



HBV Forum 1 November 15th 2016 Hyatt Regency Hotel Boston





WG Update: Diagnostics & Biomarkers

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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 following tests, if any:
 - Anti-HBc, Anti-HBs, qHBsAg, qHBeAg, HBcrAg, HBsAb/Ag complex, HBsAg Epitope Mapping, HBV DNA, HBV cccDNA, HBV RNA, HBV Genotype, HBV Resistance, HBV CP/BCP, Markers of inflammation and HCC
- Perform a systematic review of the literature supporting performance and utility of potential tests
- Identify if there are similar markers in other diseases e.g. HIV, CMV and the pathways used for their registration



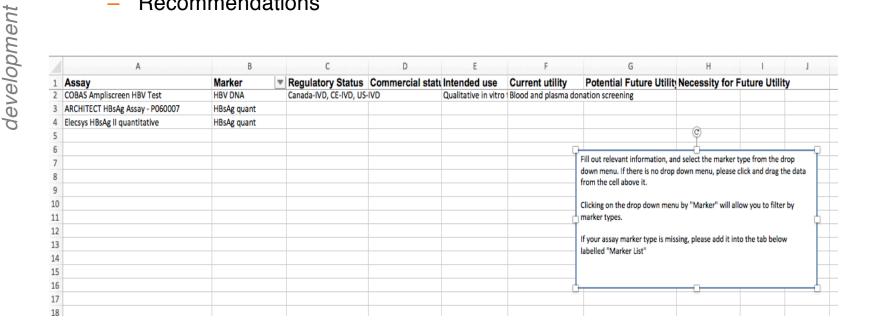
Outcomes and Products

- Markers Assessment Spreadsheet
- Review Article(s)
- Recommendations
 - Registration path(s) for key identified markers pending registration



Timelines

- Markers Assessment Spreadsheet
- Review Article(s)
 - HBsAg quant
 - Other key markers identified in the Spreadsheet
 - Recommendations





Other activities

- On-going activities
 - Markers Assessment Spreadsheet under completion
- Next steps
 - Start HBsAg quant literature review
 - Identify Lead author
 - Complete Marker Assessment Spreadsheet and start prioritization
 - Align prioritization with Surrogate Endpoints Working Group
- Additional members?



Questions

Facilitating collaborative research in drug development and health policy

