

Welcome

Enhancing the Clinical Development Process with Machine Learning

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What is Machine Learning?

Predictions based on Prior Observation

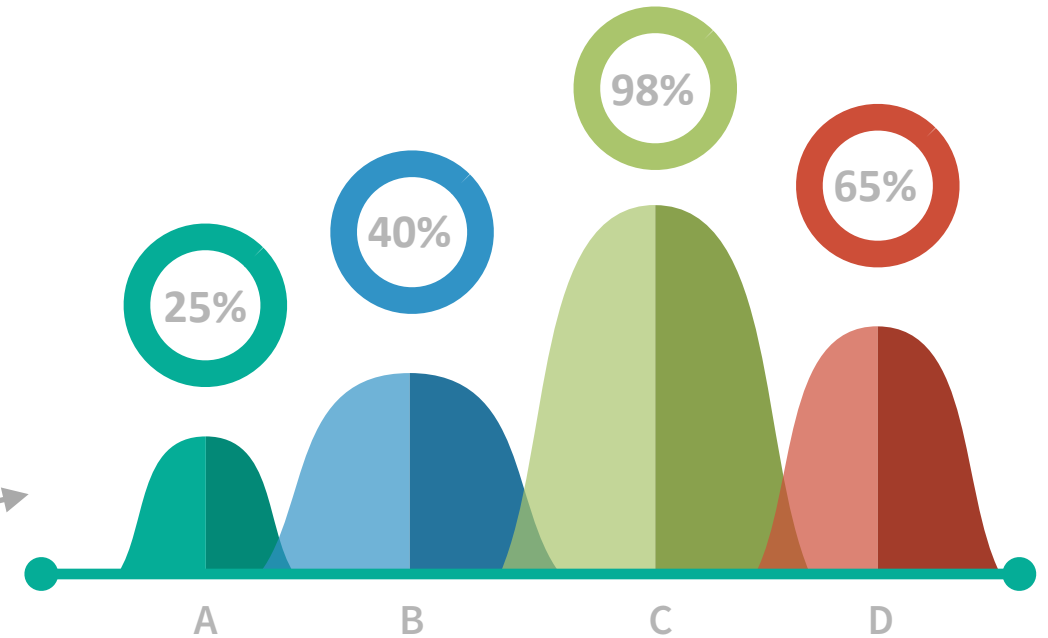
Machine learning explores the construction and study of algorithms that can learn from and make predictions on data ([wikipedia](#))

Probabilistic based computer algorithms that make predictions about observed data based on previous experience



Probabilistic Modeling

Prediction based on “features”



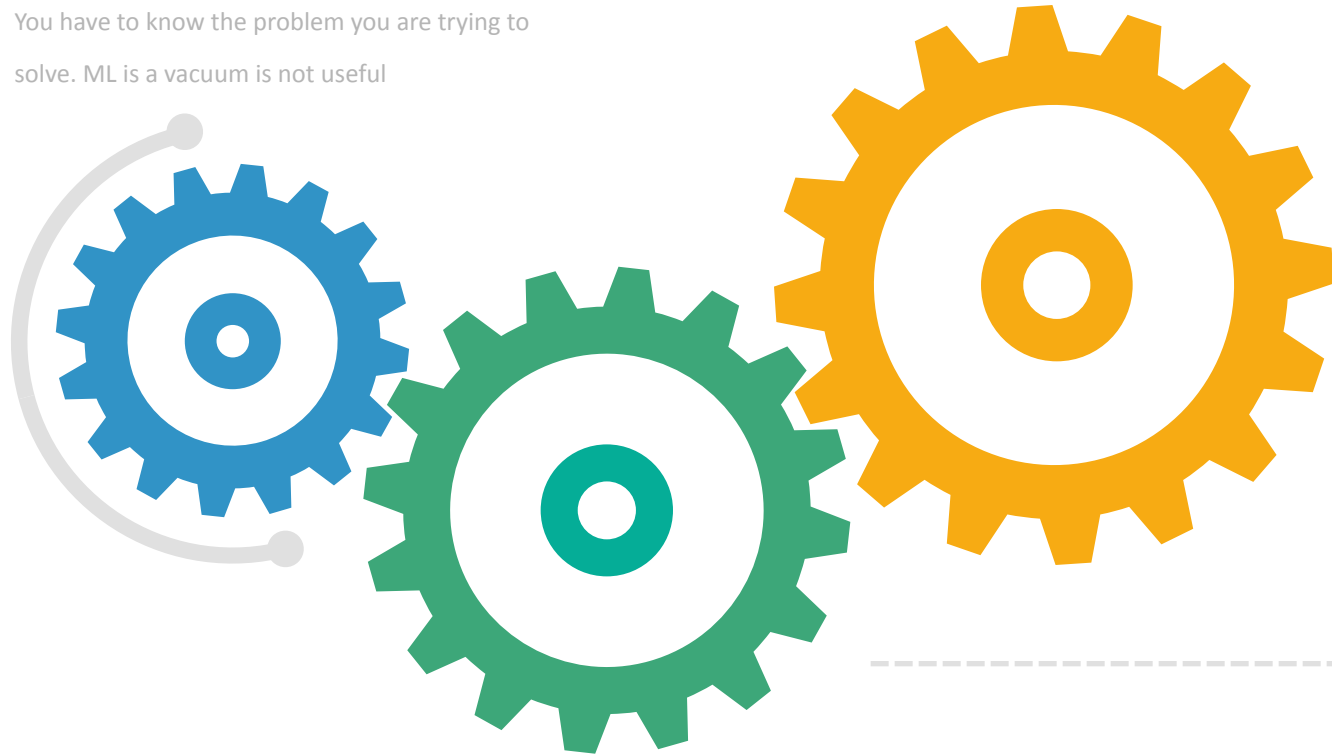
ML determines likely outcomes based on training with already classified data

ML is Multi-disciplinary

Data Science

Real world problems

You have to know the problem you are trying to solve. ML is a vacuum is not useful



Statistics

ML has underpinnings in statistical theory

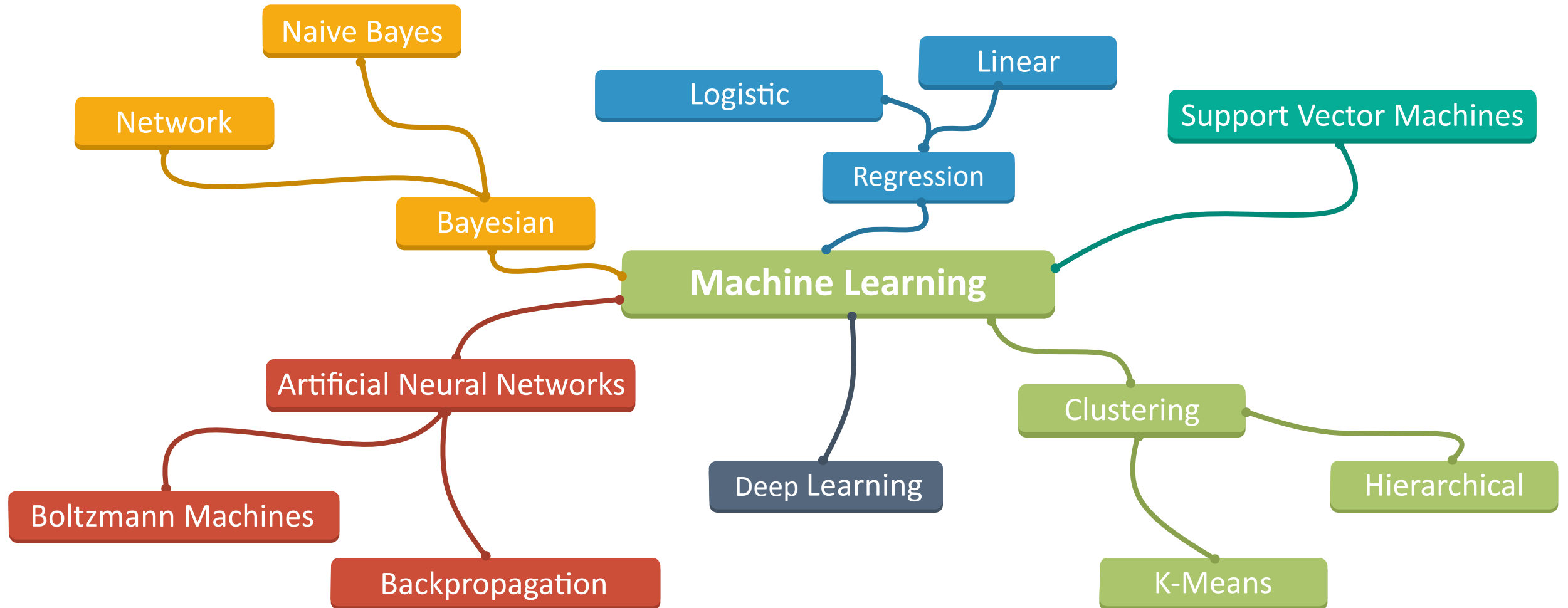
There are some specific ML extensions and terminology, but anyone with statistical training should be able to recognize much of the theory of ML

Computer Science

ML algorithms are implemented primarily in object oriented languages like Python, Scala, and R

Different kinds of Machine Learning

There are many options



You may be familiar with some of these



S P E E C H A N D T E X T



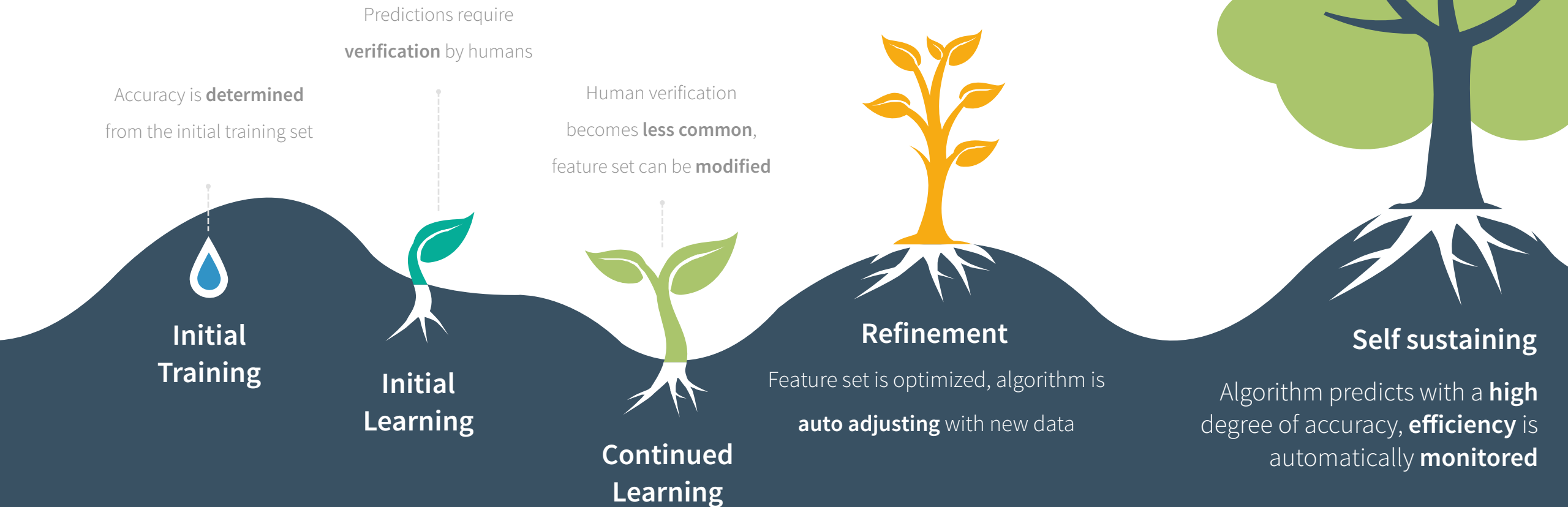
ARTIFICIAL INTELLIGENCE



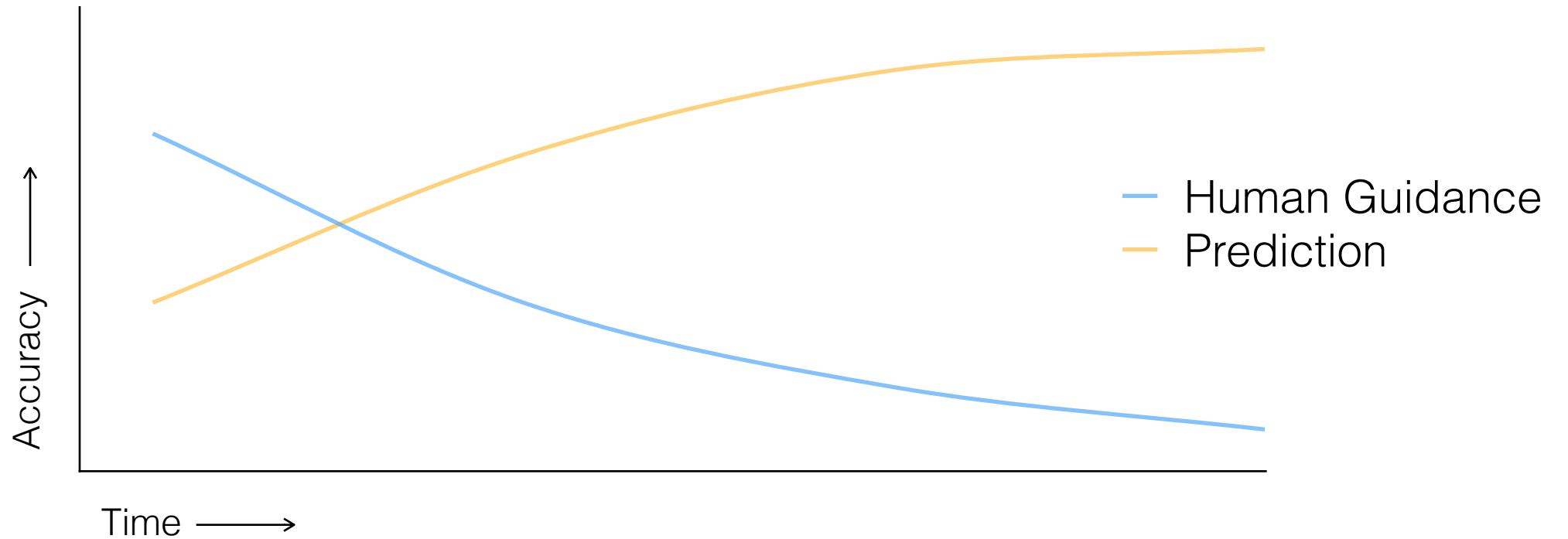
COMPUTER VISION

Learning Algorithms over time

Practical expectations



Learning Algorithms over time



Human interaction with the learning system transitions from intervention on mis-categorized predictions to maintenance of the feature set

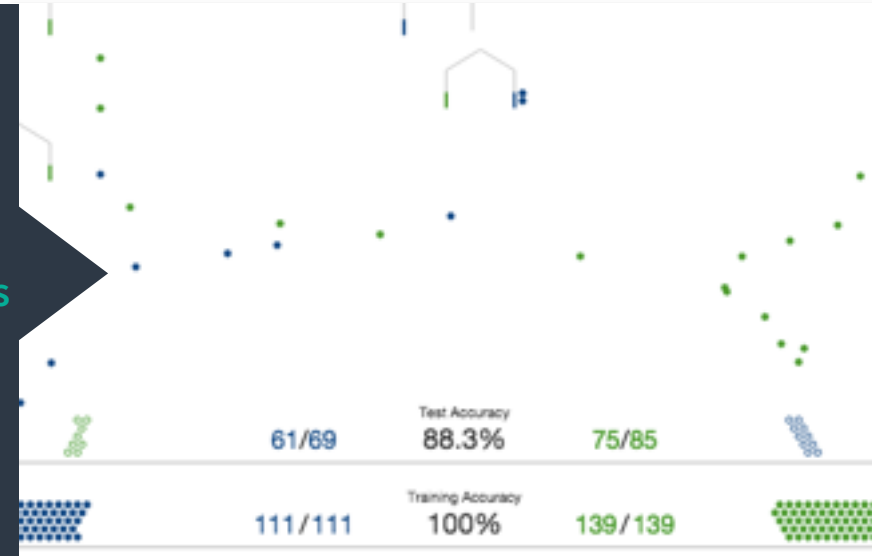
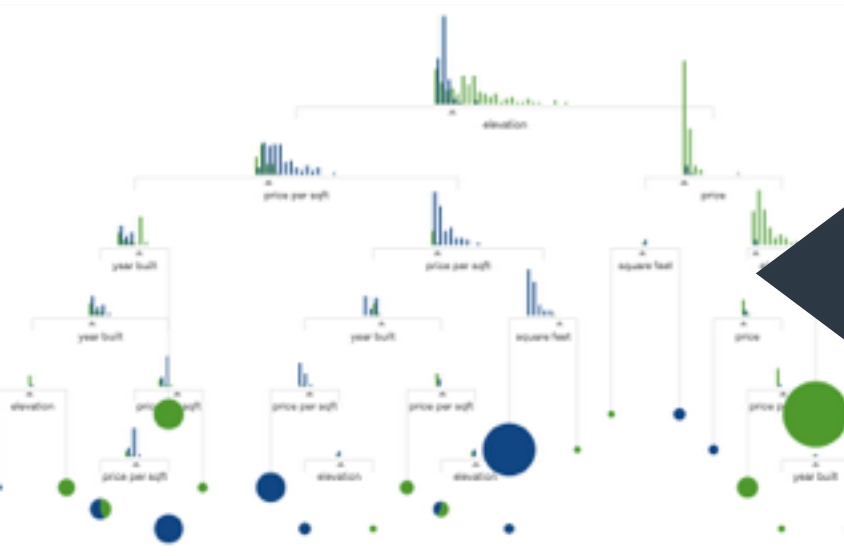
Great ML Resource

r2d3.us



Machine Learning through d3.js visualizations

d3.js is a javascript library used to build interactive data visualizations





Machine Learning can be leveraged at numerous points in the
[clinical development](#) process, facilitating better science



The Clinical Development Process

Better **future science** through learning from **past experience**

Program Planning

ML can guide program planning in determining phases, studies, and strategies based on similar programs



Study Design

Study designs can be recommended and confirmed/modified based on prior studies with similar attributes



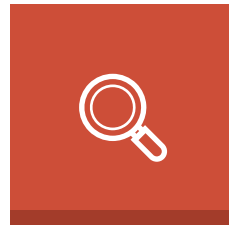
Protocol Development

Schedule of events , structured protocol information, authoring assistance



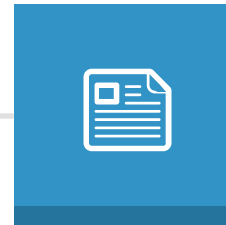
Risk Based Monitoring

Data irregularities, guided source data verification



Data Collection

Sponsor study start up, clinical site data entry workflow



Statistical Analysis

SAP content and authoring, specific analysis recommendations



Regulatory Review

Being able to identify submission aspects that may require more thorough review



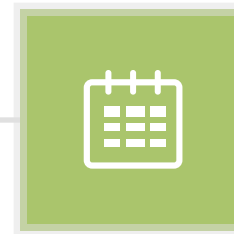
Data Integration

ML would greatly improve the identification of data into known categories



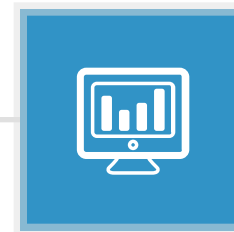
Clinical Ontologies

Development of clinical ontologies is time consuming and theoretical, ML can guide that process



Data Mining

ML can aid in the discovery of information in data that is difficult to find through human based analysis



From Theory to Reality

There are significant hurdles



Data

ML algorithms require a lot of data for training



Computer Science

Skill sets in the industry need to be adjusted to more broadly understand CS concepts



Risk

ML is prone to error by nature, so our processes need to account for this



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