

MATLAB EXPO

2021

AI for Medical Devices Design and Digital Health

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Outline

Introduction to AI, Medical Devices & Regulations

Medical Device software challenges and how to overcome them

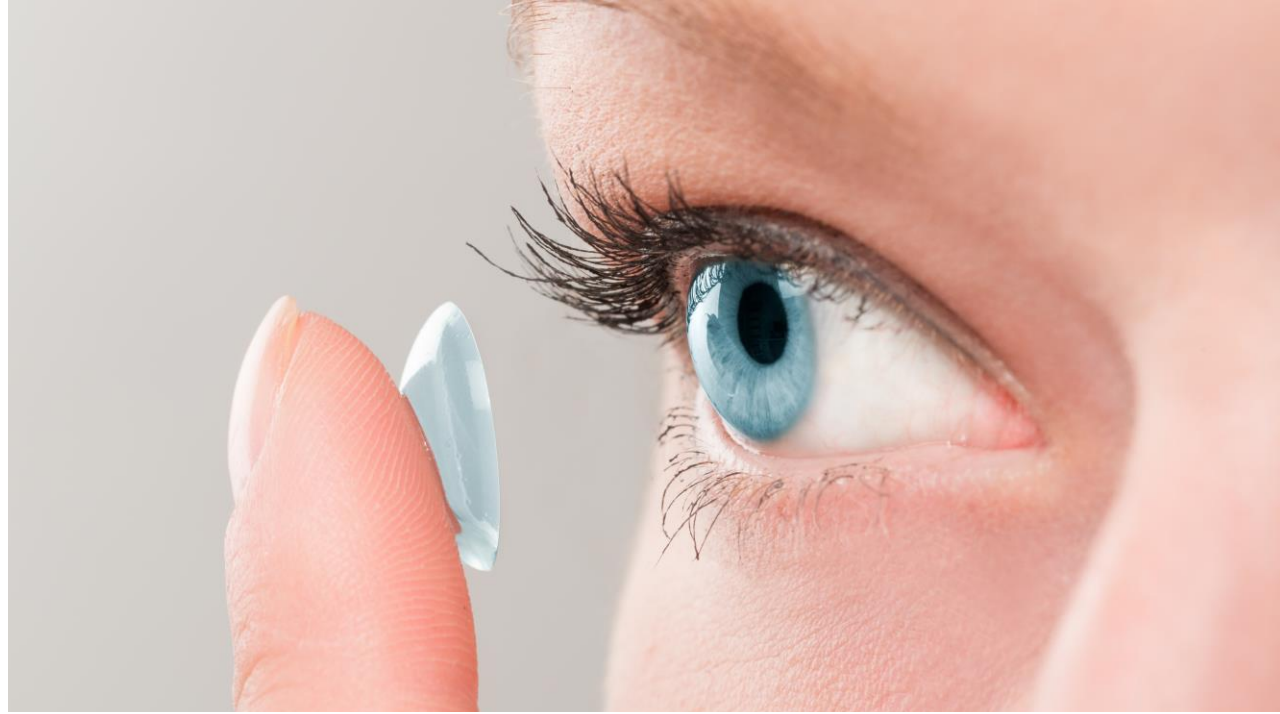
Customer Success Story

Key Takeaways

You don't need to be an expert in AI to develop smart algorithms for healthcare applications and get regulatory approvals

Use MATLAB & Simulink as a platform that:

- Manages the complexity of developing and deploying Medical Devices & Digital Health
- Addresses regulatory concerns by leveraging Model-Based Design
- Develops and optimizes AI models interactively



Existing Pathways to FDA Regulatory Approvals

PMA – Pre-Market Approval

- Section 515 of the FD&C Act. Most stringent of process – typically for Class 3 high safety devices.

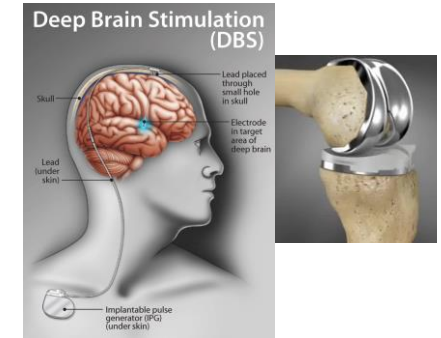
510K

- Applies to all submission that doesn't require a PMA, except those exempt from 510K.
- Compare their device similar devices in the market (predicates), and show it's at least as safe and effective as those predicates.

De-Novo

- Newer regulatory framework that address novel devices of low to moderate risk that do not have a valid predicate device and doesn't really need a PMA

Examples

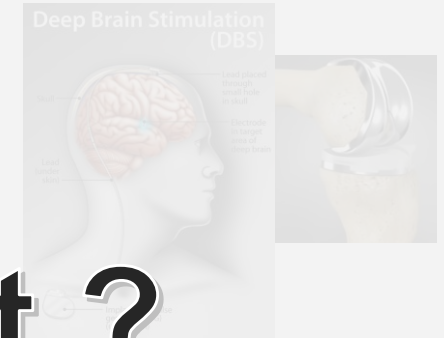


Existing Pathways to FDA Regulatory Approvals

PMA – Pre-Market Approval

- Section 515 of the FD&C Act. Most stringent of process – typically for Class 3 high safety devices.

Examples



510K

Where does Software Fit ?

- Apply to all devices unless specifically exempt from 510K, but those exempt from 510K.
- Compare their device similar devices in the market (predicates), and show it's at least as safe and effective as those predicates.



De-Novo

- Newer regulatory framework that address novel devices of low to moderate risk that do not have a valid predicate device and doesn't really need a PMA

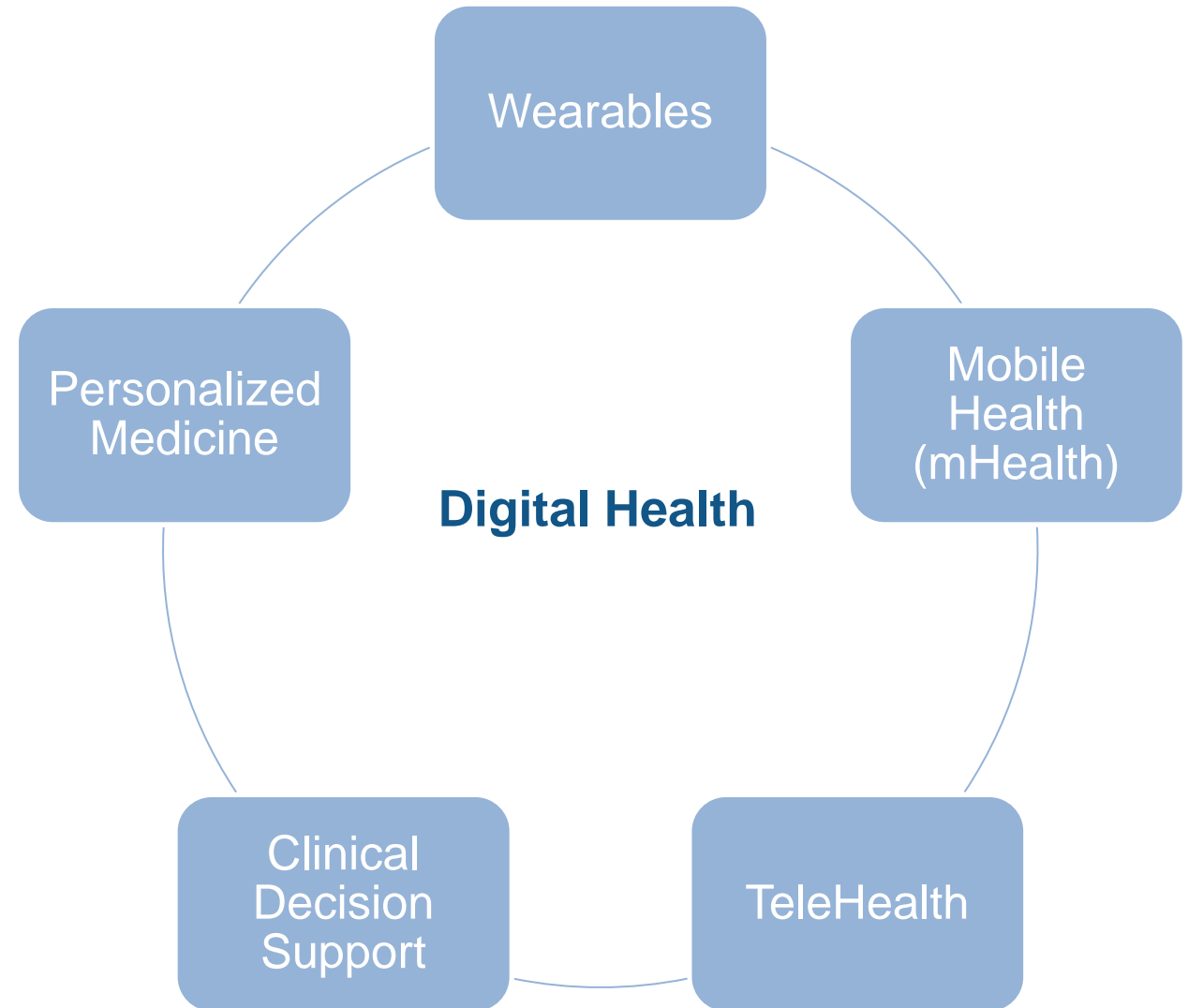


The Genesis of Software as a Medical Device

Medical Device Regulators Forum (IMDRF):

"Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

Poll #1 - What type medical device application are you working on?



FDA Encouraging use of AI/ML

- New Digital Health Center of Excellence at FDA
- Released AI based Software as a Medical Device (SaMD) Action Plan
- 2 AI enabled Ultrasound devices approved in 2020



FDA NEWS RELEASE

FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

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For Immediate Release: February 07, 2020

Outline

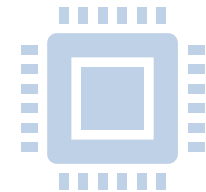
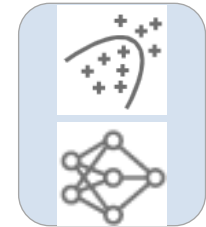
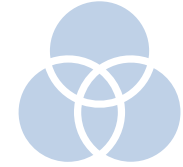
Introduction to AI, Medical Devices & Regulations

Medical Device software challenges and how to overcome them

Customer Success Story

Challenges in medical device software

- 1. Increase in complexity**
- 2. Lack of experience with AI**
- 3. System integration and deployment issues**
- 4. Rigorous V&V and certification^[1]**



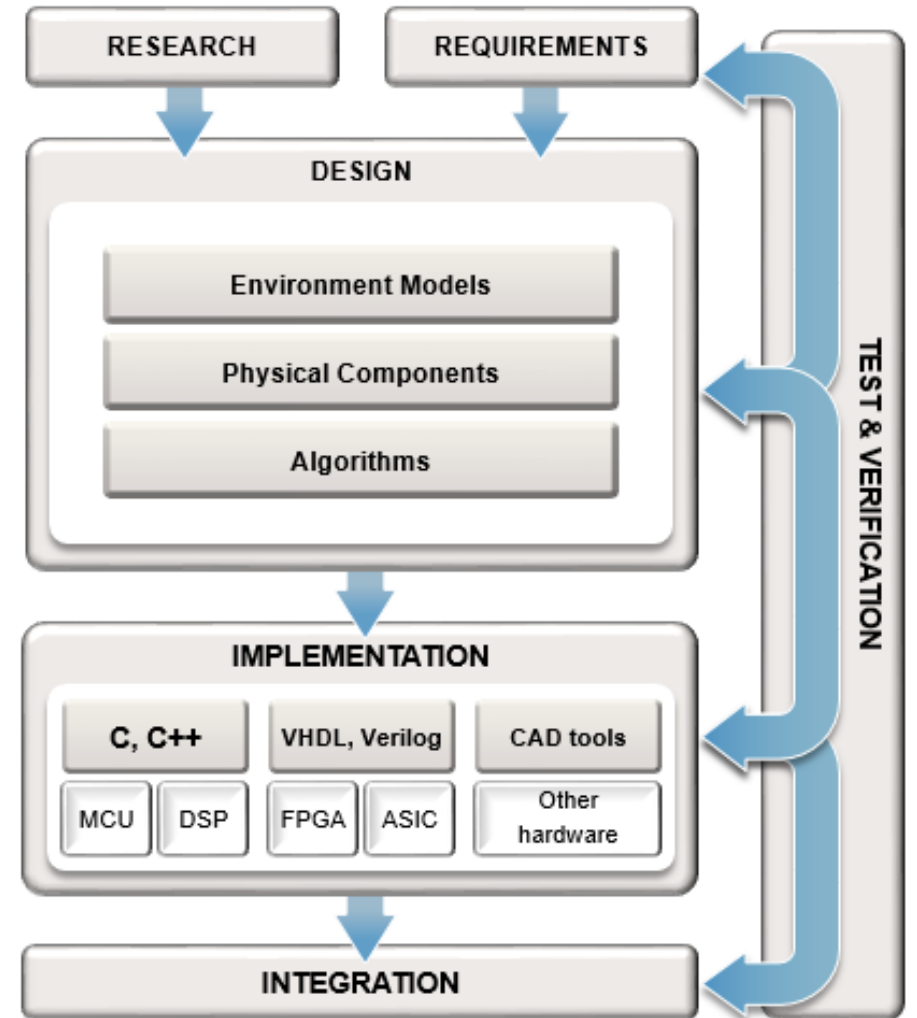
[1] <https://www.bbc.com/news/technology-56083231>

Challenge #1: Increase in complexity

Conquer Complexity with Model Based Design

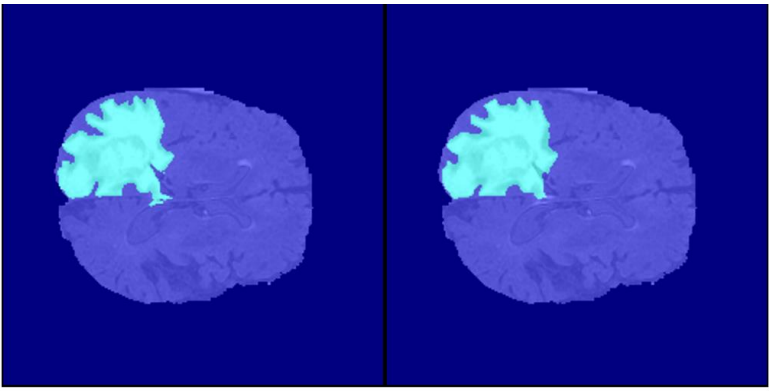
Model-based design workflows cover algorithm development through system design & test

Adopted by leading medical device companies

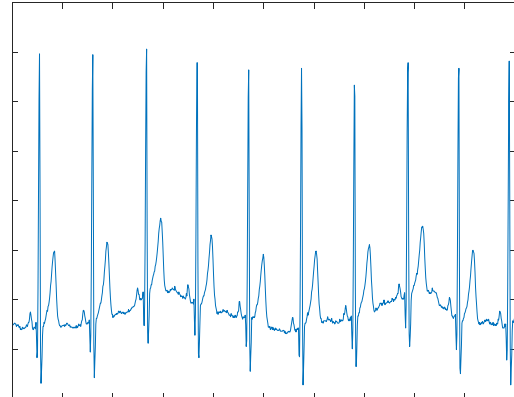


Build AI Models on Biomedical data

Image



Signal



Numeric

AgeCat	WeightQ	GroupCount	mean_BloodPressure
Under 30	Q1	6	123.17
Under 30	Q2	3	120.33
Under 30	Q3	2	127.5
Under 30	Q4	4	78
30-39	Q1	12	121.75
30-39	Q2	9	119.56
30-39	Q3	9	121
30-39	Q4	11	125.55
Over 40	Q1	7	122.14
Over 40	Q2	13	123.38
Over 40	Q3	14	123.07
Over 40	Q4	10	124.6

Text



Multi-omics

```

1 AACCCCGTCT CTACAATAAA TTAATAATTT AGCTGGGCAT GGTTGGTGT GCTTGTAGTC'
61 CCAGCTACTT GCGGGGCTGA GGTGGGAGAA TCATCCAAGC CTTGGAGGCA GAGGTTGCAG'
121 TGAGCTGAGA TTGTGACT GCACTCCAGC CTGGGAGACA GAGTGAGACT CCTACTCAAA'
181 AAAAAACAAA AAACAACAAA CAACCACAAA AACTTTCCAG GTAACTTATT AAAACATGTT'
241 TTTTGTGTTT TTTGAGACAG AGCTTGTCT TGTCGCCAG GCTGGAGTGC AGTGGAGCAA'
301 TCTCAGCTCA CTGCAAGCTC GCGCTCCCAG GTTCAACCA TTCTCTGCC TCAGCCTCCC'
361 GAGTAGCTAG GACTATAGGC ACCCGCCACC ACGCCAGCT TATTTTTTTT GTATTTTTTA'
421 GTAGAGACGG GGTTCATCG TGTTAGCCAG GATGGTCTCG ATCTCCTGAC CTCGTGATCC'
481 GCCCACCTCA GCCTCCCAAA GTGCTGGGAT TACAGGCGTG AGCCACTGCA CCCGGCTAG'
541 TTTTTGTATA TTTTTTTTAG TAGAGACAGG GTTTCACCAT GTTAGCCAGG ATGGTCTCAA'
601 TCTCCTGACC TCGTATCCG CCCGCTCGG CCTCCAAAG TGCTGGGGTT ACAGGCGTGA'
661 GCCACCGCAC ACAGCATTAA AGCATGTTTT ATTTCTTAC ACATAATGAA ATCATTACCA'
721 GATGATTGGA CATGTGACT TCATTGGAGA GGATTCTTAC AGTATATCA AAATTAATA'
781 TAATGACAAA AAATTACTAC CTAATCTATT AAAATTGGCA TAAATCATCT ATGATCATT'
841 ATGATATGCA AACATAACA AGTATTATAC CCAGAAGTGT AATTTATTGT AGCTACATCT'
901 TATGTATAAT AGTTTAGTGG ATTTTCTCTG GAAATTGTCC ATTTTAATTT TTCTCTTAAG'
961 TCTGTGGAAT TTTCCAGTAA AAGTCAAGGC AAACCAAGA T

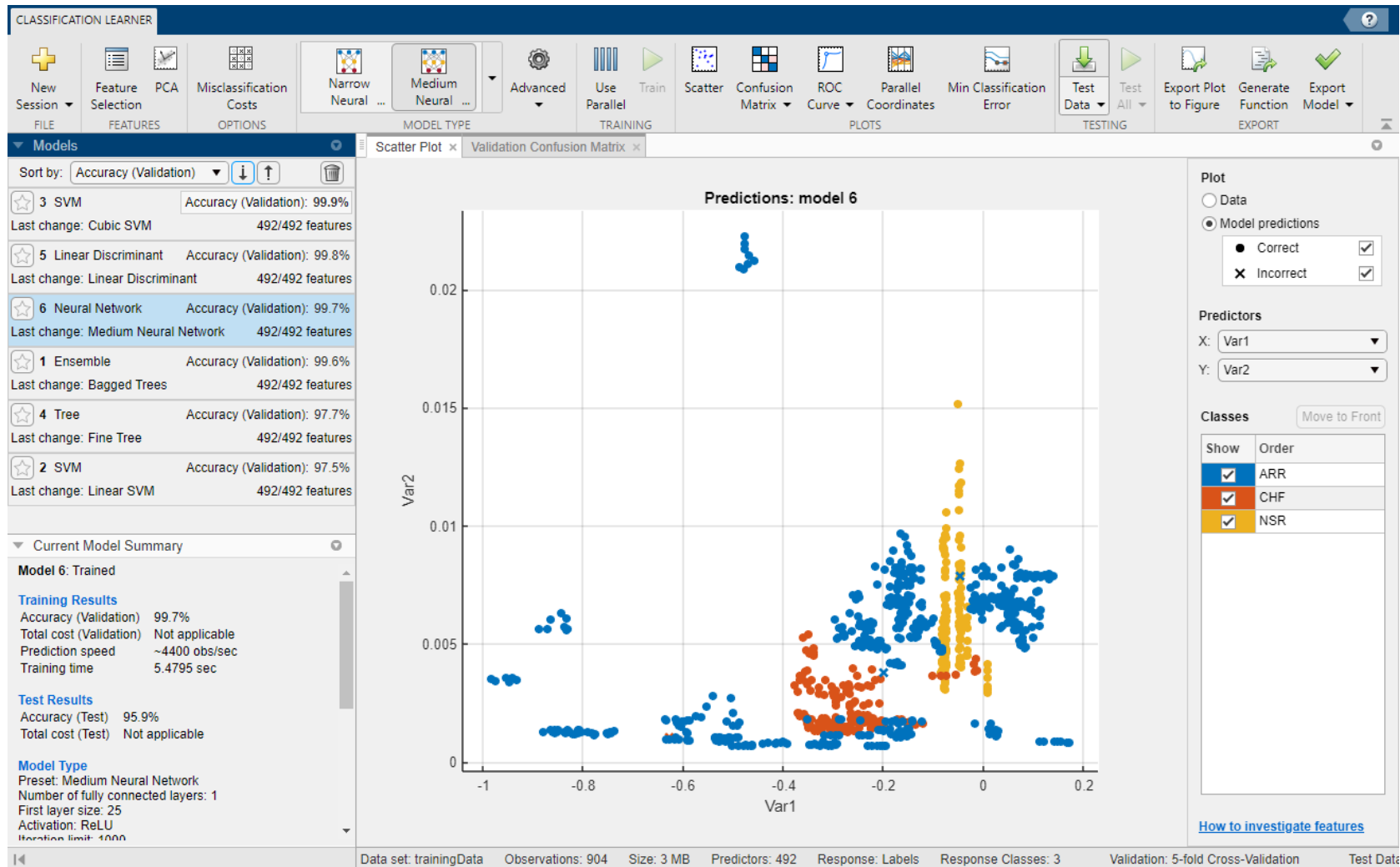
```

Poll #2 - What types of biomedical data are you working with?

Challenge #2: Lack of experience with AI

Build AI Models with Apps and AutoML

Video

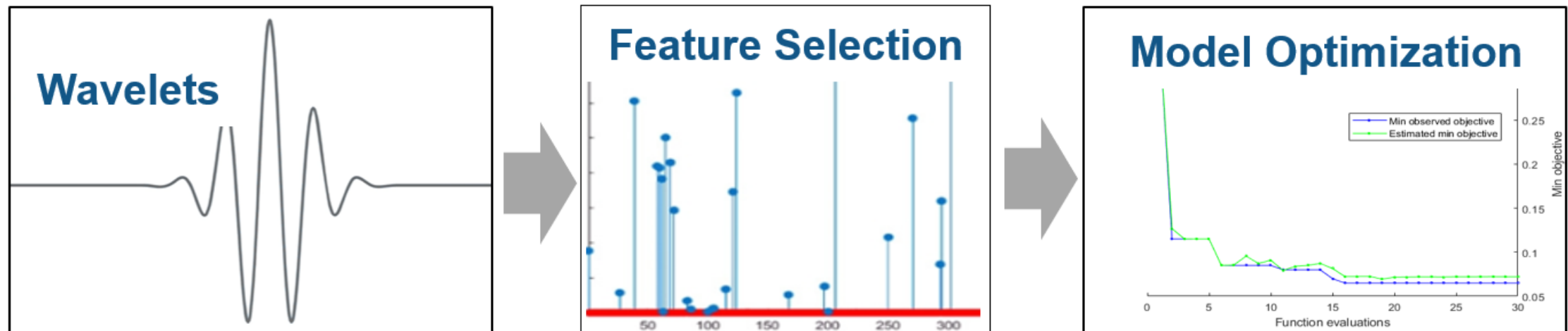


Build AI Models with Apps and AutoML cont'd

Develop Classifiers interactively also with Deep Learning:

- **Deep Network Designer** app to build, visualize, and edit deep networks
- **Experiment Manager** orchestrates, analyze and compare results of deep learning experiments

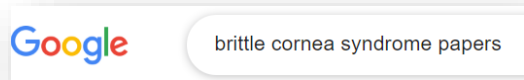
AutoML automates iterative and difficult steps in Machine Learning:



Applications of Text Analytics to Medical Devices and Pharma



Research



What do these say?



Design



Does this meet guidelines?



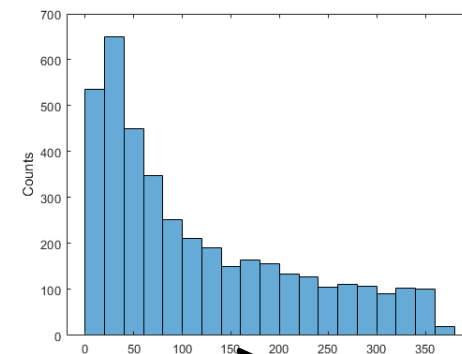
Manufacturing



Which batch may be defective?



Operations



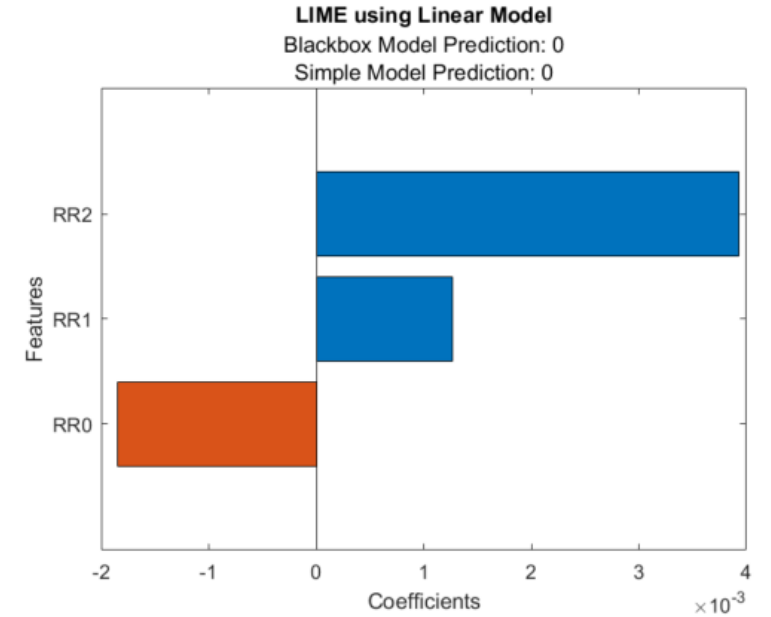
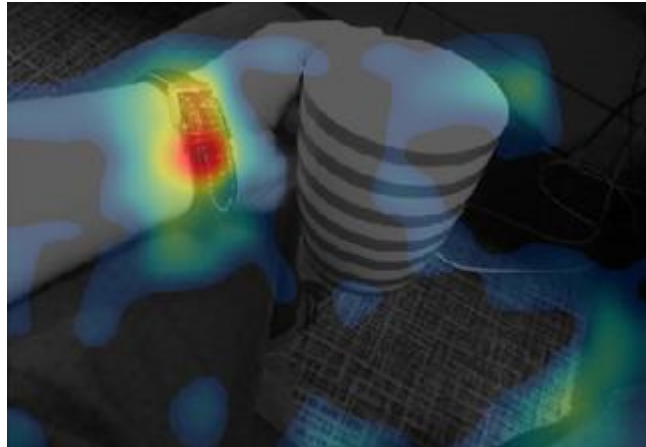
When may the patient be back?



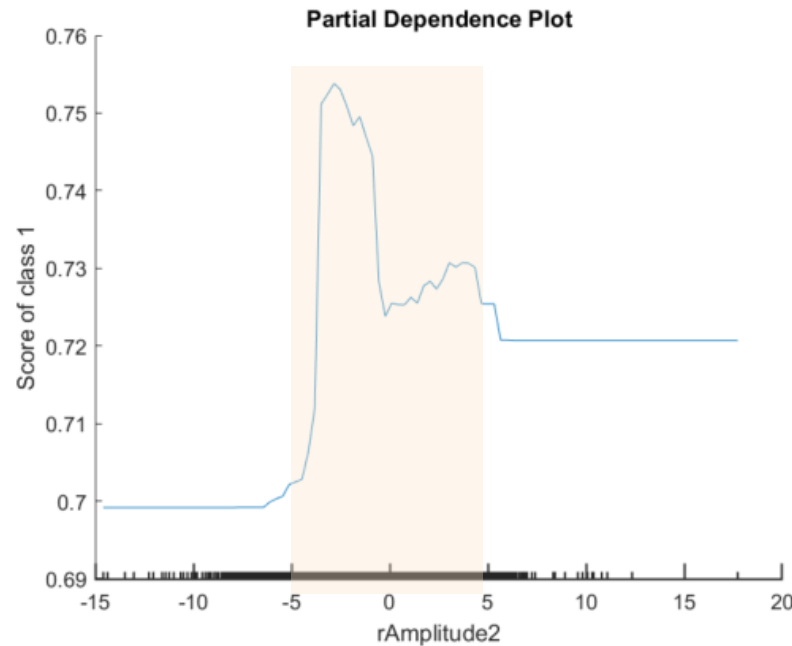
Electronic Health Records

Model Interpretability helps explain AI

1. Explain model behavior



2. Identify potential bias



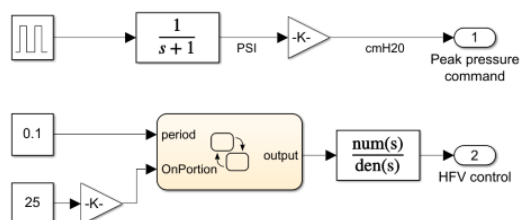
Challenge #3: System integration and deployment issues

Integrate and deploy using Simulink

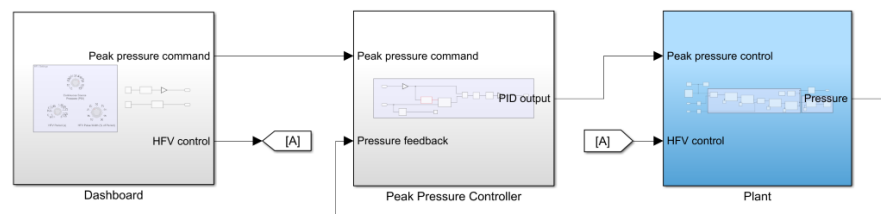
SIMULINK®



Model and Simulate Your System



Modelling & Simulation



Challenge #3: System integration and deployment issues

Integrate and deploy using Simulink



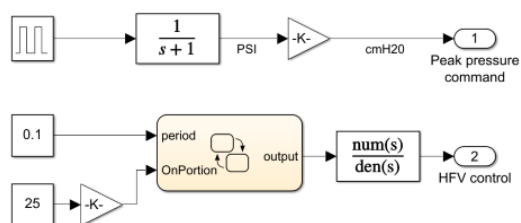
Model and Simulate Your System



Automatically Generate Code

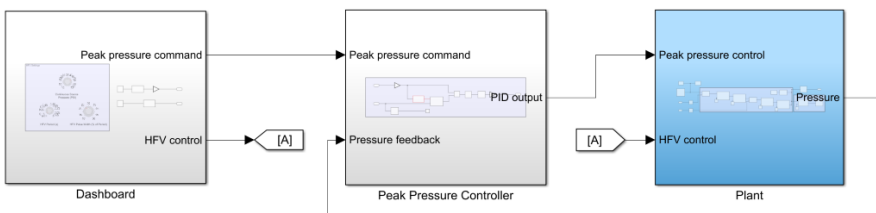


Test Early and Often

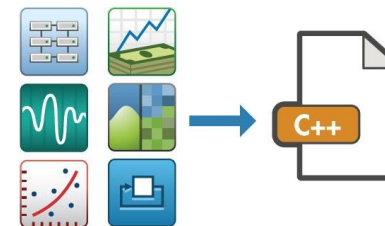


Modelling & Simulation

Testing & Verification



Code generation



ID	Summary	Implemented	Verified
#1	Driver Switch Request Handling	Yes	Yes
#2	Switch deactivation	Yes	Yes
#3	Avoid repeating commands	Yes	Yes
#4	Long Switch recognition	Yes	Yes
#7	Cancel Switch Detection	Yes	Yes
#8	Set Switch Detection	Yes	Yes
#9	Enable Switch Detection	Yes	Yes
#10	Resume Switch Detection	Yes	Yes
#11	Increment Switch Detection	Yes	Yes
#15	Decrement Switch Detection	Yes	Yes
#20	Disable Chaser Control system	Yes	Yes
#21	Choke Control Mode	Yes	Yes
#22	Calculate Target Speed and Thrust	Yes	Yes
#23	Operation mode determination	Yes	Yes
#24	Disabled case	Yes	Yes
#25	Enabled case	Yes	Yes
#31	Activated case	Yes	Yes
#32	Throttle Value Computation	Yes	Yes
#33	Next Target Speed Computation	Yes	Yes
#34	Resume mode	Yes	Yes
#44	System Interface	Yes	Yes
#45	Inputs	Yes	Yes
#46	Outputs	Yes	Yes
#47	Parameters	Yes	Yes
#48	Justifications	Yes	Yes

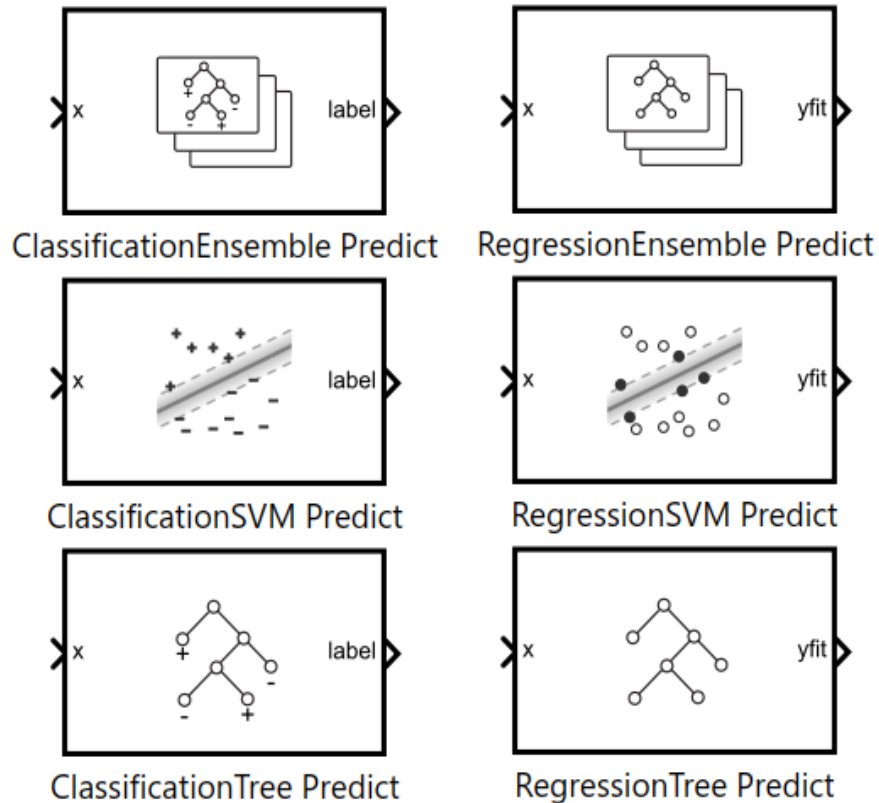
- ISO 26262, IEC 61508, IEC 62304, EN 50128, IEC 61511
- Embedded Coder
- Polyspace Bug Finder
- Polyspace Code Prover
- Simulink Design Verifier
- Simulink Check
- Simulink Coverage
- Simulink PLC Coder
- Simulink Test
- Simulink Requirements
- Supporting Artifacts

Meet Standards

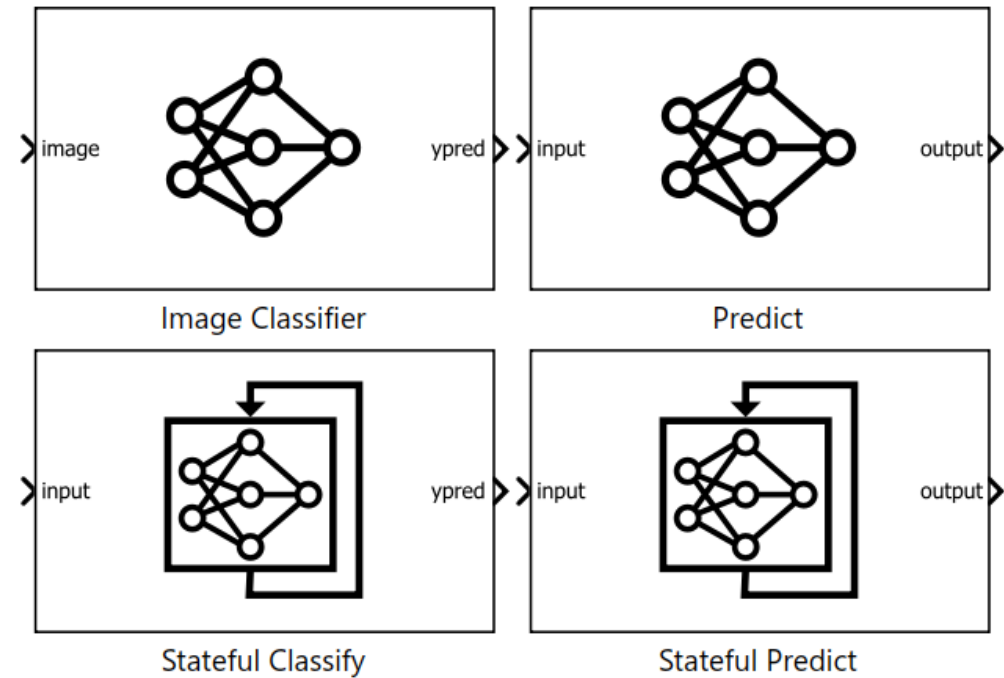
Blocks make integration of AI into Simulink easier.

R2020b

Machine Learning blocks

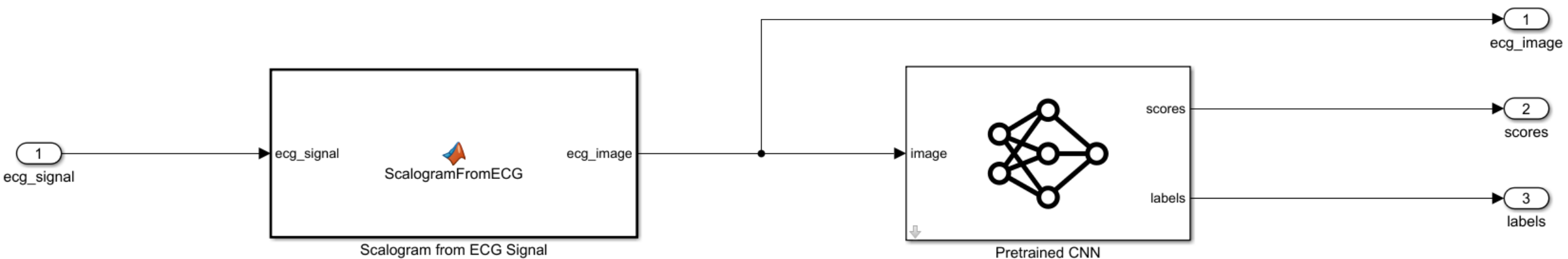
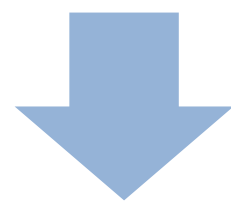
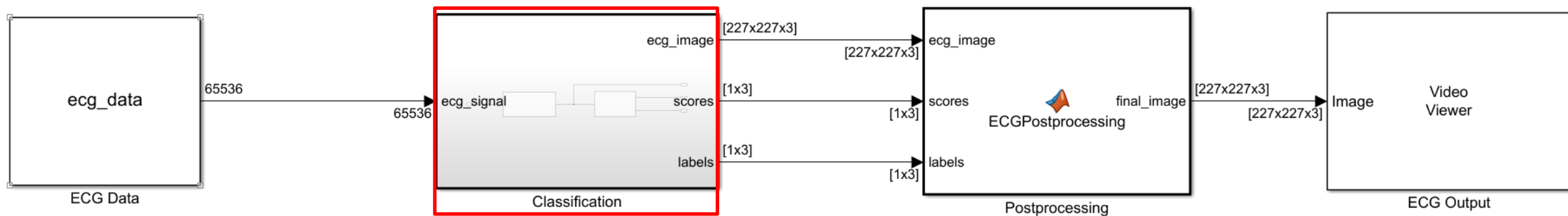


Deep Learning blocks

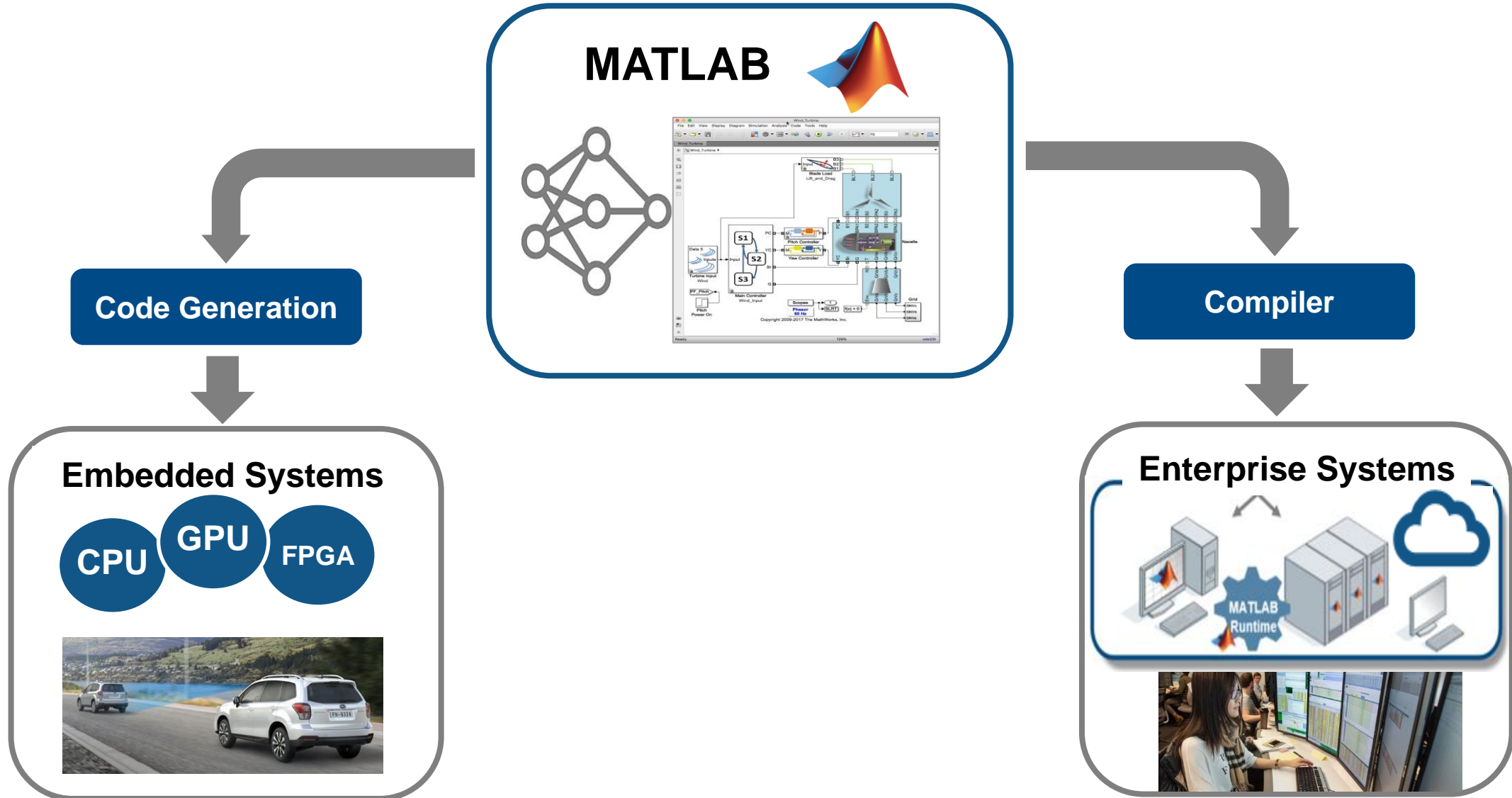


Demo: Integrating ECG Classification into Simulink

Video

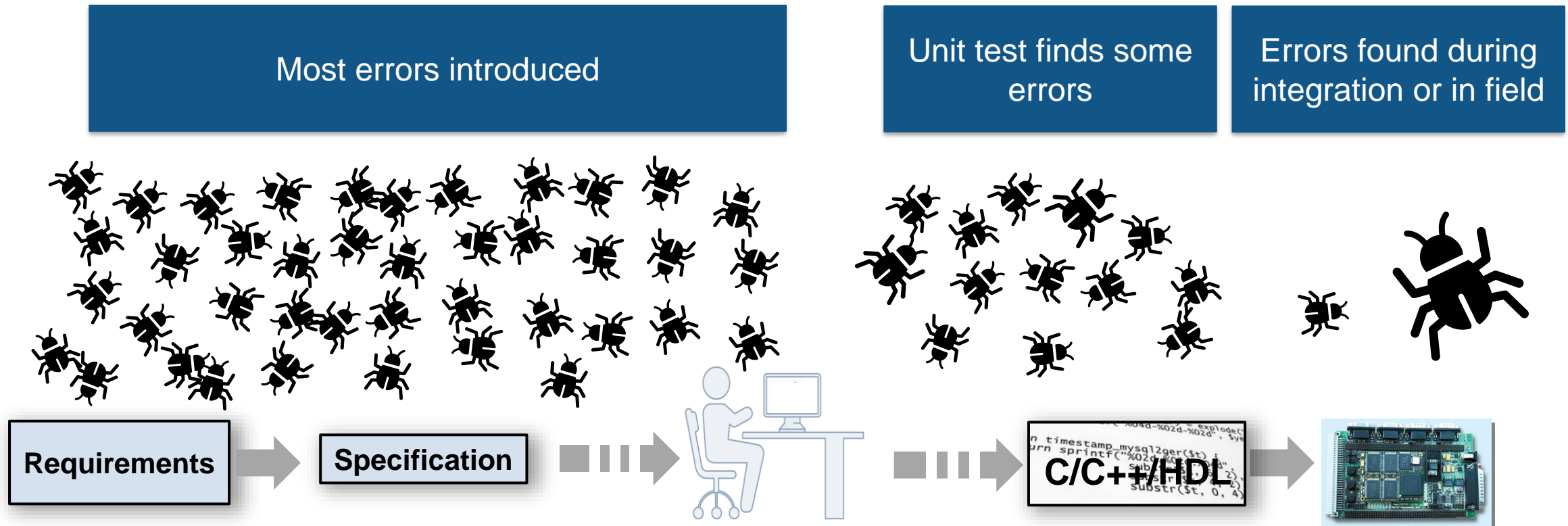


Two Approaches for integrating AI with Larger System

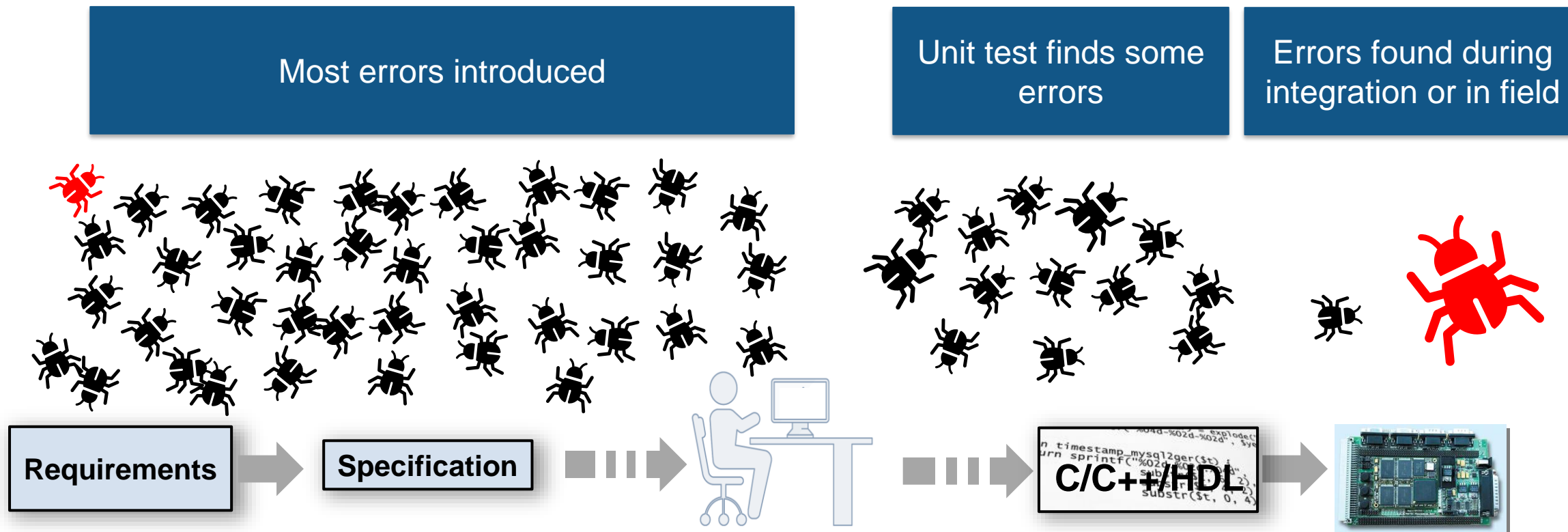


Challenge #4: Rigorous V&V and certification

V&V using solutions for FDA/CE workflows



Errors introduced early but found late



Poll #3 - Which challenge (of the 4 we discussed) applies the most in your situation?

MathWorks solutions for FDA/CE regulated workflows



FILE EXCHANGE

Tool Validation Kit

You can now download this Tool Validation Kit from MATLAB File Exchange.

[Download now](#)

If you have any questions on how to use this kit, have feedback, or need additional consulting help, please contact us at medical@mathworks.com.

Simulink Verification and Code Generation Tools Validated to IEC
62304

Strengthens confidence in Model-Based Design adoption for FDA certification

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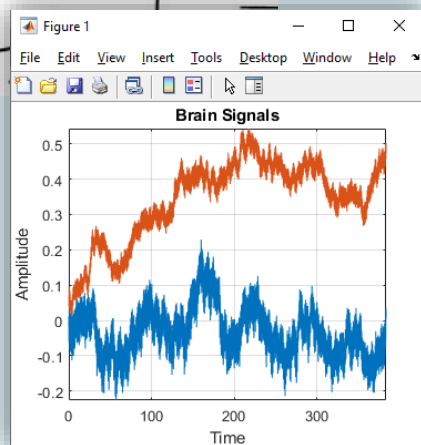
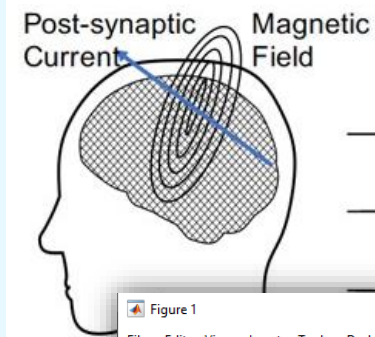


Converting Brain Signals to Words and Phrases Using Wavelets and Deep Learning – The University of Texas at Austin



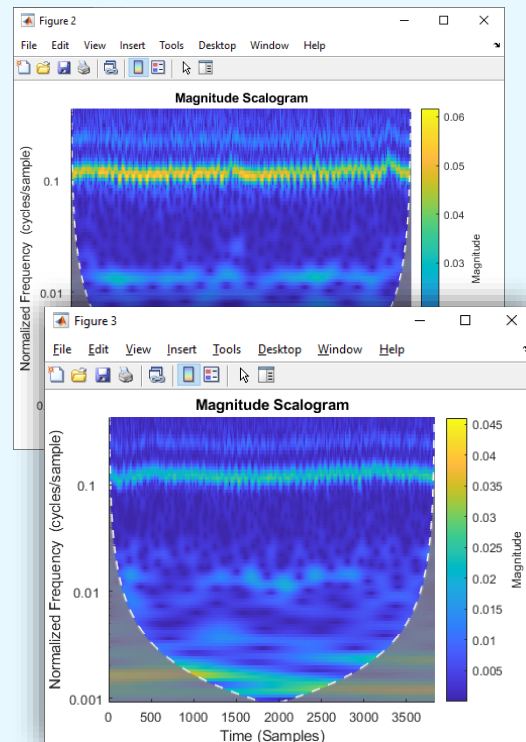
Access Data

MEG Data Acquisition



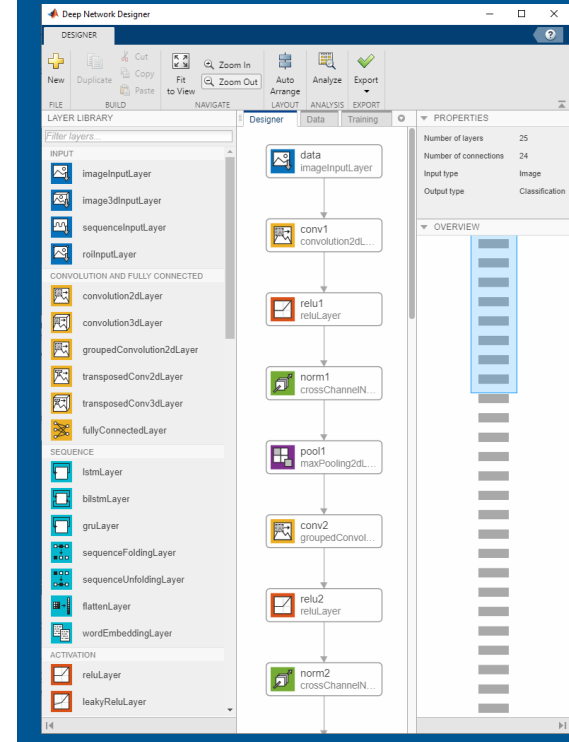
Analyze Data

Wavelet Scalograms



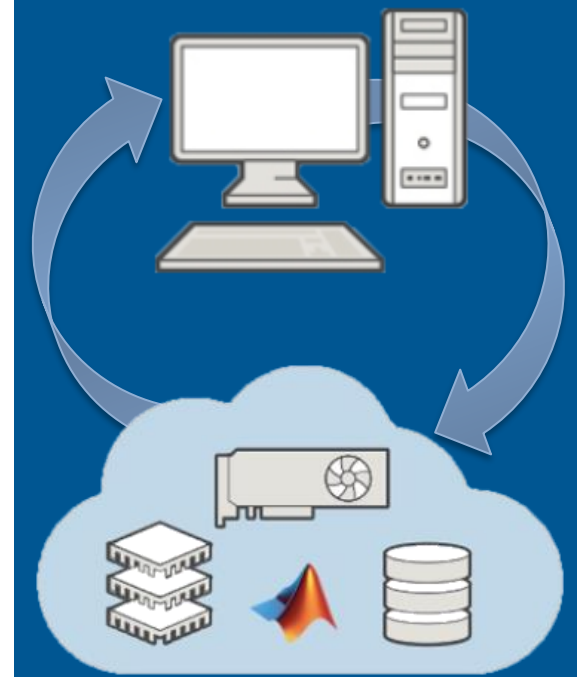
Develop

Deep Network Designer App



Deploy/Scale

Train in the Cloud on GPUs



Conclusions

MathWorks tools address key challenges in Next Gen Medical Devices and Digital Health

- Manage Complexity, Validate and Certify applying Model-Based Design and Simulink
- Interactive Apps and AutoML empower Medical SMEs to build optimized AI models
- Deploy to Embedded devices or Cloud from a single code base

You can leverage AI algorithms and while complying to medical guidelines and standards

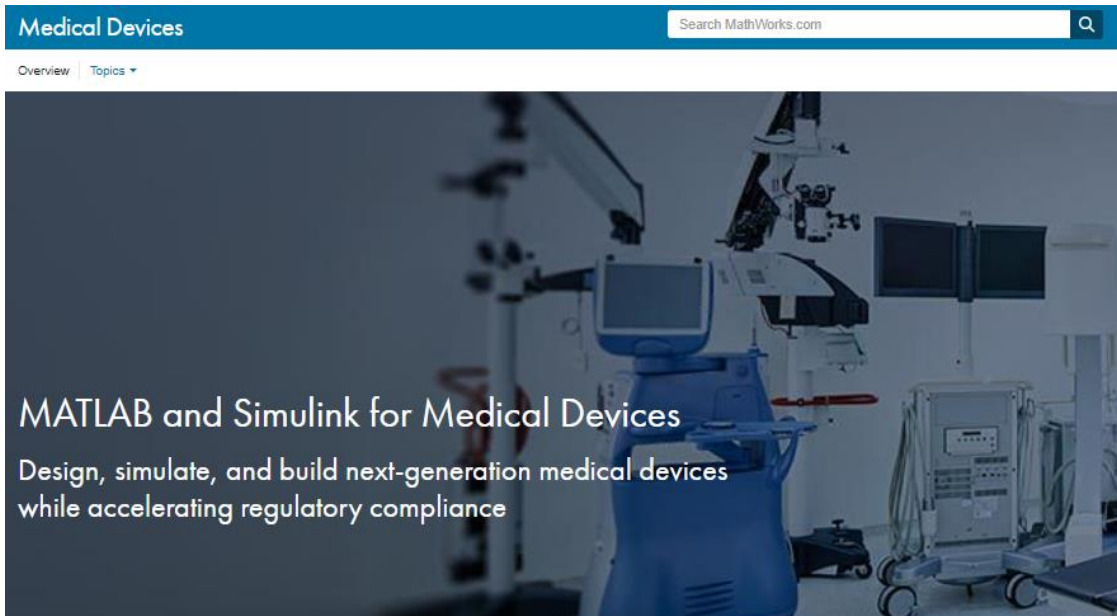
Learn More

Biomedical Reference Applications – Video Series

[AI Techniques for ECG Classification](#) [Modeling an Infusion Pump](#) [Text Analytics for Biomedical Applications](#)

Free Biomedical AI – Hands On Workshop – 3 hours

[contact: medical@mathworks.com](mailto:medical@mathworks.com)



Medical Devices

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Overview | Topics

MATLAB and Simulink for Medical Devices

Design, simulate, and build next-generation medical devices while accelerating regulatory compliance

- [Biomedical Data Analysis using MATLAB & Simulink](#)
- [Medical Device Development using MATLAB & Simulink](#)
- [Compliance with FDA/CE Regulations and Standards](#)

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Thank you

