Data Analytics & Machine Learning in Healthcare

solutions for biotech & medical devices industry
Arvind Ananthan
A Brief introduction

- M.S.E.E – Signal/Image Processing, Machine Learning

- 14+ years of technical, marketing, and business expertise

- Medical Devices Industry Manager since 2012
  - Worldwide responsibility
  - FDA and regulatory affairs
Cheaper, Plenty, Everywhere

1. Low-cost and powerful sensors.
2. Lots of data. Health data.
3. Storage and computing is cheaper.

... but how about using smart algorithms to process all this data to achieve better patient outcomes?

MATLAB & Simulink form a technical foundation for this fusion and transformation.
Medtronic launches smartphone App enabling diabetics to remotely monitor their condition

Fierce Medical Devices 28th September 2015

APPLE’S RESEARCH KIT IS A NEW WAY TO DO MEDICAL RESEARCH

The Wired March 9th 2015

GOOGLE TAKES ON THE CHALLENGE OF MAKING ROBOT SURGERY SAFER

The Wired March 30th 2015

Quest Diagnostics launches patient analytics tool for healthcare providers

Fierce Medical Devices September 30th 2015
Medtronic launches smartphone App enabling diabetics to remotely monitor their condition.

Quest Diagnostics launches patient analytics tool for healthcare providers.

IBM estimates images account for 90% of all medical data.

IBM's Watson deepens engagement with Apple, adds new customers.

Biogen CEO says tech aims to wearable and ingestible devices.

Quest Diagnostics launches patient analytics tool for healthcare providers.
Focus for today...

- **Examples of smart analytics for healthcare**
  - #1 Bio-signal acquisition and ECG processing
  - #2 Computer vision in biomedical imaging
  - #3 Machine learning for diagnostic classification

- **System development using Model-Based Design**
  - Quick overview

- **Certification and Regulatory Impact**
  - FDA’s views on modeling and simulation
Bio-signal Acquisition and processing

#1 Stream and process live ECG signal in MATLAB
Connect to low-cost Bitalino hardware using Bluetooth
Process ECG data to identify heart rate and other parameters
Patient Monitoring

Compute Heart Rate
Fine Location of QRS, ST, PR, etc.
Analyzing ECG signals

Using **Wavelets Toolbox**

**Explore** advanced algorithm ideas on different test ECG signals

**Identify candidates** for implementation

```matlab
%% Load ECG signal
load hECG; x = hECG(1300:5300);
load noisyECG; x = noisyECG(1:5000);

%% Create Continuous Wavelet Transform and plot the scalogram
wlets = {'rbio2.8', 'gaus2', 'db3', 'bior3.1', 'gaus8', 'sym8', 'mexh', 'dmey'};
wname = wlets{1}; scales = 10:5:350;
coefs = cwt(x,scales,wname);
s = wscalogram('contour',coefs,'scales',scales,'ydata',x);
```
Analyzing ECG signals

Using **Wavelets Toolbox**

**Implement streaming version** that can run on saved or live ECG signals

See MathWorks table for demo
Wearables that detect cardiac arrhythmias

“The **fixed-point** test platform we built with **MATLAB** enabled us to conduct rigorous tests at every stage and automatically identify discrepancies in the results.”

-VivaQuant

The arrhythmia service uses an FDA 510k cleared Holter recorder to non-invasively record a 24-hour or longer three-lead ECG.
#2 Measuring Drug Effectiveness from Motion Detection

Object recognition, and tracking

Quantification of movement to position \((x,y)\) and velocity
Pixels → Features → Object

Detection / Tracking / Classification

Image Pixels

Feature Extraction

Object Detection

Object Tracking

Object Classification
Using Vision System Objects

**simple video loop**

```matlab
%% Set up Input/Output Vision System Objects
vReader = vision.VideoFileReader('ZebraFish.avi'); %<--- Reader
vPlayer1 = vision.VideoPlayer('Position', [20, 400, 700, 400]); %<--- Player

%% Loop through frames
frameNumber = 0;
while frameNumber < 100 %
    frameNumber = frameNumber + 1;
    frame = vReader.step();
    frame = imcrop(frame,[225 220 672 235]); %<--- Standard function call
    vPlayer1-step(frame);
end

%%
% Release the objects used
release(vReader)
release(vPlayer1)
```

- Initialize vision objects
- Loop through frames
- Release objects
Using Vision System Objects

simple video loop + object detection
Using Vision System Objects

object detection + object tracking + motion analysis

See MathWorks table for demo
#3 Classify parasite type in blood smear images

Handle large sets of images

Develop and evaluate classifiers
Pixels $\rightarrow$ Features $\rightarrow$ Object

Detection / Tracking / Classification

- Image Pixels
- Feature Extraction
- Object Detection
- Object Tracking
- Object Classification
Machine Learning Workflow

Machine learning uses **data** and **produces** a **program** to perform a **task**

**Train:** Iterate till you find the best model

**Predict:** Integrate trained models into applications
Classification of Parasites in Blood

Step 1. Detect features

Class 1  Class 2  Class 3

Bag of Visual Words
Classification of Parasites in Blood

2. Create Classifiers with Machine Learning App

See MathWorks table for demo
Deploying Applications with MATLAB
MATLAB Beyond the Desktop

- **Share Applications**
- **Scale Computation**
- **Scale Data**
- **Integrate with Web & Enterprise**

- **MATLAB Compiler SDK**
- **MATLAB Production Server**
- **Support for Hadoop/Cloud Computing**

**Tools and Resources**
- MATLAB Compiler
- MATLAB Coder
- Parallel Computing Toolbox
- MATLAB Distributed Computing Server
Mobile healthcare app with cloud-based analytics

The AirSonea device connects to an asthma patient’s smartphone and communicates with wheeze analysis algorithms on iSonea’s server.

“MATLAB enables us to rapidly develop, debug, and test sound-processing algorithms, and **MATLAB Coder** simplifies the process of implementing those algorithms in C.

There’s no other environment or programming language that we could use to produce similar results in the same amount of time.”

- iSonea
Now that you have developed your smart algorithms...

How do you implement and verify in software...

...as part of the full system?
Model-Based Design
for safer and faster medical devices

RESEARCH

REQUIREMENTS

DESIGN

Environment Models
Physical Components
Algorithms

IMPLEMENTATION

C, C++
VHDL, Verilog
Structured Text
MCU
DSP
FPGA
ASIC
PLC

TEST AND VERIFICATION

Design as Executable Specification
Requirements Traceability
Continuous and early Verification
Document & Report Generation

INTEGRATION
Why Model-Based Design?

Weinmann Medical

**Developing and reviewing code for ventilators 50% faster**

“Model-Based Design enabled us to generate 100% of the embedded software... We also spent about 50% less time on internal review, because we worked with the models instead of low-level source code.” – Dr. Florian Dietz, Weinmann

ITK Engineering

**Accelerating dental drill motor development by 2x**

“We completed controller development in about four months. Without Model-Based Design it would have taken at least twice as long.” – Michael Schwarz, ITK Engineering

Philips Healthcare

**Reducing risk and accelerating FPGA design by 80x**

“Design changes that took us a week to hand-code in VHDL and test on hardware can be simulated and verified in 30 minutes with Model-Based Design.”

– Mark van Helvoort, Philips Healthcare
What about certification?

...and the FDA?
MBD as a new approach
January 2010

Model-Based Development: A New Approach to Engineering Medical Software
Arnab Ray and Raoul Jetley

With an increasing number of medical device features being implemented in code, the amount of software that is present in a modern device as well as its complexity and criticality has grown sharply over the years. Existing quality-control regimes for software, dependent as they are on traditional inspection and ad-hoc testing, are no longer able to meet many of these challenges. In 1998, close to 8% of devices were recalled due to software errors. Today, the rate of device recalls due to software issues has some to be about 18%.

Model-based development (MBD) as a candidate solution, a novel approach to software development and quality control. So what does model-based development mean for professionals working in the implementation field? Read on.

MBD has attained increasing popularity in the aerospace and automotive industry because of how it supports the production of better software.

Compilation
Auto-coding

Machine/Assembly language
(load, stores, moves)

Procedural/IO languages
(“high-level” constructs: guarded loops)

Executable modeling notations (captures “high-level” design information, portable and re-usable)

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FDA Suggests Model-Based Design for infusion pumps

~ 2011

The FDA has recognized that if product developers had tools that enable them to examine and evaluate software earlier in the development cycle, then there would be a greater likelihood that the resulting software would be more robust. Just as architects now have 3D modeling tools that allow them to take their clients on virtual tours of a new building before ground has been broken, the software engineering community has been developing tools for modeling software and its interactions with the system it controls. The safety properties of the model can be systematically examined, and once the model has been verified, the software derived from it can be proven to conform to the model. The result is software designs that are far more robust than those developed using traditional methods.
Research and Collaboration Agreement between MathWorks and CDRH
April, 2013

• Signed April 2013
• 5-Year validity
• Topics of focus
  • MBD
  • Formal software verification
• Principal Investigators
  • FDA: Paul Jones
  • MW: Arvind Ananthan

http://www.mathworks.com/tagteam/76380_80633v00_rcasummary.pdf
MBD Workshop for FDA @ MathWorks
September, 2014

• Experiential Learning Program (ELP)
• 2-Day Workshop conducted in Natick at MathWorks
• 10 attendees from CDRH (ODE/DAGRID)
• Collaboration with Dräger Medical, Germany
• Blog published in Medical Design Technology
PCLC Devices Workshop @ FDA’s campus
October 2015

• **Physiological Closed Loop Controller (PCLC) Devices workshop**
  • Organized by ODE members focusing on computational modeling and simulation activities
  • Focus on critical care devices (ventilators, anesthesia, etc.)

• Oct 13th and 14th @ FDA’s campus in Silver Springs

• MathWorks invited to participate and present on Model-Based Design

• Key industry thought leaders/researchers using MBD invited to present
Tool Validation Kit

- **IEC Certification Kit**
  - TÜV SÜD certificates and reports
  - Templates for delivering documentation to certification authorities
  - Test suites for tool validation/qualification

- **FDA Tool Validation Planning Kit** for MATLAB (prototype)
MATLAB & Simulink form a technical foundation for this fusion and transformation.

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