Analytical Chemistry Seminar

Tuesday, March 5, 2024
3:30 p.m. ~ WTHR 320

"Pharmaceuticals are Accurate and Precise, but Patients are Neither. What Could Go Wrong? And How Can Analytical Chemistry Help?"

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Abstract:

An inconvenient truth for biopharma is the disconnect between clinical trials and clinical application. Preclinical and clinical trials consider the diversity of mammalian study subjects, but always limit that diversity with necessarily narrow inclusion/exclusion criteria. This is reasonable with hope for improved statistics through a reduced number of variables. As trials move to Phase III and IV, we have more patient diversity, but make far fewer measurements per participant. Fully inclusive trials are not feasible. In the end, prescribing information is based on averages with some caveats from trial observations.

The complications of drug-drug interactions and comorbidities are hard to sort out as are the even greater variances in genotype and lifestyle. We necessarily arrive at prescribing recommendations that reflect doses selected for trials and the observed response averages. The full range of data for clinical trials is rarely published despite demands for more. I suspect this reflects the complications of unusual responses for a small number of patients. Requests to include more trial subjects in future studies are common, although this can delay approval and drive costs. For example, demands to include more trial subjects with different visible characteristics (e.g. skin color, handicaps, ethnicity, weight) are misplaced. After approval, we learn more over time with real world experience. That's a slow process and thus we have the cry for Personalized Medicine. But what does this mean? It is happening for drug choice (esp in cancer). It is not commonly happening for drug dose in spite of four decades of interest. Being aware of this challenging healthcare systems problem may suggest possible approaches.

Bio:

Pete Kissinger received BS degree in 1966 from Union College, Schenectady, PhD from UNC in 1970, and postdoc at KU in 1970-1972. He started as Assistant Professor at Michigan State in 1972-1975, and then was Professor at Purdue in 1975-2019. He is currently Emeritus Professor of Analytical Chemistry at Purdue. He has >250 peer reviewed publications. He founded BAS in Michigan in 1974 to fill a gap in low-cost electroanalytical instrumentation that had recently become feasible due to the development of integrated circuit operational amplifiers in the 741 formats. The first standalone cyclic voltammetry instruments and amperometric detectors for liquid chromatography were initial 'garage products'. The product line was quickly supplemented by liquid chromatography, the first digital electroanalytical workstation (1985) (partnering with the Univ. of Illinois), and several in vivo sampling technologies for neuroscience and pharmaceutical discovery. The latter involved collaboration with the Karolinska Institute, Eli Lilly, and others. BAS was rebranded as Inotiv, Inc. in 2018 and today has over 2200 employees throughout the USA and in several EU countries. Pete retired from active management in 2007. He is a Fellow of AAAS and AAPS and was appointed a Sagamore of the Wabash by Indiana Governor Eric Holcomb.

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