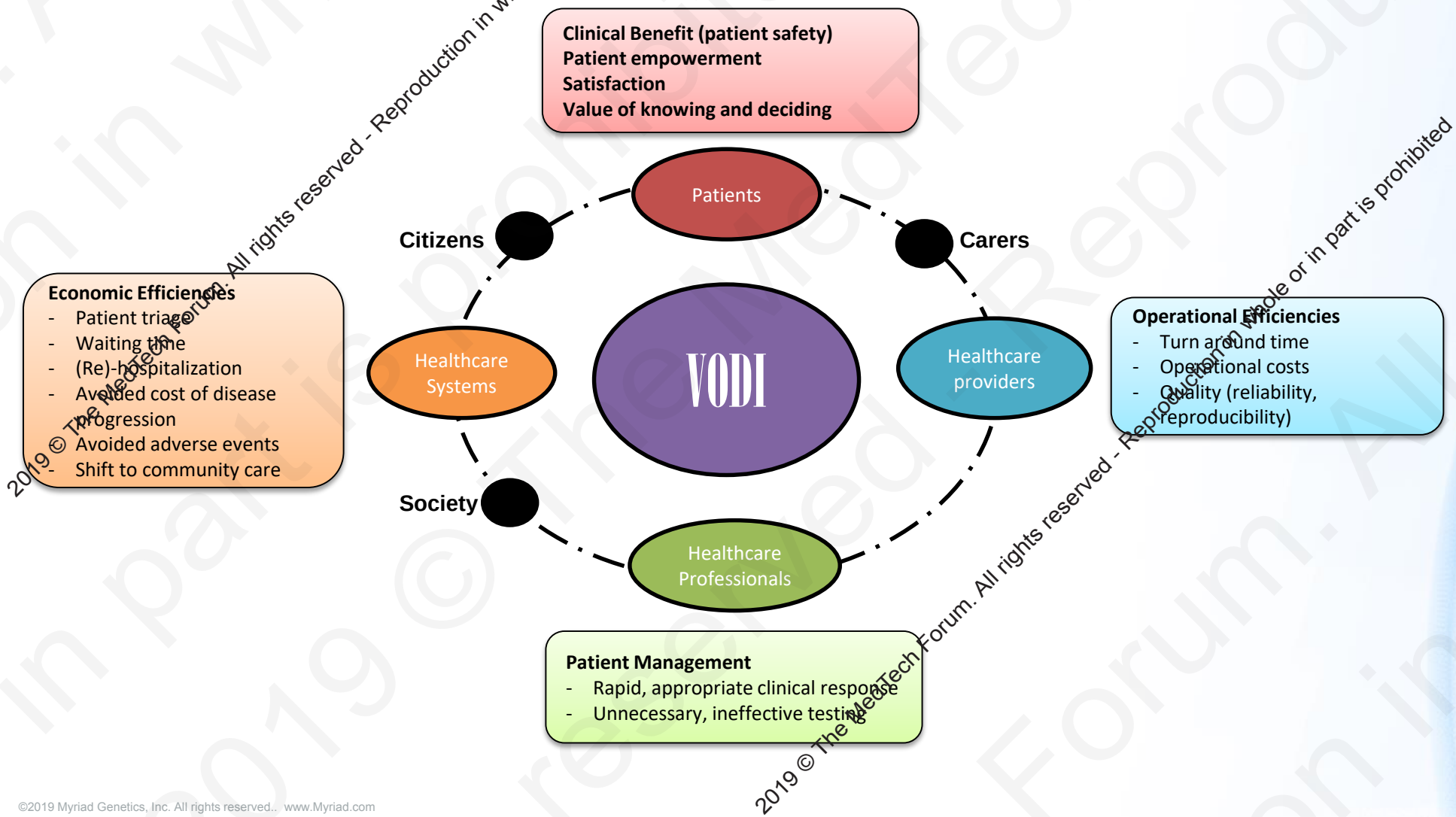
We know that diagnostic Information Brings Multidimensional Value

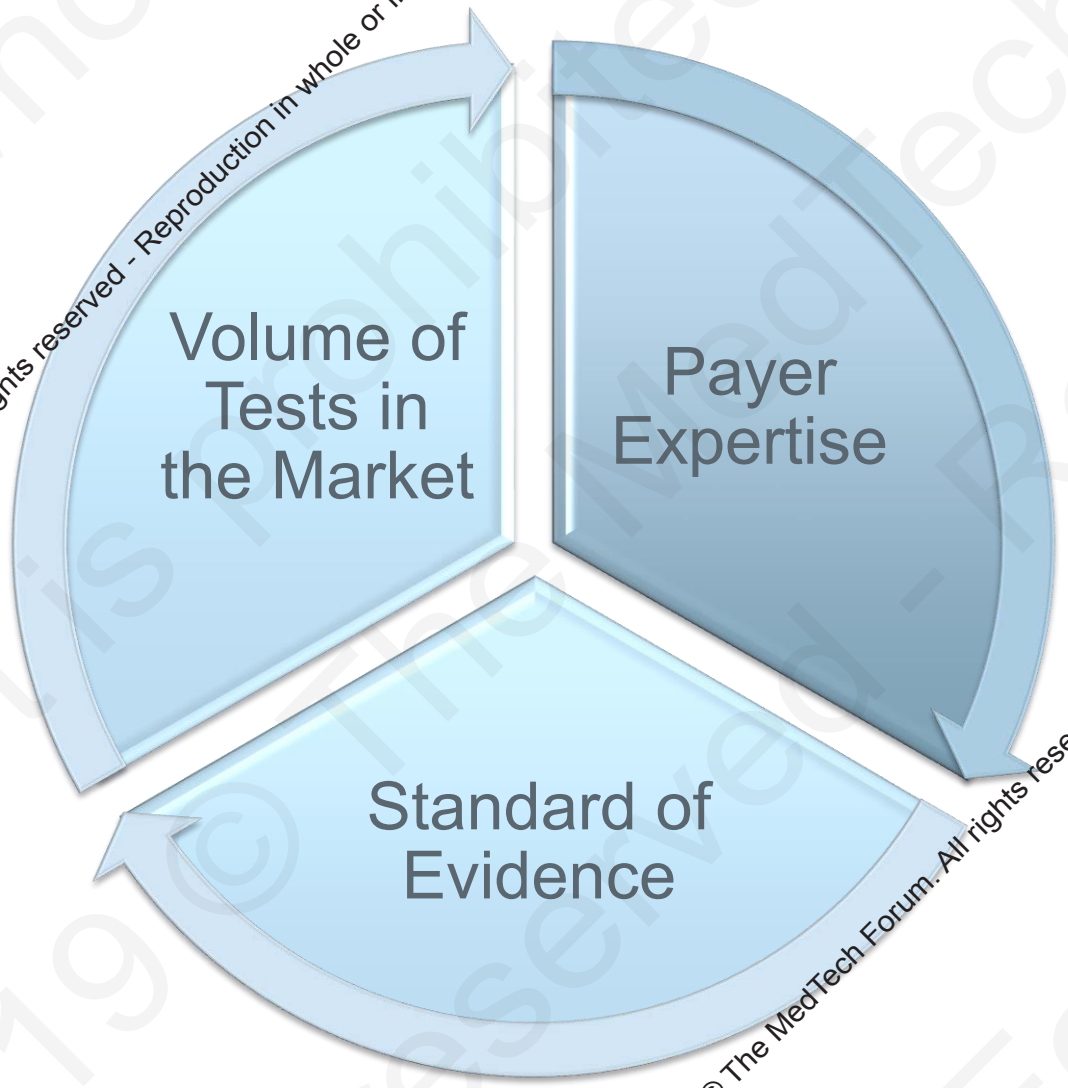


However significant challenges remain in value assessment for IVDs

France is a good example of current trends in Europe

- Pathways for IVDs are in Iteration
- There is an increasing demand of demonstration of cost-effectiveness
- Request of real-world data is increasingly used to support access decisions
- The IVDR will result in an increased interplay and data-sharing between regulatory and HTA bodies
- Collaboration with Stakeholders is essential

Work together to address the potential of Personalized Medicine – IVDs & Molecular Genetic Testing are a great case study



The Need for Collaboration

Personalized medicine is entering a hyper-growth phase

Molecular diagnostics & IVDs are the keystone to improving patient outcomes and eliminating wasted spend

IVD companies will innovate and must partner with health systems and payers

IVD, Genomic testing & personalized medicine : common issues to be solved all over Europe?

- The lack of knowledge of the sector and its role by the authorities with, consequently, a lack of recognition at its fair value
- The obsolescence of the assessment methodology, because of the current holistic approach, does not allow to differentiate technical service, intellectual act and medical advice
- The lack of valorization of the technological solutions developed by the industry, for lack of a procedure of direct access to the regulatory authorities
- The dysfunctional innovation support mechanisms which no longer allow the introduction of new technological solutions
- Malfunctions on the continuum of the taking over of the acts which prevent any dynamic management of the nomenclatures
- The evolution of the European regulatory context for which compliance with the new regulation will require a major effort
- Regulation that seems more to be part of an accounting logic than a medical one