



HBV Forum 2 April 18th 2017 Hilton Amsterdam





Working Group Update: Diagnostics & Biomarkers

Diagnostic & Biomarkers WG

Ed Marins

Introduction

Working Group Charge:

- Map out the markers that might be needed for drug development and approval
- Review and discuss potential regulatory paths for these

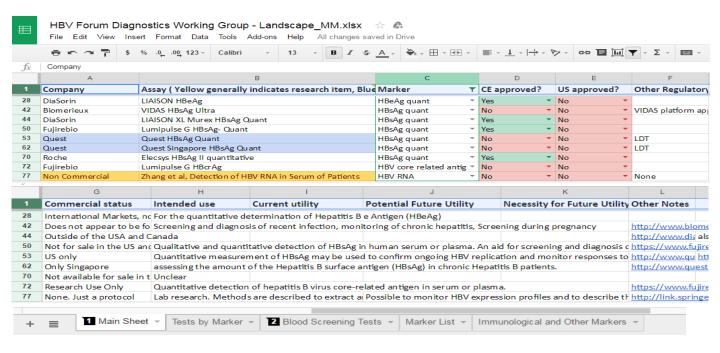
Activities

- Identify what is the current regulatory approval status of the different HBV markers:
 - Spreadsheet created and reviewed by the WG
- Review and discuss potential regulatory paths for these markers:
 - Prioritize the markers that are not CE and/or FDA approved to discuss what would be the regulatory pathway to get them registered and what different approaches could be used to try to expedite their availability

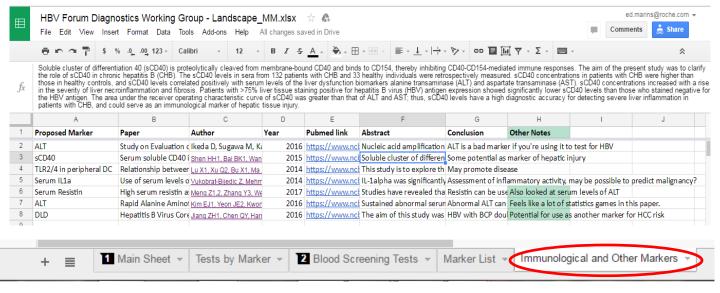
Outcomes and Products

- List of regulatory Status for HBV markers:
 - https://docs.google.com/spreadsheets/d/17YRNg 1d12fFW1qmcDq5gmifUuQiAcd4p8D7aYvMvco0/ edit#gid=1540366547

Regulatory Status of HBV Markers



Regulatory Status of HBV Markers



Other

- On-going activities:
 - Review Article: Overview of HBV diagnostics (Maria Ma)
- Next steps:
 - Prioritization of unregistered markers
 - Connect with the other WG to validate priorities and discuss clinical utility of new markers

Questions









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