Planning Meeting for the Drug Development Tool for Kidney Disease (DDT-KD) Consortium

Major Objectives of Drug Development Tools for Kidney Disease Consortium

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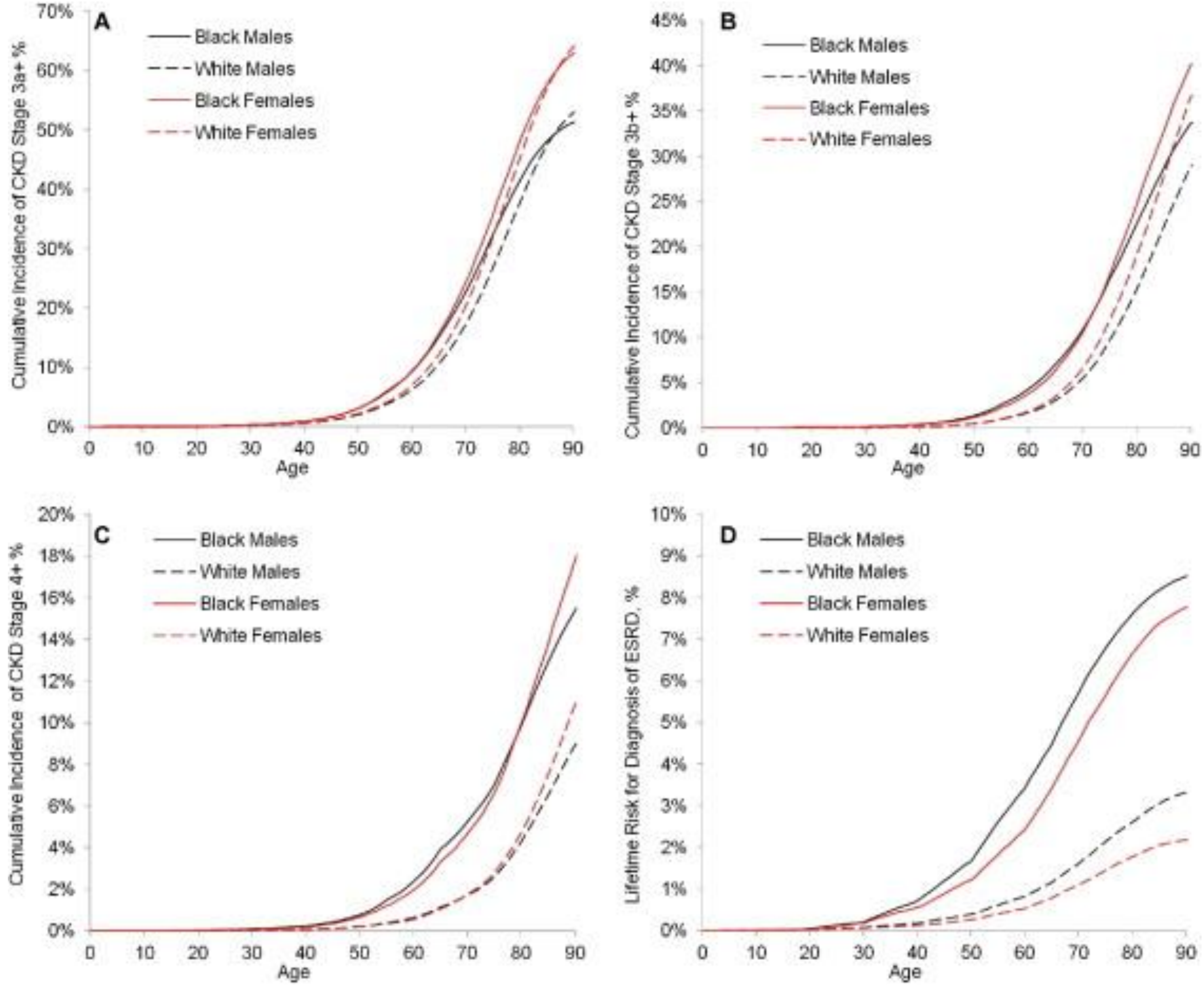
DDT-KD Consortium Objectives

DDT-KD
Consortium

- **Primary Goal: Identify, prioritize and qualify novel biomarkers for AKI and CKD**
- Develop drug-development tools for new therapies for acute and chronic kidney disease
- Harmonize definitions and goals
- Facilitate qualification of kidney biomarkers for nephrology community
- Learn from completed clinical trials to help us develop new approaches and designs for AKI and CKD (Adaptive trials)

Lifetime Risk of CKD >50%

DDT-KD Consortium



Am J Kidney Dis. 2013 Aug;62:245-52

Why do we need a DDT-KD C-Path Consortium?

- AKI Biomarkers accepted by the FDA for pre-clinical testing
- Recent qualification of TKV as stratification tool for PKD
- KHI has a Data Standards in DKD Workgroup in place
- CPAST-DKD project ongoing
- CKD-Biocon recently established (2015)
- JDRF Network for DKD Biomarkers recently established (2015)

- Challenge remains-How do we coordinate the data emerging from these initiatives to improve future clinical trials and make them more insightful?

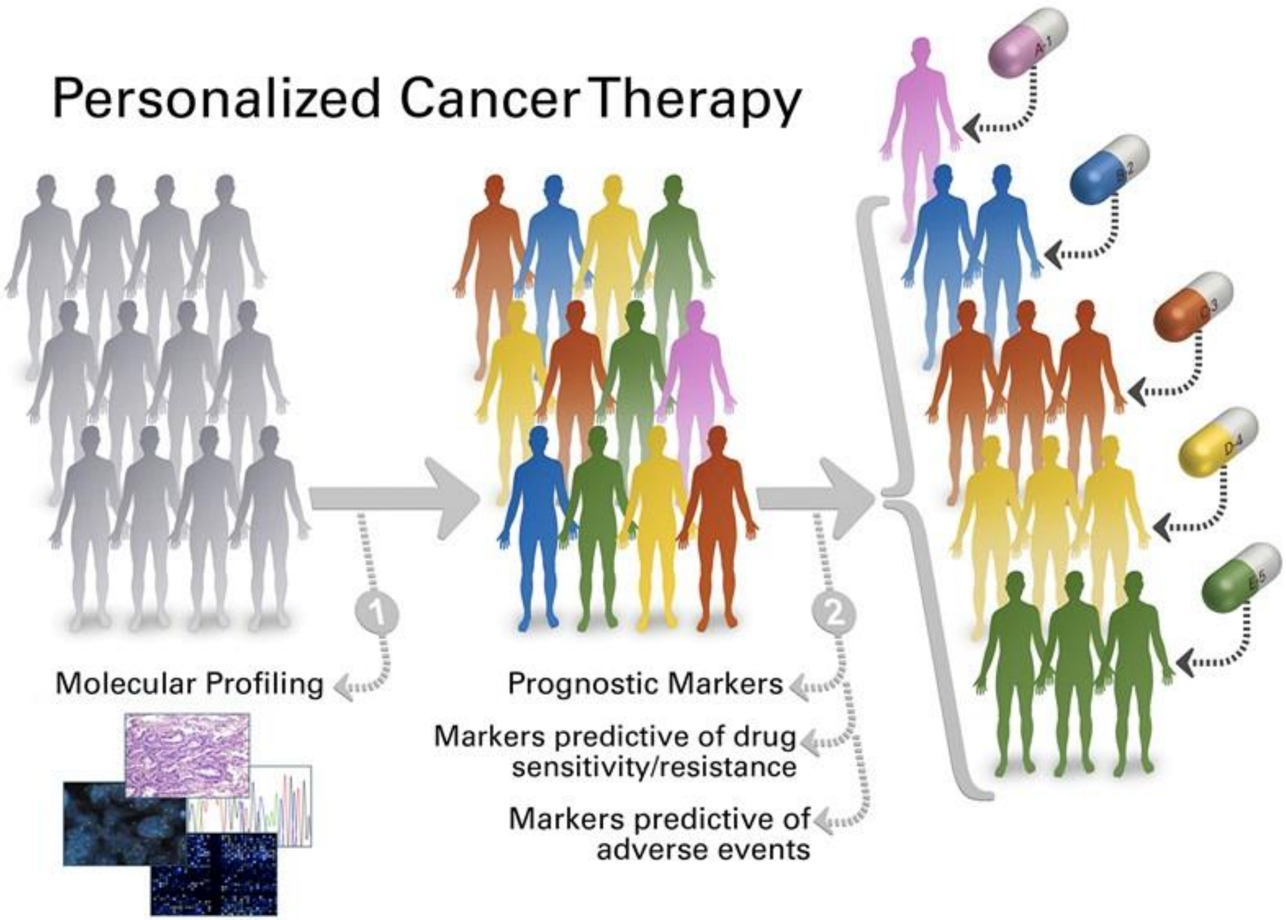
Working Principles of DDT-KD

Coordinately and transparently evaluate data for biomarkers in each of the FDA accepted categories of qualification

- Prognostic
- Diagnostic
- Predictive
- Pharmacodynamic
- Surrogate

CKD has a similar prognosis as many cancers but far fewer therapies

DDT-KD Consortium



New Generation of Insightful and Efficient Clinical Trials

- Stratify patients to only include patients who will likely progress with their CKD in a 6m-1yr, 2y, 3yr timeframe for Phase II/III trials (Prognostic)
- Identify patients who will likely benefit from a specific drug before they are given the drug (Predictive)
- Monitor treatment with biomarkers to assess degree of efficacy or toxicity while on the drug (Pharmacodynamic)
- Measure a set of biomarkers at 1-6 months to assess potential renal benefit during a Phase II-III trial (Surrogate)
- Clinical trials that will include qualified biomarkers will have a higher chance of success and will increase insight towards personalizing medicines for kidney disease