

# Jeff Allen, PhD

## **CONTACT INFORMATION**

Jeff Allen, PhD



## **EMPLOYMENT HISTORY**

### **President & CEO – Friends of Cancer Research – Present**

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed life-saving treatments to patients. Responsibilities include creating and implementing research and policy initiatives, engaging with congressional leaders, federal officials and scientific experts, organizational governance and coordinating staff for scientific programs, fundraising, communication and media, policy activities and public education symposia.

### **Executive Director – Friends of Cancer Research – 2008-2016**

Manage a leading non-profit cancer research policy and advocacy organization that focuses on innovative research partnerships and healthcare policy particularly related to the Food and Drug Administration (FDA).

### **Director of Science Policy – Friends of Cancer Research – 2006-2008**

Created and led science policy activities with major focus on drug safety legislation, FDA oncology programs, and advancement of personalized medicine.

### **Research Fellow – National Institutes of Health**

National Center for Complementary and Alternative Medicine, Laboratory of Clinical Investigation – 2005-2006

## **EDUCATION & TRAINING**

### **Post-Doctoral Fellow**

Department of Cell Biology, College of Medicine, Georgetown University  
2004-2005

### **Georgetown University, Washington, DC**

PhD, Cell and Molecular Biology, 2004

### **Bowling Green State University, Bowling Green, OH**

Bachelor of Science, 1999

Major: Biology      Minor: Chemistry      University Honors, Cum Laude

## **POLICY & LEGISLATIVE EXPERIENCE**

### **Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:**

- *Improving Safety and Transparency in America's Food and Drugs.* January 29, 2020

### **Making Objective Drug Evidence Revisions for New (MODERN) Labeling Act of 2020**

- Developed research study that served as the basis for legislative action by quantifying drug labels that had become outdated
- Worked with congressional leaders and stakeholders to draft legislative language

**Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:**

- *Examining FDA's Prescription Drug User Fee Program.* March 22, 2017

**Testimony before the Senate Committee on Health, Education, Labor & Pensions:**

- *Laboratory Testing in the Era of Precision Medicine.* September 20, 2016

**21<sup>st</sup> Century Cures Act**

- Developed legislative language based on prior Friends' scientific programs that led to new programs and provisions in the Act:
  - Sec. 3001. Patient experience data
  - Sec. 3002. Patient focused drug development guidance
  - Sec. 3011. Qualification of drug development tools
  - Sec. 3031. Summary level review
  - Sec. 3072. Hiring authority for scientific, technical, and professional personnel
  - Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes.

**Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:**

- *21<sup>st</sup> Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation* May 20, 2014

**Breakthrough Therapy Designation / Food and Drug Administration Innovation and Safety Act (FDASIA)**

- Developed legislative language to create Breakthrough Therapies designation (Sec. 902)
- Established coalition support for legislation (40 organizations)
- Frequent press engagement and public speaking to develop support for the program

**Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:**

- *FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain.* March 8, 2012

**Patient Protection and Affordable Care Act:**

- Drafted legislative language suggestions incorporated in Senate Finance version (Subtitle D – Patient Centered Outcomes Research)
- Developed coalition support for legislation (68 advocacy organizations)
- Developed coalition support for comparative effectiveness research provisions (34 organizations)
- Worked extensively with both Senate and House Democrats and Republicans
- Amicus brief participant and signatory supporting minimum coverage requirement

**Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:**

- *NCI Research: Today's Progress, Tomorrow's Challenge.* March 23, 2010

**Food and Drug Administration Amendments Act of 2007:**

- Drafted legislative language incorporated in final bill (Title VI – Reagan-Udall Foundation, Title IX – Enhanced Authorities Regarding Post-Market Safety of Drugs)
- Developed coalition support for bill provisions (65 advocacy organizations)
- Worked extensively with both Senate and House Democrats and Republicans
- Wrote editorials for publication supporting drug safety provisions
- Press interviews describing importance of legislative provisions
- Prepared written and oral testimony for House Energy & Commerce Drug Safety hearing

## **RESEARCH & REGULATORY PROJECTS**

### **Research Partnerships**

#### **ctMoniTR**

The use of ctDNA to monitor treatment response has been particularly challenging to properly investigate its role as a monitoring tool for treatment response due to variability in the way ctDNA assessment has been designed into clinical trials, the various collection methods used and the way ctDNA changes are reported by different ctDNA assays. The first step of this alignment pilot project is a collaboration with 5 pharmaceutical companies, 4 diagnostic companies, and Johns Hopkins University with the objective to harmonize the use of ctDNA to monitor treatment response (ctMoniTR), to assess if changes in ctDNA levels accurately reflect the therapeutic effect of cancer therapies. Demonstrating the utility of ctDNA monitoring will enable an earlier determination of treatment response for patients and more rapid evaluation of the effect of new therapies.

#### **Real-World Evidence Pilot Project Series**

There is a need for better characterization of the role real-world endpoints may play in evaluating product effectiveness. This project brings together 10 leading health research organization to assess several frontline treatment regimens in real-world patients with advanced non-small cell lung cancer (aNSCLC). This project evaluates the extent to which real-world endpoints (such as time to treatment discontinuation) relates to traditional clinical measures of response to therapies. This will better enable development of new research methods, consistent result reporting, and further the use of quality real world data to accelerate research.

#### **TMB Harmonization**

Tumor mutation burden (TMB) has emerged as a potentially predictive biomarker for identifying patients with increased likelihood to respond to IO therapy. Currently, there is a lack of standardization for TMB calculation and reporting. This collaborative partnership brings together 15 leading laboratories, FDA, NCI, and expert researchers to align different tests used to assess TMB. Ultimately, this project will help ensure consistent identification of patients who are likely to respond to IO therapies.

#### **Lung-MAP: Lung Cancer Master Protocol**

Based on the concept paper developed for the Conference on Clinical Cancer research in 2012, a large-scale collaborative effort was established between *Friends*, FDA, NCI, SWOG Oncology, the Foundation for the NIH, several pharmaceutical and biotech companies, Foundation Medicine, and numerous patient advocacy organizations. This led to the 2014 launch of Lung-MAP a multi-drug, biomarker-driven master protocol designed to increase efficiencies in drug development and improve access to cutting-edge new products. Today the trial is available at over 700 research institutions.

### **Regulatory Initiatives**

#### **FDA Oncology Center of Excellence**

- Worked with a broad group of stakeholders, including FDA leadership, to promote the concept of oncology-focused, cross-functional process between existing medical product Centers at the FDA.
- Developed coalition support across the oncology community and implemented legislative strategy for the inclusion of the concept in the 21<sup>st</sup> Century Cures Act and the Obama Administration Cancer Moonshot

#### **Blueprint for Breakthroughs**

Building on the establishment of the 2012 Breakthrough Therapy Designation, this scientific conference series developed consensus recommendations for challenging aspects to the efficient development a Breakthrough Designated Drug

- 2013 - A Risk-based Approach for In Vitro Companion Diagnostic Device FDA Approval Process Associated with Therapies that have a Breakthrough Designation
- 2014 – A Blueprint for Drug/Diagnostic Co-Development: Next-Generation Sequencing (NGS) in Oncology
- 2015 - Examining Manufacturing Readiness for Breakthrough Drug Development
- 2016 – Exploring the Utility of Real-world Evidence
- 2017 – Charting the Course for Precision Medicine
- 2018 – Research and Reimbursement in the Age of Precision Medicine
- 2019 – Validating Real-World Endpoints for an Evolving Regulatory Landscape

### **Collaborations to Develop and Submit Proposed FDA Guidance Documents**

- *Co-development of Two or More Unmarketed Investigational Drugs for Use in Combination* (FDA Draft Released 2011)
- *Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement.* Kim E, et al. *Journal of Clinical Oncology.* Vol 35 No. 33, Nov 2017.
  - Expert working groups developed recommendations for expanding cancer clinical trial eligibility related to minimum age for enrollment, patients with HIV, patients with brain metastases, organ dysfunction and prior and current malignancies.
  - FDA Guidance Series Released 2019

### **Conference on Clinical Cancer Research**

A goal-oriented conference that convenes leaders from NCI, FDA, Academia, Industry, and Advocacy to address specific scientific and regulatory issues impacting drug development. This conference series has evolved to the Friends of Cancer Research Annual Meeting (13<sup>th</sup> Annual) and provided the foundation for future policy initiatives.

### **SELECTED POLICY & RESEARCH PUBLICATIONS**

Stewart M, McCall B, Pasquini M, Yang A, Britten C, Chuk M, De Claro A, George B, Gormley N, Horowitz M, Kowack E, McCoy C, Morrow P, Okoye E, Ricafort R, Rossi J, Sharon E, Theoret M, Vengi F, Yu T, **Allen J.** **Need for Aligning the Definition and Reporting of Cytokine Release Syndrome (CRS) in Immuno-Oncology Clinical Trials.** *Cytotherapy.* 2022 Feb 23 doi: 10.1016/j.jcyt.2022.01.004

Horvat P, Gray CM, Lambova A, Christian JB, Lasiter L, Stewart M, **Allen J,** Clarke P, Chen C, Reich A. **Comparing Findings From a Friends of Cancer Research Exploratory Analysis of Real-World End Points With the Cancer Analysis System in England.** *JCO Clin Cancer Inform.* 2021 Dec;5:1155-1168. doi: 10.1200/CCI.21.00013.

Rivera DR, Henk HJ, Garrett-Mayer E, Christian JB, Belli AJ, Bruinooge SS, Espirito JL, Sweetnam C, Izano MA, Natanzon Y, Robert NJ, Walker MS, Cohen AB, Boyd M, Enewold L, Hansen E, Honnold R, Kushi L, Mishra Kalyani PS, Pe Benito R, Sakoda LC, Sharon E, Tymejczyk O, Valice E, Wagner J, Lasiter L, **Allen J.** **The Friends of Cancer Research Real-World Data Collaboration Pilot 2.0: Methodological Recommendations from Oncology Case Studies.** *Clin Pharmacol Ther.* 2021 Oct 18. doi: 10.1002/cpt.2453.

Lasiter L, Tymejczyk O, Garrett-Mayer E, Baxi S, Belli AJ, Boyd M, Christian JB, Cohen AB, Espirito JL, Hansen E, Sweetnam C, Robert NJ, Small M, Stewart MD, Izano MA, Wagner J, Natanzon Y, Rivera DR, **Allen J.** **Real-world Overall Survival Using Oncology Electronic Health Record Data: Friends of Cancer Research Pilot.** *Clin Pharmacol Ther.* 2021 Oct 16. doi: 10.1002/cpt.2443.

Gallo L, Walters RS, **Allen J,** Ahlstrom J, Alspach C, Biru Y, Schatz A, Martin K, Carlson RW. **Accelerating Advances in Cancer Care Research: A Lookback at the**

**21st Century Cures Act in 2020.** J Natl Compr Canc Netw. 2021 Apr 1;19(4):378-384. doi: 10.6004/jnccn.2021.7005. PMID: 33845456.

Collins G, Stewart M, Sigal E, **Allen J. Expedited Development Programs at the Food and Drug Administration: Insights and Opportunities.** Ther Innov Regul Sci. 2021 May;55(3):619-621. doi: 10.1007/s43441-021-00258-z.

Stewart M, Rodriguez-Watson C, Albayrak A, Asubonteng J, Belli A, Brown T, Cho K, Das R, Eldridge E, Gatto N, Gelman A, Gerlovin H, Goldberg SL, Hansen E, Hirsch J, Ho YL, Ip A, Izano M, Jones J, Justice AC, Klesh R, Kuranz S, Lam C, Mao Q, Mataraso S, Mera R, Posner DC, Rassen JA, Siefkas A, Schrag A, Tourassi G, Weckstein A, Wolf F, Bhat A, Winckler S, Sigal EV, **Allen J. COVID-19 Evidence Accelerator: A parallel analysis to describe the use of Hydroxychloroquine with or without Azithromycin among hospitalized COVID-19 patients.** PLoS One. 2021 Mar 17;16(3):e0248128. doi: 10.1371/journal.pone.0248128.

Huang R, Lasiter L, Bard A, Quinn B, Young C, Salgado R, **Allen J, Lennerz JK. National Maintenance Cost for Precision Diagnostics Under the Verifying Accurate Leading-Edge In Vitro Clinical Test Development (VALID) Act of 2020.** JCO Oncol Pract. 2021 Nov;17(11):e1763-e1773. doi: 10.1200/OP.20.00862.

Connors D, **Allen J, Alvarez JD, Boyle J, Cristofanilli M, Hiller C, Keating S, Kelloff G, Leiman L, McCormack R, Merino D, Morgan E, Pantel K, Rolfo C, Serrano MJ, Pia Sanzone A, Schlange T, Sigman C, Stewart M. International liquid biopsy standardization alliance white paper.** Crit Rev Oncol Hematol. 2020 Dec;156:103112. doi: 10.1016/j.critrevonc.2020.103112.

Stewart M, Keane A, Butterfield L, Levine B, Thompson B, Xu Y, Ramsborg C, Lee A, Kalos M, Koerner C, Moore T, Markovic I, Lasiter L, Ibrahim R, Bluestone J, Sigal E, **Allen J. Accelerating the Development of Innovative Cellular Therapy Products for the Treatment of Cancer.** Cytotherapy.22.5. (May 2020) 22, 239–246. Doi: 10.1016/j.jcyt.2020.01.014

Merino D, McShane L, Fabrizio D, Funari V, Chen S, White J, Wenz P, Baden J, Barrett J, Chaudhary R, Chen L, Chen W, Chen J, Cyanam D, Dickey J, Gupta V, Hellmann M, Helman E, Li Y, Maas J, Papin A, Patidar R, Quinn K, Rizvi N, Tae H, Ward C, Xie M, Zehir A, Zhao C, Dietel M, Stenzinger A, Stewart M, **Allen J. Establishing Guidelines to Harmonize Tumor Mutational Burden (TMB): In Silico Assessment of Variation in TMB Quantification Across Diagnostic Platforms- Phase 1 of the Friends of Cancer Research TMB Harmonization Project.** Journal for ImmunoTherapy of Cancer. 8. 1. (Mar 2020) doi: 10.1136/jitc-2019-000147

Stewart M, Norden A, Dreyer N, Henk H, Abernethy A, Chrischilles E, Kushi L, Mansfield A, Khozin S, Sharon E, Arunajadai S, Carnahan R, Christian J, Miksad R, Sakoda L, Torres A, Valice E, **Allen J. An Exploratory Analysis of Real-World End Points for Assessing Outcomes Among Immunotherapy-Treated Patients with Advanced Non-Small-Cell Lung Cancer.** JCO Clinical Cancer Informatics. (July 2019) Special Article. 1-15. Doi: 10.1200/cci.18.00155.

Stenzinger A, **Allen J, Maas J, Stewart M, Merino D, Wempe M, Dietel M. Tumor Mutational Burden Standardization Initiatives: Recommendations for Consistent Tumor Mutational Burden Assessment in Clinical Samples to Guide Immunotherapy Treatment Decisions.** Genes Chromosomes and Cancer. 58: 8. (Jan 2019) 578-88. Research Article. Doi: 10.1002/gcc.22733.

Shea M, Stewart M, Van Dyke H, Ostermann L, Allen J, Sigal E, **Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice.** Ther Innov Regul Sci. 52: 6. (Nov 2018) 771-7. Research Article. Doi: 10.1177/2168479018759662

**Allen J**, Stewart M, Roberts S, Sigal E. **The Value of Addressing Patient Preferences.** Value in Health. 20: 2. (Feb 2017) 283-5.

Audibert CM, Shea MB, Glass DJ, Kozak ML, Caze AP, Hohman RM, **Allen JD**, Sigal EV, Leff JS. **Use of FDA-Approved and Laboratory-Developed Tests in Advanced Non-Small Cell Lung Cancer: Results of a Retrospective Market Analysis.** Personalized Medicine in Oncology. 5: 7. (Sept 2016) 278-84.

Shea M, **Allen J**, Sigal E. **A Century of Medical Product Regulation: The Historic Framework for Personalized Medicine in Oncology.** Personalized Medicine in Oncology. (Mar 2016) 1-16.

Shea M, Ostermann L, Hohman R, Roberts S, Kozak M, Dull R, **Allen J**, Sigal E. **Regulatory Watch: Impact of breakthrough therapy designation on cancer drug development.** Nat Rev Drug Discov. 15: 3. (Mar 2016) 152.

Hohman R, Shea M, Kozak M, Roberts S, **Allen J**, Sigal E. **Regulatory decision-making meets the real world.** Sci Transl Med. 11: 7 (Nov 2015) 313.

Rubin E, **Allen J**, Nowak J, Bates S. **Developing Precision Medicine in a Global World.** Clin Cancer Res. 15;20(6) (Mar 2014) 1419-27.

Hayes D, **Allen J**, Compton, C, et al. **Breaking a Vicious Cycle.** Sci Tans Med 5:196 (July 2013) 1-7.

Roberts S, **Allen J**, Sigal E. **Despite Criticism of the FDA Review Process, New Cancer Drugs Reach Patients Sooner in the United States than in Europe.** Health Affairs 30:7 (July 2011) 1375-81.

## **PROFESSIONAL BOARDS & COMMITTEES**

**Alliance for a Stronger FDA:** Board of Directors member, Past President (2015)

**American Association for Cancer Research**

**American Society of Clinical Oncology**

**Lung-MAP:** Policy Leadership Committee Member

**National Cancer Institute:** *Director's Consumer Liaison Group*, Federal Advisory Committee Member (2010-2013)

**President's Council of Advisors on Science and Technology (PCAST):** Provisional Working Group Member, Advancing Innovation in Drug Development and Evaluation

## **SELECTED PRESENTATIONS**

*Regulatory Requirements for Companion Diagnostics Testing: Current Regimes and Potential Reforms.* American Society for Gene & Cell Therapy Annual Meeting. September 23, 2021

*Tumor Mutational Burden (TMB): Harmonization and Future Application.* Society for Immunotherapy in Cancer Annual Meeting. November 9, 2019

*The Use of Real-World Endpoints in Cancer Drug Development.* 2019 AMCP Foundation 9th Annual Research Symposium. October 29, 2019

*Recent policy initiatives that have helped facilitate drug development for rare cancer population.* World Orphan Drug Congress. April 11, 2019

*Physician-Built and Evidence-Based: How Electronically Accessible Pathways standardize world-class Cancer Care.* 2019 Health Datapalooza. March 27, 2019

*Future Directions in Regulatory Policy: The Role of Real World Evidence.* 19th Annual AcademyHealth National Health Policy Conference (NHPC) February 4, 2019

*Companion Diagnostics: Trends and Perspectives.* AdvaMed Med Tech Conference. September 24, 2018

*Correlation of real-world endpoints to overall survival among immune checkpoint inhibitor-treated aNSCLC patients.* Establishing a Framework to Operationalize and Validate Real-World Data Sets. July 10, 2018

*Safeguarding the Public Health: Enhancing Information About Prescription Drugs.* Congressional Briefing. March 20, 2018

*Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.* FDA Public Workshop on Patient-Focused Drug Development. March 19, 2018

*Optimizing Early Clinical Strategies to Support Breakthrough Therapy Designation.* DIA Annual Meeting. June 21, 2017

*Real-World Evidence in Oncology and its Implication.* American Association of Cancer Research Annual Meeting. April 1, 2017

*FDA Oncology Center of Excellence: Implications for Intercenter Coordination.* DIA Combination Products Annual Meeting. October 25, 2016

*The Future of Precision Medicine & Patient Care: Policy Solutions to Address the Current Genomic Testing Landscape.* Senate Briefing. October 13, 2016