

The **TELEMETRIC** *and* **HOLTER ECG** **WAREHOUSE** *Project*

URMC/FDA Proposed Project for Cardiac Safety Research and Integration of Telemetric/Holter Data to Regulatory Review

AGENDA

- 13:00-13:10** **Introductory Comments – *N Stockbridge***
- 13:10-14:00** **The Telemetric and Holter Warehouse Project - *JP Couderc***
- 14:00-15:15** **Interest of Using Holter Technologies in Cardiac Safety Studies**
- Continuous 12-lead ECG Recording in Clinical Trials**
Justin Mortara (Mortara Instrument)
- Holter Technology in Drug Safety: A Technical Point of View**
Fabio Badilini (AMPS LLC)
- Advantages of 12-lead Holter Technology in TQT Studies**
Marek Malik (on behalf of GE Health Care Inc.)
- ECG Restitution of the Beat-to-beat QT-TQ Intervals in Humans**
Anthony Fossa (Pfizer Inc.)
- Holter-Based Methods for Improved Cardiac Safety Assessment**
Mikael Totterman (iCardiac Technologies Inc.)
- 15:15-15:30** **Break**
- 15:30-15:45** **CSRC : Involvement and Update - *P Kligfield***
- 15:45-16:00** **FDA Perspectives - *N Stockbridge***
- 16:00-17:00** **Discussion**

