

# Optimizing Digital Data Collection and Warehousing

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## An Industry Perspective

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# What can ECG devices do today?

- Generally ECG devices produce printed ECGs and electronic versions of them, e.g. PDF or TIFF files
- Some devices provide **display quality waveform data** that can be drawn by other ECG display software
  - Often heavily filtered, e.g. 0.5 – 35 Hz
  - May only include enough waveforms to draw 3x4 layout, e.g. 2.5 seconds of most leads
- These are only suitable for physician viewing, **not for research**

# What can ECG devices do today?

- Some devices can provide **research quality** waveform data that can be further analyzed by other ECG software
  - Unfiltered, e.g. 0.05 – 150 Hz, or 0.05 – 300 Hz
  - Includes all leads, e.g. 10 seconds of all 12 leads
- These devices can also provide automatic analysis:
  - Heart rate
  - PR interval, QRS duration
  - QT, QTc
  - P-QRS-T axes
  - Interpretation
- These are **suitable for research** purposes

# ECG Data Standards

- **HL7 Annotated ECG**
  - Intended as export format from research tools, not devices
  - Standard measurements and interpretation not widely supported by vendors
- **SCP ECG**
  - Fewer manufacturers supporting it
  - Implementations vary
  - Lossy compression may affect research quality of waveforms
- **DICOM ECG Waveform**
  - More manufacturers starting to adopt it; endorsed by IHE
  - Supports all features needed for research
  - More likely supported by image archives that also store ultrasound images

# ECG Demographics

- Required ECG demographics
  - **Unique Screening ID** – for linkage to **other screening data**
  - **Age** – for interpretation algorithm
  - **Sex** – for interpretation algorithm
  
- Optional ECG Demographics for linkage to **other patient records**
  - Name
  - Birthdate
  - Full or partial SSN
  - Birthplace

# Unique Screening IDs

- Suggested method for making globally unique IDs
  - Organization ID
  - Event ID
  - Subject ID
- **ORG-EVNT-SUBJ**
- Using a field separator allows variable-length IDs
- An organization would be responsible for assigning the unique Organization IDs

# Need an ECG data custodian...

- Support an easy way to submit data over the web
- Encrypt transport and storage of data
- Establish supported data format and validate submitted data accordingly
- Establish way to submit additional information about ECGs, e.g. CSV files
  - Subject identification
  - Other data collected during exam
  - Links to other data stored elsewhere, e.g. ultrasound images
- Establish a way for researchers to request anonymous data
- Establish a way for researchers to request subject identifiers

# FDA ECG Warehouse

- Pros
  - Established method for uploading data
  - Validates data before import
  - Secure place for long-term storage
  - Access control down to users and studies
- Cons
  - Only stores aECG files
  - Visualization and analysis tools tuned for FDA's Thorough QT needs
  - Not optimized for extracting research data sets



# Call to Action

- Publish requirements for “research quality” ECG data
- Help screening organizations evaluate their existing ECG solutions
- Identify a data custodian
- Support custodian in developing requirements and testing solution
- If necessary, create solutions to translate and transport existing and future data to data custodian
- **Let's go!**