



DATA DRIVERS FOSTERING INNOVATIONS IN ONCOLOGY

 **AMCP**
Foundation

9th Annual Research
Symposium

Highlights Webinar
January 16, 2020

 *held in conjunction with*
AMCP NEXUS 2019

Funding Partners



 **MERCK**



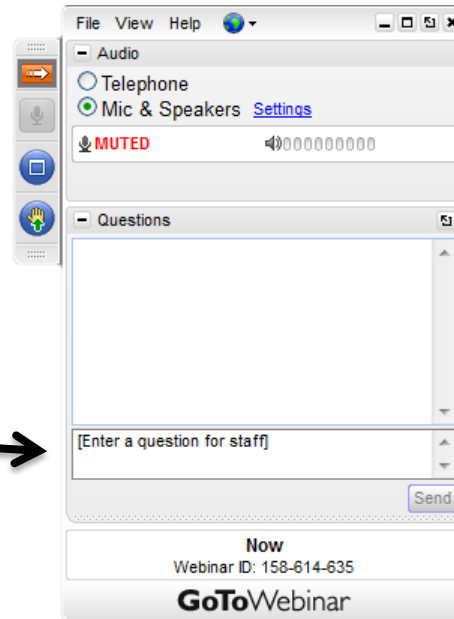
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How to Ask a Question

Type your question here →



Moderator



Matt Hurlburt, MHA

Global Access Transformation Lead
Pfizer Innovative Health Center

Presenter



Breanna Popelar, PharmD, MS

Assistant Director, Strategic Market
Access & Intelligence

Xcenda

Trends in Healthcare: Expedited Drug Approvals

*Summary Highlights from the AMCP Foundation
Research Symposium*

January 16, 2020

DATA DRIVERS

Fostering Innovations
in Oncology

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TIMING IS EVERYTHING

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Objective and Approach

Identify significant trends and best practices to assist stakeholders who interact with managed care pharmacy to better adjust to and maximize opportunities for cost-effective, affordable, and integrated patient care

Trends scan

30 trends/
areas of impact

Thought leader working group

6 key trends **+** **2** global influencers



Desktop research
>170 sources identified



20 multi-stakeholder
1:1 interviews



Payer survey
N=70











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Initial List Included Over 30 Topics

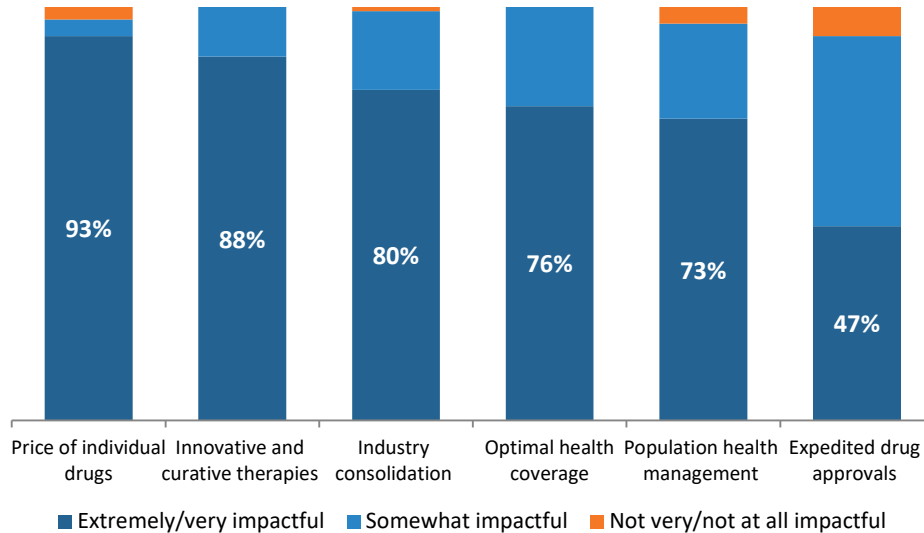
Affordability and value	Government policy	Patient voice in drug development	Optimal health coverage	Aging population
Mobile health	Diagnostics	Biosimilars	Preventive medicine	Disruptive innovators
Adherence	Expedited drug approval	Plan design	Health crises	Industry consolidation
Transparency	Artificial intelligence (AI)	Gene therapy	Population health management	Health information technology (IT)
Big data	Value-based contracting	Opioid abuse	Pandemics	Delivery system
Care coordination	Privacy	Innovative and curative therapies	Social determinants	Consumerism

6 Key Trends Identified and 2 Key Global Influencers

Affordability and value 	Government policy	Patient voice in drug development	Optimal health coverage 	Aging population
Mobile health	Diagnostics	Biosimilars	Preventive medicine	Disruptive innovators
Adherence	Expedited drug approval 	Plan design	Health crises	Industry consolidation 
Transparency	Artificial intelligence (AI) 	Gene therapy	Population health management 	Health information technology (IT) 
Big data 	Value-based contracting	Opioid abuse	Pandemics	Delivery system
Care coordination	Privacy	Innovative and curative therapies 	Social determinants 	Consumerism

All Key Trends Were Identified as Being Impactful on the Future of Healthcare, Including Expedited Drug Approvals

Impact of Key Trends on the Future of Healthcare
(Payer Perspective)



- Key trends affecting healthcare are **interrelated**
- Overall, **affordability** is a central issue, especially for innovative therapies in areas such as **oncology**
- The complexity of these trends demands **solutions with multiple factors**

Question: How impactful do you think each of the following is to the future of healthcare? (N=70)

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Expedited Drug Approval



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FDA Mission

- The Food and Drug Administration is responsible for **protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation
- The FDA is responsible for **advancing the public health by helping to speed innovations** that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health

The FDA Has 4 Programs for Expedited Approval of New Drugs

Fast track designation¹

Benefit: Collaboration with the FDA to expedite the development and review process



Breakthrough therapy designation¹

Benefit: Fast track benefits with additional intensive FDA guidance



Priority review designation¹

Benefit: Reduces the decision time from 10 to 6 months

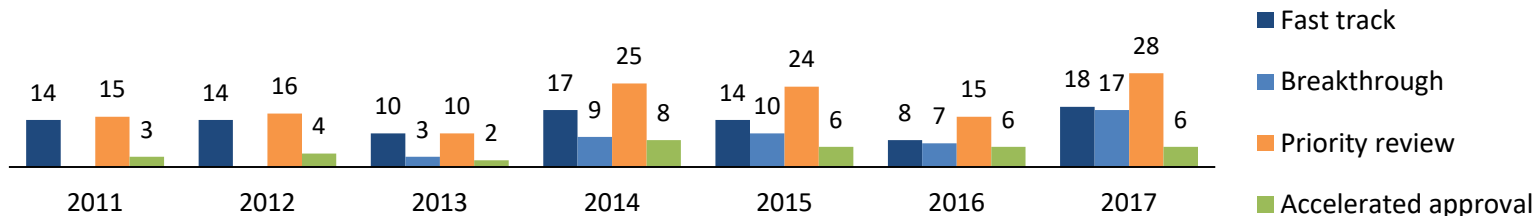


Accelerated approval pathway¹

Benefit: Approval based on surrogate or intermediate endpoints, coverage by state Medicaid programs



FDA Drug Approvals Under Expedited Review Programs (2011–2017)²



1. Drummond M, Sampsel E. Coping with the consequences of accelerated approval. February 22, 2018. <https://www.amcp.org/Resource-Center/coping-consequences-accelerated-approval>. Accessed October 24, 2019.
2. FDA. Guidance for industry: expedited programs for serious conditions – drugs and biologics. Published May 2014. <https://www.fda.gov/downloads/Drugs/Guidances/UCM358301.pdf>. Accessed October 24, 2019.

Expedited Programs Require That a Drug Be Intended to Treat a Serious Condition

Serious Condition

...a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a *matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.*

Must Be Intended to Have an Effect on the Following:

Diagnosis

Leading to improved outcomes via detection/diagnosis



Adverse events

Mitigate or prevent serious treatment-related side effects



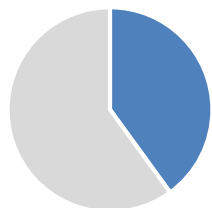
Progression

Prevent a serious condition or reduce the likelihood of progression



Expedited Approvals Are Especially Necessary in Areas of Significant Unmet Need

Perceived Need for Expedited Drug Approval (Payer Perspective)



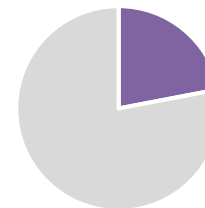
40%

Extremely/
very necessary



38%

Somewhat
necessary



22%

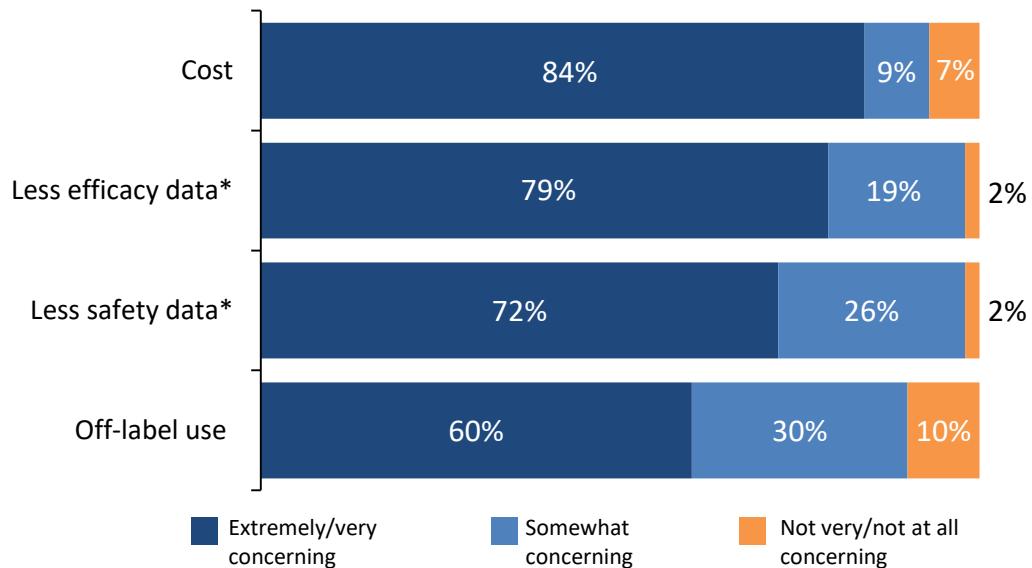
Not very/not
at all necessary

“Accelerated approval is impactful if addressing a significant unmet need, but this can be a subjective call, and not all drugs with accelerated approvals are necessarily impactful.”

– PBM

Concerns Center Around Cost, Clinical Data, and Coverage

Level of Payer Concern About Elements of Expedited Approval Products



“While [expedited approval products] certainly offer faster solutions for patients, it can be challenging to know exactly how to cover them and when.”

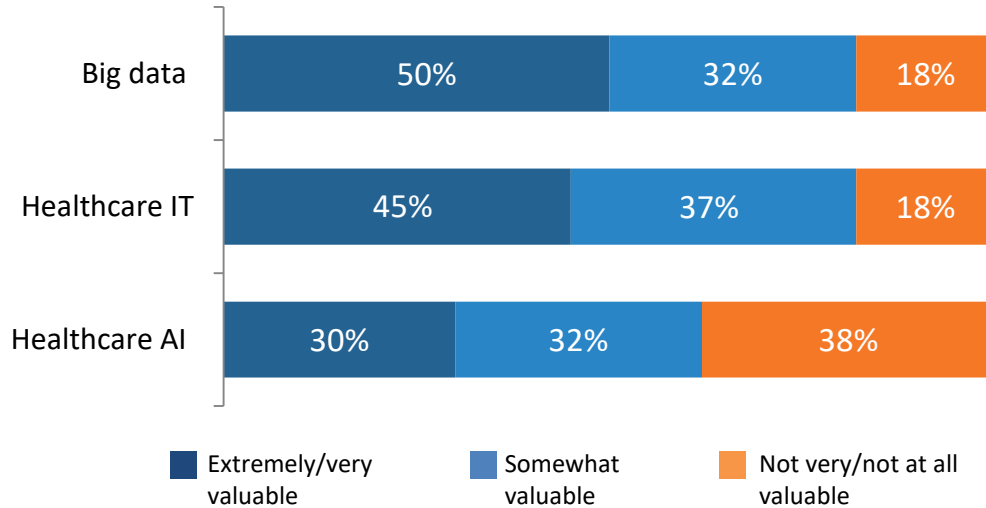
– Health Plan

*vs therapies approved via non-expedited pathways

Question: How concerning are each of the following with respect to expedited drug approval? (N=70)

The Best Is yet to Come

Value of New Technologies with Regard to Accelerated Drug Approval



“We can get to the information quicker than ever before with big data and predictive analytics. Then, we wouldn't necessarily need this fast tracking approach to occur. It would almost occur on its own.”

– Academia

Thank You

Breanna Popelar, PharmD, MS
Assistant Director, Strategic Market Access & Intelligence
Xcenda

Presenter



Petra Schultz, PharmD
Associate Chief Health Officer
IBM Watson Health



AI: Achieving and Utilizing its Potential

Challenges, Progress, and the Art of the Possible

Petra Schultz, PharmD

Associate Chief Health Officer

IBM Watson Health

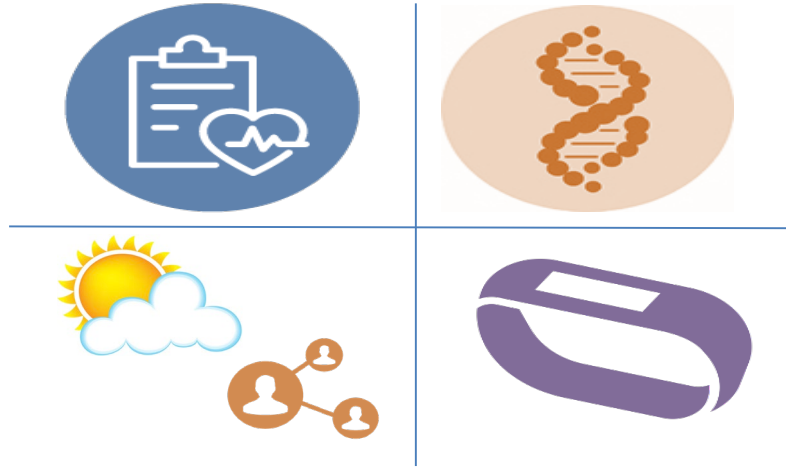
Information Explosion and Industry Challenges



- By the year 2020, medical knowledge is expected to double every 73 days¹
- Proportion of US population 60 years or older expected to increase between 2000 and 2050 for males (17% to 25%) and females (20% to 28%).²
- Primary care physicians spend $\frac{1}{2}$ of the workday³ (nearly 6 hours) interacting with EHRs during and after clinic hours
- Global shortage of health workers expected to reach 15 million⁴ by 2030

1. Densen P. *Trans Am Clin Climatol Assoc.* 2011;122:48-58.
2. Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. website. <http://www.cdc.gov/ckd>
3. Arndt BG et al. *Ann Fam Med.* 2017;15:5:419-426.
4. Liu JX et al. *Hum Resour Health.* 2017;15(1):11.

Merging Health + Healthcare



*Source: Adapted from Health Policy Brief,
"The Relative Contribution of Multiple
Determinants to Health Outcomes," Health
Affairs, August 21, 2014.*

Progress and Art of the Possible

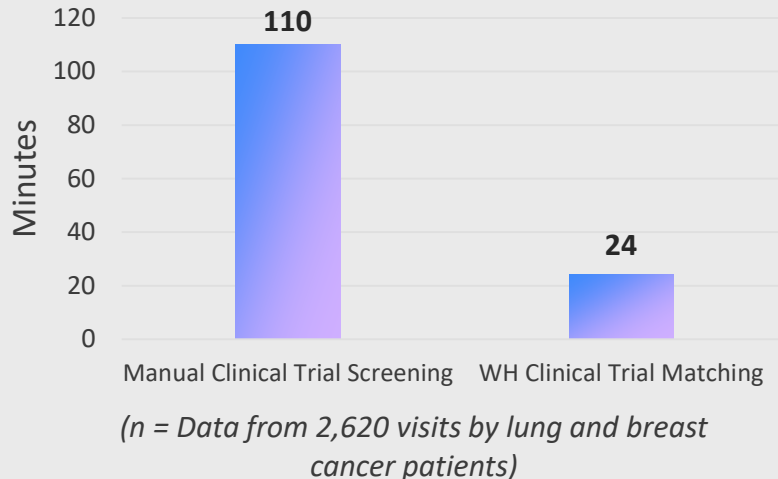
Cognitive Technology Addressing Optimal Cancer Clinical Trial Matching and Protocol Feasibility in a Community Cancer Practice

| Beck J et al. ASCO Annual Meeting 2017:
abstract 6501.

Watson excluded **94%** of the ineligible patients automatically, providing criteria level evidence regarding the reason for exclusion.

78%

reduction in time compared to manual clinical trial coordinator screening when using
Watson for Clinical Trial Matching (CTM)



“IBM Watson CTM can help expedite the screening of patient charts for clinical trial eligibility and therefore may also help determine the feasibility of protocols to optimize site selection and enable higher and more efficient trial accruals.”

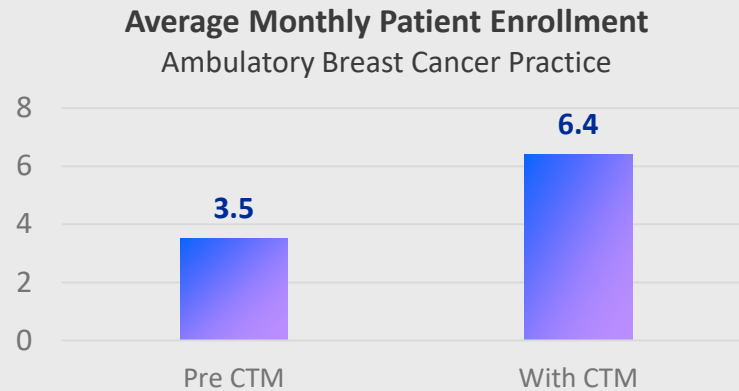
Impact of a Cognitive Computing Clinical Trial Matching System in an Ambulatory Oncology Practice

| Haddad T et al. ASCO Annual Meeting 2018: abstract 6550.

Cognitive technology supports increased enrollment in clinical trials for breast cancer.

In July 2016, Mayo Clinic implemented IBM Watson for Clinical Trial Matching with a team of screening clinical research coordinators in its ambulatory practice for patients with breast cancer at the Rochester campus.

In the 18 months after implementation, there was on average an 84 percent increase in enrollment to Mayo's systemic therapy clinical trials for breast cancer. The time to screen an individual patient for clinical trial matches also fell when compared with traditional manual methods.



84 % increase in monthly enrollment

This was further increased to **8.5** patients/month when including accruals to breast cancer cohorts of multi-disease, phase I trials within the experimental cancer therapeutics program.



Use of IBM Watson to Identify Additional RNA-binding Proteins Altered in Amyotrophic Lateral Sclerosis

| *Bakkar N et al. Acta Neuropathologica.*
2017;135(2):227-247.

Watson found 5 RBPs previously unlinked to ALS, hnRNPU, Syncrin, RBMS3, Caprin-1 and NUPL2, showed significant alterations in ALS compared to controls.



5 RBPs

“Overall, we successfully used IBM Watson to help identify additional RBPs altered in ALS disease, highlighting the use of artificial intelligence tools to accelerate scientific discovery in ALS and possibly other complex neurological disorders.”



Enhancing NGS-guided Cancer Center Care Through Cognitive Computing

| Patel N et al. The Oncologist. 2018;23(2):179-185.

Providing current, accurate information on newly approved therapies and open clinical trials requires considerable manual curation performed mainly by human "molecular tumor boards" (MTBs).

Watson for Genomics analyzed

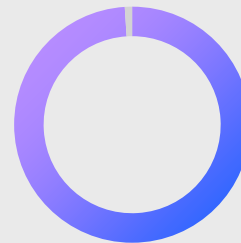
1,018



patient cases previously sequenced and analyzed



< 3 min



99%



32%

“Molecular tumor boards empowered by cognitive computing can significantly improve patient care by providing a fast, cost-effective, and comprehensive approach for data analysis in the delivery of precision medicine.”

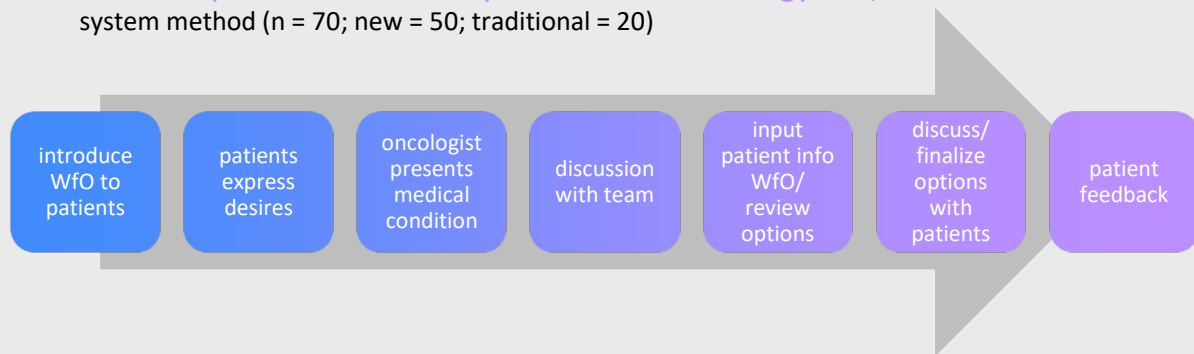


Artificial Intelligence-based Clinical Decision-support System Improves Cancer Treatment and Patient Satisfaction

| Wang Z et al. ASCO Annual Meeting 2019: abstract e18303.

Enhanced patient knowledge around disease and treatment options can increase confidence in achieving positive outcomes. A new model of cancer care consultation assisted by Watson for Oncology (WfO) was evaluated.

New **7-step model assisted by Watson for Oncology** compared to non-CDS system method (n = 70; new = 50; traditional = 20)



Patients in 7-step process indicated higher satisfaction in treatment options, confidence in health care workers, and willingness to follow treatment regimen.

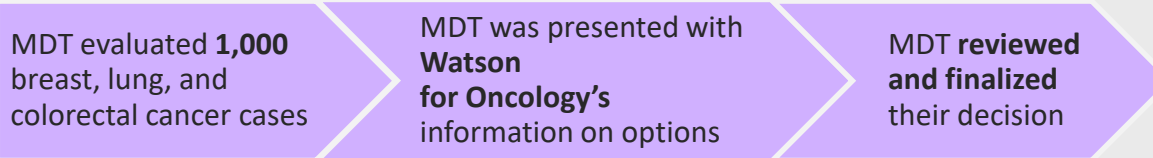
“...patients build stronger confidence with their health care team and are willing to believe they will benefit from the treatment plans.”



A Prospective Blinded Study of 1000 Cases Analyzing Role of Artificial Intelligence. Watson for Oncology in Change of Decision Making of a Multidisciplinary Tumor Board (MDT) From a Tertiary Care Cancer Centre

| Somashekhar SP et al. ASCO Annual Meeting 2019: abstract 6533.

The MDT reviewed and ultimately chose treatments not previously considered based on information from WFO in **13.6%** of cases.



Reason for Decision Change	Percent
Evidence for newer treatment(s)	55%
More personalized treatment alternatives	30%
New genotypic, phenotypic, and clinical insights	15%

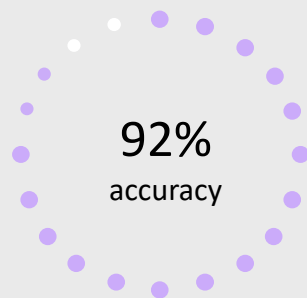
“The study suggest[s] that cognitive computing decision support system[s] holds substantial promise to reduce cognitive burden on oncologist[s] by providing expert, updated, recent evidence-based [evidence-informed] insights for treatment-related decisions making.”



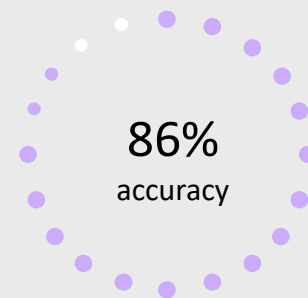
Speech and language are impacted by various types of dementia and may be important markers for psychiatric assessment. A mobile application to classify speech may be useful in assessing and detecting early stage dementia and mild cognitive impairment.

Use of Speech Analyses within a Mobile Application for the Assessment of Cognitive Impairment in Elderly People

| König A et al. *Curr Alzheimer Res.* 2018;15(2):120-129.



Subjective cognitive impairment v. Alzheimer's
(N=165)



Mild cognitive impairment v. Alzheimer's
(N=165)

“This tool can provide the clinician with meaningful information for assessment and monitoring of people with MCI and AD based on non-invasive, simple and low-cost method.”

Epileptic Seizure Prediction Using Big Data and Deep Learning: Toward a Mobile System.

| Kiral-Kornek et al. *EBioMedicine*. 2018 Jan;27:103-111.

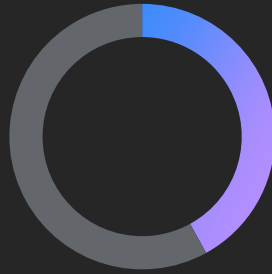
Seizure activity can be disabling; predicting high-risk periods may allow patients to alter daily routines, improve quality of life, and assist in titrating therapeutic interventions.

Deep learning classifier trained to distinguish between preictal and interictal iEEG data from 10 patients (2817 seizures)



69%

Sensitivity to predict seizure activity



42%

Improvement over chance



“This study demonstrates that deep learning in combination with neuromorphic hardware can provide the basis for a wearable, real-time, always-on, patient-specific seizure warning system with low power consumption and reliable long-term performance.”

Humans + Machines = “Augmented Intelligence”

People excel at:



Common
sense



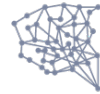
Dilemmas



Morals



Compassion



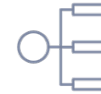
Imagination



Dreaming



Abstraction



Generalization

AI systems excel at:



Natural
Language



Pattern
Identification



Locating
Knowledge



Machine
Learning



Minimize
Bias



Endless
Capacity

True transformation takes time
and happens over several
horizons.



@PetraSchultzRx

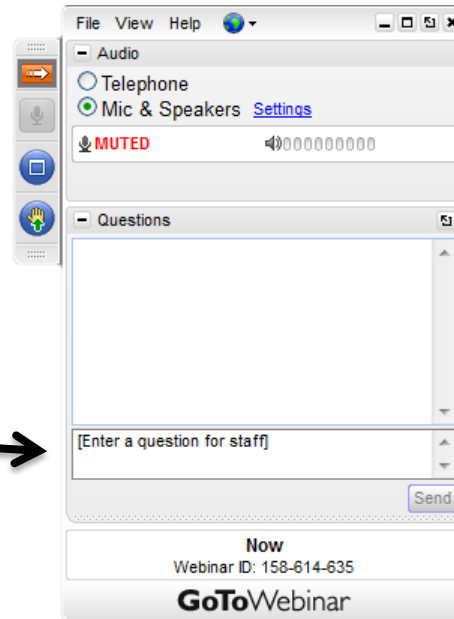
Thank you!



Petra Schultz - LinkedIn

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