Resources

This is the initial resources page for Yale BENG 406b (Medical Software Design.) The textbook for the class is

- Papademetris X., Quraishi A.N., and Licholai G.P. Introduction to Medical Software: Foundations for Digital Health, Devices and Diagnostics. Cambridge University Press (2022). ISBN 9781316514993

Here are a couple of additional books that might be of interest:

- Digital Health: Building Mobile and Wearable Applications for Participatory Health.
  Editors: Shabbir Syed-Abdul, Xinxin Zhu, Luis Fernandez-Luque. 2020. Elsevier. eBook ISBN: 9780128200780. Paperback ISBN: 9780128200773.
- Personal Health Informatics: Patient Participation in Precision Health.
  Editors: Pei-Yun Sabrina Hsueh, Thomas Wetter, Xinxin Zhu, Springer; 1st ed. 2022 edition Paperback ISBN 978-3-031-07698-5, Hard Cover ISBN 978-3-031-07695-4, eBook ISBN 978-3-031-07696-1

Software Mishaps/Accidents Links (For Student Presentations)

This page contains links to the various accident stories that the students will present in pairs during the semester: https://www.xpapademetris.com/medical-software-articles/accident-stories.

The following is the best description of the Therac-25 accidents. This is Appendix A (http://sunnyday.mit.edu/papers/therac.pdf.) of Leveson NG. Safeware: System Safety and Computers. Addison-Wesley; 1995.

Some Key Regulatory Documents

Good Summary Documents

- Singapore Health Sciences Authority (HSA). Regulatory Guidelines for Software Medical Devices – A Lifecycle Approach [Internet]. 2022 Apr. Available from: https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gudiance-documents-for-medical-devices/regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach_r2-(2022-apr)-pub.pdf. (This is probably the best single regulatory document coverage of the topic -- see also my description of this here: https://www.linkedin.com/pulse/singapore-guidance-software-medical-devices-xenophon-papademetris/.)
- International Organization for Standardization (ISO). ISO/IEC/IEEE 90003 Software Engineering — Guidelines for the application of ISO 9001:2015 to computer software [Internet]. First. Geneva, CH; 2018. Available from: https://ieeexplore.ieee.org/document/8559961.-- **This is one relevant industry standard that is freely available if you have access to IEEE Xplore (Most universities do.)**

Core Software-As-A-Medical Device (SaMD) Guidance Documents

- International Medical Devices Regulator Forum (IMDRF): SaMD Working Group. Software as a Medical Device (SaMD): Key Definitions [Internet]. 2013. Available from: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.

- International Medical Devices Regulator Forum (IMDRF): SaMD Working Group. Software as Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations [Internet]. 2014. Available from: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf.
- International Medical Devices Regulator Forum (IMDRF): SaMD Working Group. Software as a Medical Device (SaMD): Application of Quality Management System [Internet]. 2015. Available from: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf.
- U.S. Food and Drug Administration (FDA): Center for Devices and Radiological Health. Software as Medical Device (SAMD): Clinical Evaluation. Guidance for Industry and Food and Drug Administration Staff [Internet]. 2017. Available from: https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd.

Early AI/ML Guidance

- U.S. Food and Drug Administration (FDA). Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback [Internet]. FDA; 2019. Available from: https://www.fda.gov/media/122535/download.
- U.S. Food and Drug Administration (FDA), Radiological Health. Good Machine Learning Practice for Medical Device Development [Internet]. 2021 Oct. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles.

Other Issues (Privacy, Cybersecurity, Usability)

- U.S. Department of Health and Human Services (DHSS): Office of Civil Rights. Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule [Internet]. 2012. Available from: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.
- U.S. Food and Drug Administration (FDA): Center for Devices and Radiological Health. Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff [Internet]. 2016. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.
- International Medical Devices Regulator Forum (IMDRF): Medical Device Cybersecurity Working Group. Principles and Practices for Medical Device Cybersecurity [Internet]. 2020. Available from: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-pp-mdc-n60.pdf.

Clinical Decision Support -- At least one of the projects falls into this category

- Center for Devices, Radiological Health. Clinical Decision Support Software - Guidance for Industry and Food and Drug Administration Staff [Internet]. U.S. Food and Drug Administration. FDA; [cited 2022 Sep 28]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software.
- Giantsidis J. FDA Vs. Congress: The Software Showdown [Internet]. [cited 2022 Nov 14]. Available from: https://www.meddeviceonline.com/doc/fda-vs-congress-the-software-showdown-0001.

Some Recent Government Reports on AI and Related Issues

- Scientific Foresight Unit (STOA). Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts [Internet]. European Parliamentary Research Service; 2022 Jan. Report No.: PE 729.512 –. Available from: https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729512/EPRS_STU(2022)729512_EN.pdf.(Section 2 of this has an excellent review of AI applications in healthcare.)
- NHS AI Lab & Health Education England. Understanding healthcare workers confidence in AI [Internet]. HS; 2022 May. Available from: https://digital-transformation.hee.nhs.uk/building-a-digital-workforce/dart-ed/horizon-scanning/understanding-healthcare-workers-confidence-in-ai.
- Schwartz R, Vassilev A, Greene K, Perine L, Burt A, Hall P. Towards a standard for identifying and managing bias in artificial intelligence [Internet]. National Institute of Standards and Technology; 2022 Mar. Available from: https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1270.pdf.

Not So Good News from Europe (When Regulations Go Wrong.)

- Taylor NP. MedTech Europe calls for urgent clarification of EU artificial intelligence proposal [Internet]. 2021 [cited 2022 Dec 25]. Available from: https://www.medtechdive.com/news/medtech-europe-criticizes-eu-artificial-intelligence-proposal/606433/.
- Bes A, Pérez FJG. The much-needed harmonisation between the AI Act and MDR/IVDR [Internet]. MedTechNews. [cited 2022 Dec 25]. Available from: https://www.med-technews.com/medtech-insights/medtech-regulatory-insights/the-much-needed-harmonisation-between-the-ai-act-and-mdrivdr/.

AI/ML Talk

This is a link to the talk I gave at the NIH last December. The bibliography contains some interesting links as well, see https://www.xpapademetris.com/talksvideos.

Here is also a set of interview videos I recorded with colleagues in both Academia and Industry (and FDA): https://www.medsoftbook.com/the-expert-interviews.