



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization



Medical Algorithm Amplify the early-stage signs of HCC

Asmaa Awad- Global Regulatory Policy EEMEA

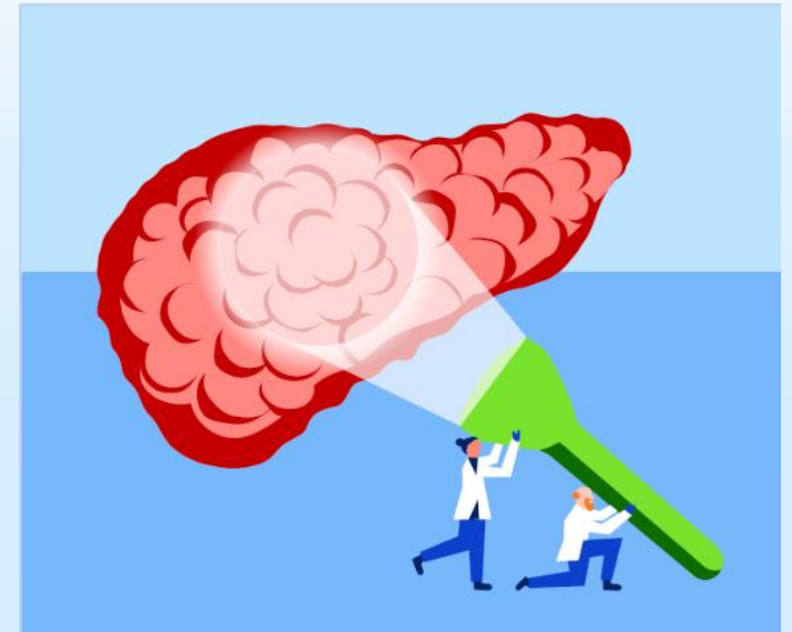
Roche Diagnostics

Liver cancer (HCC) is a global disease burden

If diagnosed early, the 5 year survival rate for HC increases significantly to 40-70%^{1,2}

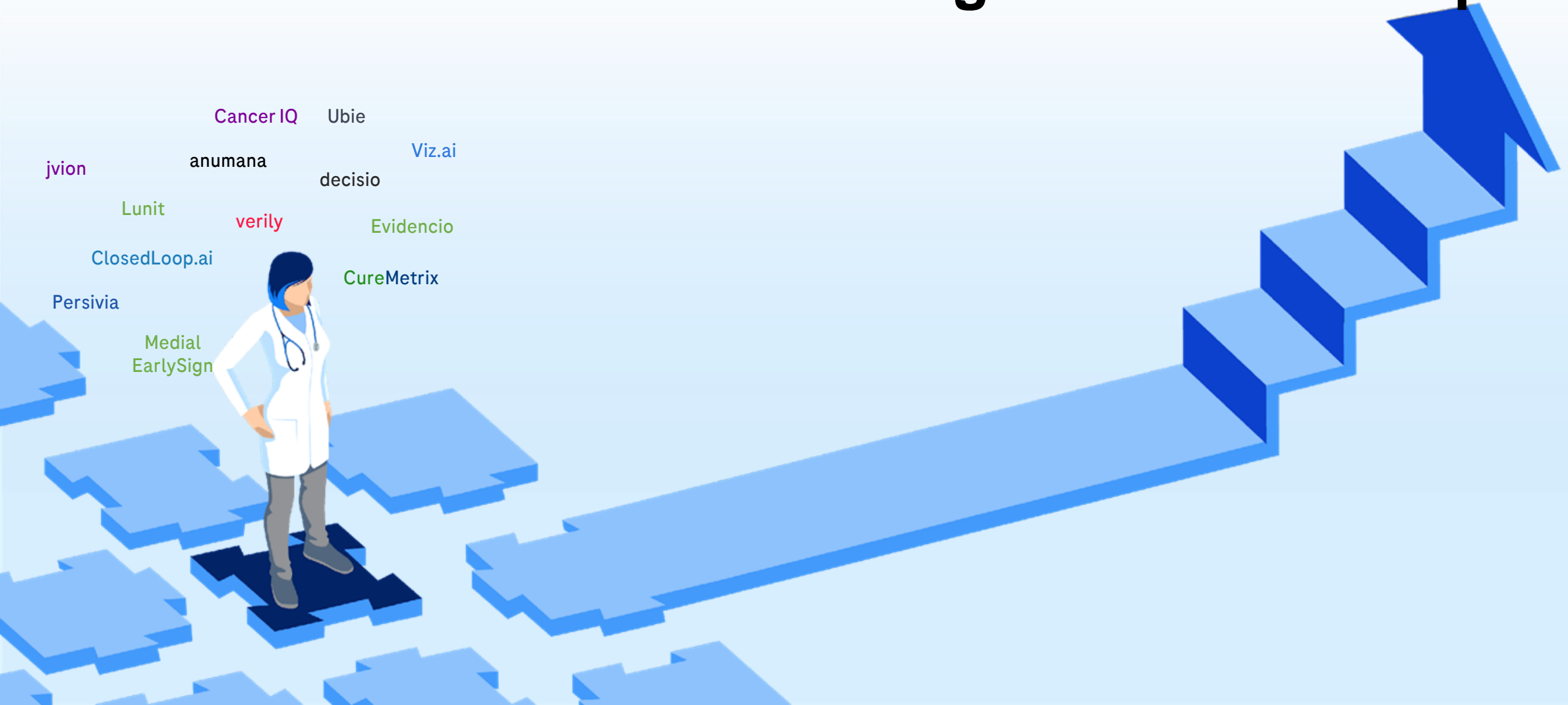
Occurring almost exclusively in patients with chronic liver disease³, HCC is most common form of liver cancer, accounting for nearly 90% of cases, and is also the third leading cause of cancer death.^{1,4,5}

We need to diagnose HCC earlier. In fact, in high risk groups, biannual screening has decreased HCC mortality by 37%.⁶



1. El-Serag HB et al. Surveillance for hepatocellular carcinoma: in whom and how? *Ther Adv Gastroenterol* 2011; 4: 5-10.
2. Kao, Wei-Yu et al. "Prognosis of Early-Stage Hepatocellular Carcinoma: The Clinical Implications of Substages of Barcelona Clinic Liver Cancer System Based on a Cohort of 1265 Patients." *Medicine* vol. 94,43 (2015): e1929.
3. Bartosch B. Hepatitis B and C Viruses and Hepatocellular Carcinoma. *Viruses* 2010;2:1504.
4. Llovet JM et al. Hepatocellular carcinoma. *Nat Rev Dis Prim* 2016;14:2:16018.
5. Ferlay J, et al. (2020). *Global Cancer Observatory: Cancer Today*. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.fr/today>, accessed August 2021.
6. Zhang BH et al. Randomized controlled trial of screening for hepatocellular carcinoma. *J Cancer Res Clin Oncol* 2004;130: 417-22.

How do we create value in a fragmented landscape?

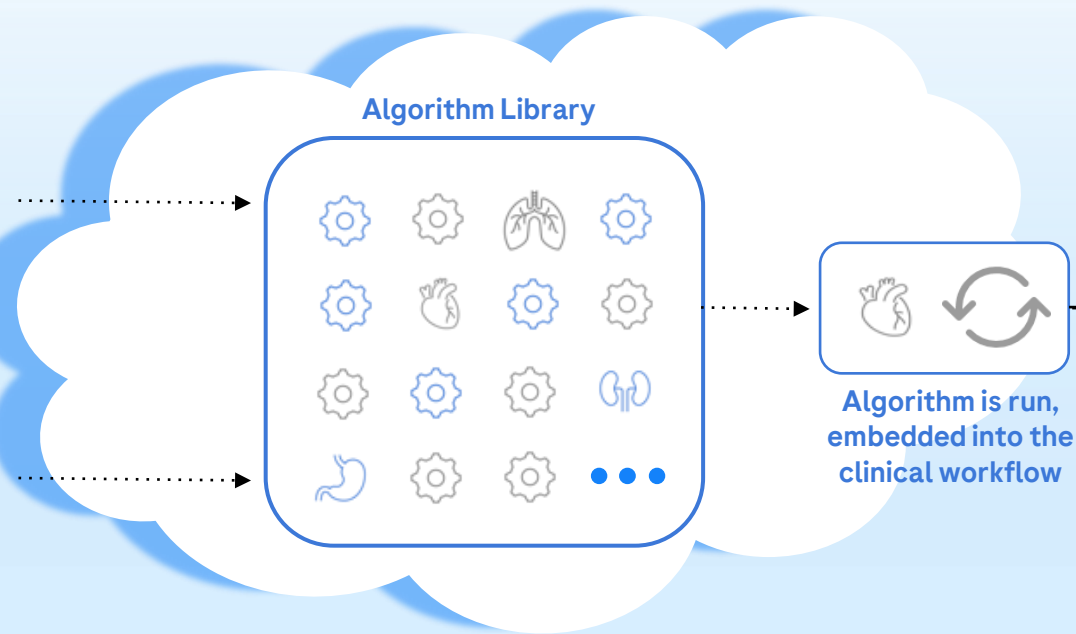




Algorithm Suite

A one-stop shop
cloud-based Platform

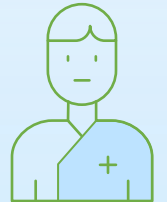
Algorithm Sources



Hospital



Patient



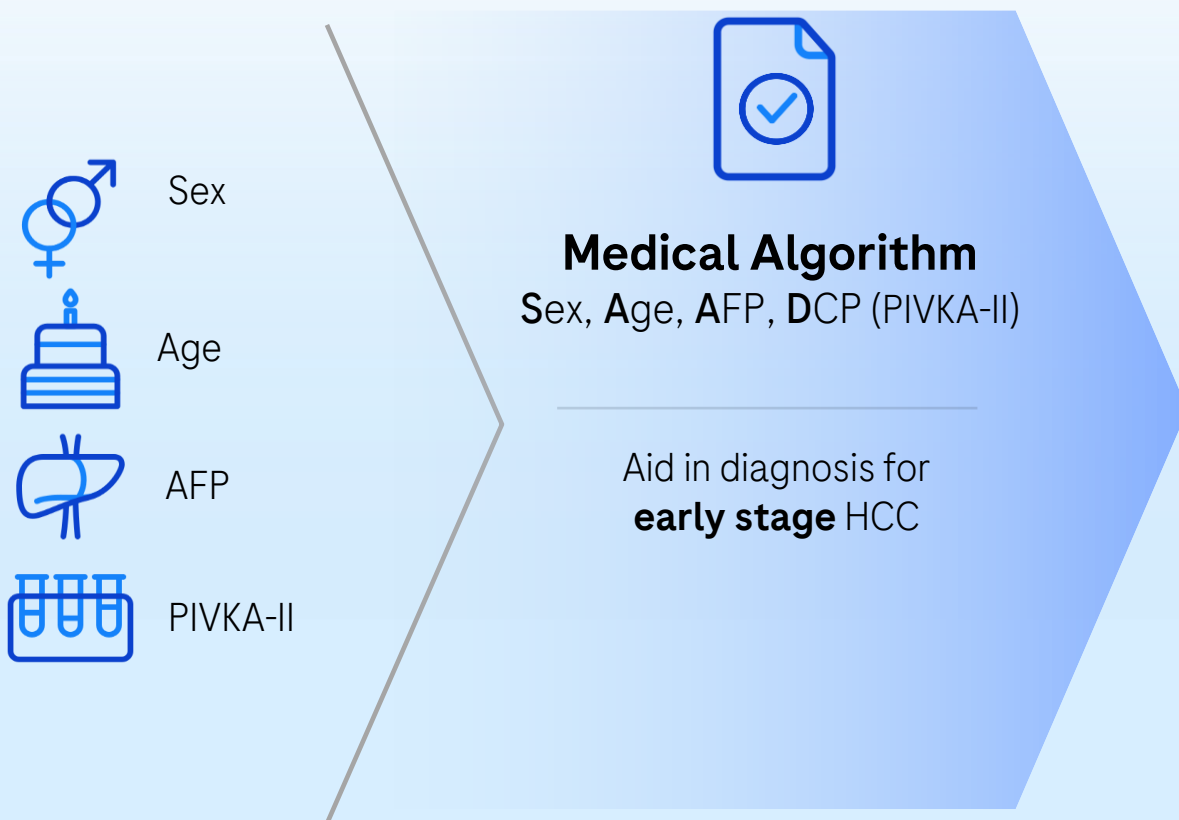
Algorithm Output Informs
for Clinical decision



Lab

Medical Algorithm

1st multivariate surveillance HCC test



Both biomarkers on a **fully automated IVD** platform¹



Clinical performance demonstrated in early evaluation in publication²



Superior performance to AFP alone²

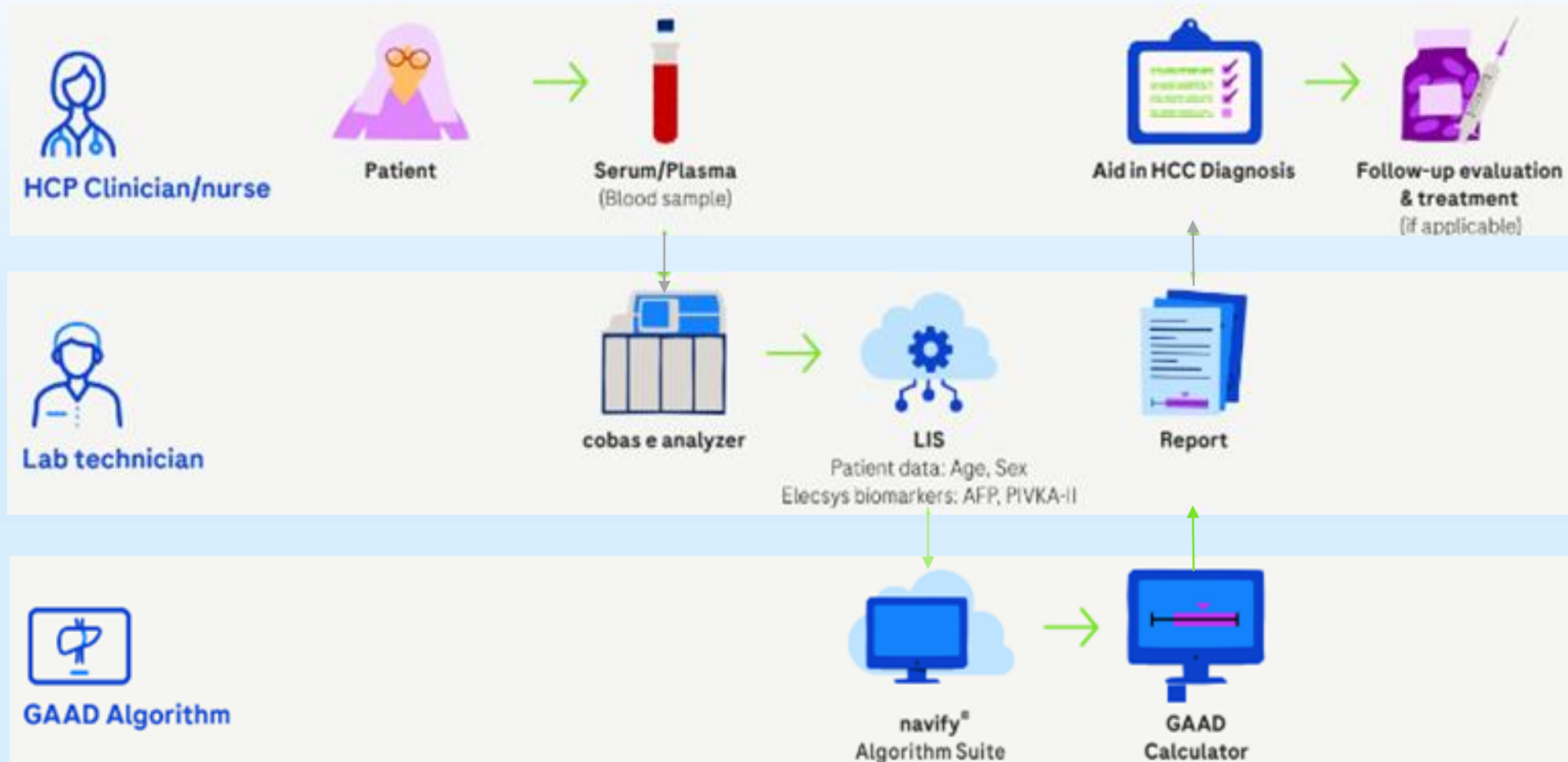
PRECAUTION: Assay results from other manufacturers have not been validated for the use of the Elecsys[®] GAAD test. The Elecsys[®] GAAD test should not be used without an independent clinical/radiological evaluation for the diagnosis of Hepatocellular Carcinoma (HCC). For each Elecsys[®] GAAD determination the measurement of the Elecsys[®] AFP and Elecsys[®] PIVKA-II assays must be determined from the same sample and measurement performed on the same analyzer type (either on **cobas e 402**, **cobas e 411**, **cobas e 601**, **cobas e 602** or **cobas e 801** analyzers)

¹ Elecsys[®] GAAD Method Sheet

² Chan et al. (2022) Poster 3345 Presented at EASL ILC 2022, 22-26 June, 2022. International Liver Congress

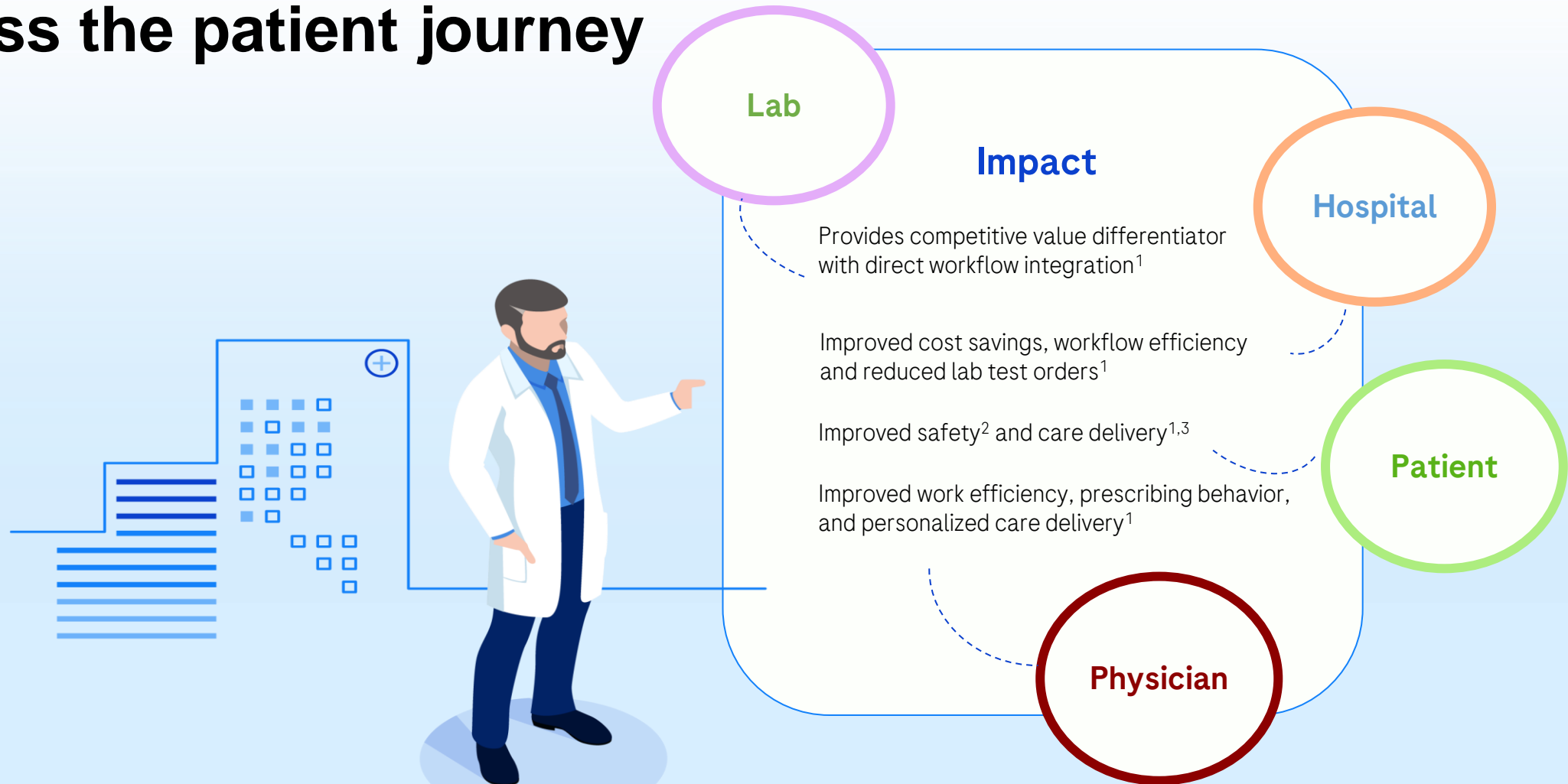
Seamless workflow integration

GAAD integrates directly into the current workflow with navify Algorithm Suite





Medical algorithms support clinical decision-making across the patient journey



1. Muhiya Addin, R. et al. 'The Impact of Clinical Decision Support Systems (CDSS) on Physicians: A Scoping Review'. 2020 June 26;272:470-473; <https://pubmed.ncbi.nlm.nih.gov/32604704/>

2. Sutton, R.T. et al. 'An overview of clinical decision support systems: benefits, risks, and strategies for success'. npj Digital Medicine (2020) 3:17; <https://www.nature.com/articles/s41746-020-0221-y>

3. Basile, J. 'Clinical Inertia and Blood Pressure Goal Attainment'. The Journal of Clinical Hypertension. 2009. SUPPL. 1 VOL. 11 NO. 12; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8673201/3>



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization



**Thank
You!**

Asmaa Awad

asmaa.awad@roche.com