



Regulatory pathways for medical devices products in the post-covid area

Philippe Auclair, Abbott

GHWP TC Industry Advisor



Science & technology
evolution

Urgent reply to healthcare
crisis

Need for agility

Possible early wins to
adjust regulations

Regulatory capacity
building and reliance

Example: Diabetes monitoring – Europe 19th century



A physician examining a urine flask brought by a young woman. Oil painting, 19th century, after Hendrik Heerschop -The Wellcome Collection , London

Diabetes monitoring -end of 20th century- finger-prick test (*)



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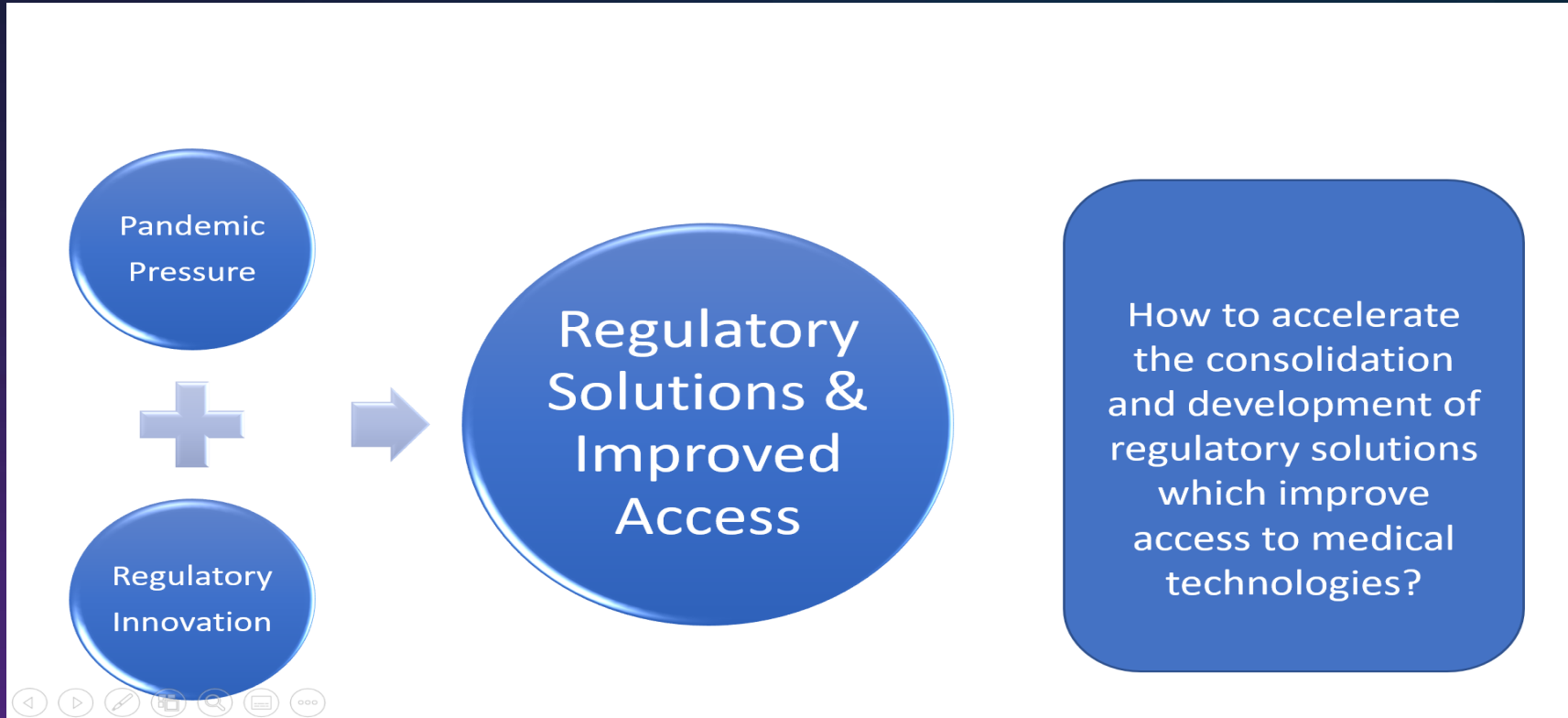
Diabetes monitoring today- wearable technology (*)



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Regulatory systems beyond the Covid pandemic



Immediate recommendations - “ low hanging fruits” (*)

- **RELIANCE**

Participate in a pilot for across countries premarket approvals reliance with industry involvement in the design and execution.

- **SIMPLIFICATION**

Encourage greater acceptance of MDSAP

- **NIMBLENESS**

Encourage acceptance of electronic labeling under a common format.

() GMTA 2023 April 2023*

The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology

*“When one door closes another door opens;
but we so often look so long upon the closed
door, that we do not see the ones which
open for us.”*



Alexander Graham Bell (1847-1922)



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