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!