National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases

Preparing for Kidney Precision Medicine Clinical Trials Workshop

Natcher Conference Center
NIH Main Campus, Building 45
45 Center Drive
Bethesda, MD, 20894
and Via Zoom Virtual Platform

March 18–19, 2024

EXECUTIVE SUMMARY

Meeting Objectives

The National Institutes of Health (NIH) sponsored a scientific workshop on March 18 and 19, 2024, titled "Preparing for Kidney Precision Medicine Clinical Trials," which was hosted by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The purpose of the workshop was to gain a better understanding of the therapeutic journey of patients with kidney disease and to define candidate indicators for precision medicine pathway, target, and trial readiness. The workshop comprised patient and expert panels, as well as breakout sessions, to identify barriers to kidney precision medicine clinical trials and potential solutions and to identify ways to advance precision medicine clinical trials that have not yet been considered. Approximately 400 virtual and in-person attendees participated in the event.

Progressive kidney disease affects how individuals feel, function, and survive. Therapies for individuals with kidney disease have only modest efficacy; neither the selection of treatments nor the risk for severe toxicity is well informed by precise assessment of disease mechanism(s) active at the time of decision-making. In this standard-of-care context, many people with chronic kidney disease (CKD) undergo a series of therapies that have limited efficacy and, ultimately, they progress to kidney failure. Scientific advances are increasing awareness and improving the ability to assess the molecular mechanisms of kidney disease and clarify associated therapeutic targets.

An external organizing committee (Dr. Joseph Bonventre, Dr. Glenn Chertow, Mr. Paul Conway, Dr. Rasheed Gbadegesin, Dr. Melanie Joy, Dr. Matthias Kretzler, Dr. Mark David Lim, Dr. Kathleen Liu, and Dr. Aliza Thompson) was recruited to work with NIDDK staff (Drs. Kevin Abbott, Kevin Chan, Debbie Gipson, Raquel Greer, Paul Kimmel, Susan Mendley, Afshin Parsa, Tracy Rankin, Cindy Roy, and Ivonne Schulman) to develop the meeting agenda. The objectives of the workshop were to—

- Bring in the patient's voice to advance treatments for kidney disease.
- Define candidate indicators for precision medicine pathways, targets, and trial readiness.
- Identify barriers to kidney precision medicine clinical trials and potential solutions.
- Identify concepts relative to advancing precision medicine clinical trials not yet considered.

Following opening remarks from the Director of the NIDDK Division of Kidney, Urologic and Hematologic Diseases (KUH) and the Program Director of the KUH Precision Clinical Trials program,

kidney patients and their family members shared their experiences with kidney treatments. The patient panel was followed by five scientific sessions during which leading experts presented scientific considerations for kidney precision medicine trials; regulatory, industry, and patient advocacy perspectives; and lessons learned from relevant fields and studies. Both days of the workshop concluded with breakout sessions; participants assessed the current state of kidney precision medicine trials and identified challenges and potential opportunities for improved clinical care.

Session 1: Kidney Patient and Family Panel Discussions

Kidney patients and their families discussed how they have been affected by kidney disease and described their encounters with kidney care in the United States. During the discussions, panelists identified the following gaps and opportunities associated with treating kidney disease, including expansion of precision therapeutics.

Treatment Gaps and Opportunities

- People with kidney disease suffer severe disruptions to their daily lives, including losing the ability to walk and extreme symptoms that require hospitalization. Kidney disease and its treatments also can have serious emotional consequences for patients, a side effect that caregivers rarely address.
- Patients and their families likely will encounter health care providers who lack expertise in kidney disease. Misdiagnosis is common, and patients can receive incorrect and even harmful treatments. Patients must advocate for and educate themselves, including driving discussions about their health and investigating treatment options.
- Access to specialists is a major challenge, and even experts overlook the nuances of kidney disease. Dialysis centers specializing in the care of patients with kidney failure often do not differentiate between acute kidney injury (AKI) and CKD. Expert advice about kidney disease management can be confusing.
- People with kidney disease are presented with limited treatment options that often are grueling, associated with severe risks, and not guaranteed to succeed. Caregivers often do not include patients in the decision-making process or discuss the risks and benefits of various therapies.
- Patients rely on personal networks of family and friends for support, advocacy, education, and referral to expert care. Navigating the disease without these resources is extremely challenging.

Session 2: Scientific Considerations for Kidney Precision Medicine Trials

Presenters discussed mechanisms, endophenotypes, and targets associated with AKI and CKD, as well as the development and assessment of precision interventions for kidney disease. During the presentations and subsequent question-and-answer period, the speakers and participants identified the following research gaps and opportunities.

Research Gaps and Opportunities

- Precision kidney medicine requires dividing patients into discrete subgroups with shared disease mechanisms and pathophysiologies that targeted therapies can address. Reverse translation and molecular diagnostics can be combined using multi-scalar data integration to identify kidney disease subphenotypes and enable patient-level disease targeting. Several studies have shown prognostic and predictive enrichment using a single or small set of biomarkers.

- AKI originates from heterogeneous causes, which has limited the identification of agents for its treatment or prevention. Researchers have used unbiased clustering analysis of clinical variables and circulating markers to stratify AKI patients into subtypes with different clinical outcomes. An example simplified model was presented to differentiate among the AKI subtypes using three biomarkers with associated differential responses to clinical trial therapy and improved clinical outcomes in *post hoc* analysis.
- In CKD, gene expression profiles are heterogeneous within individual disease etiologies and common profiles across a spectrum of kidney diseases. Classification of patient samples by molecular category (rather than clinical diagnosis) reveals novel subgroups with shared and potentially targetable biological pathways.
- Such resources as the Human Biomolecular Atlas Program (or HuBMAP), Human Cell Atlas, Kidney Precision Medicine Project, and Nephrotic Syndrome Study Network (or NEPTUNE) are examples of programs available for use when developing molecular definitions of kidney disease phenotypes.
- Current challenges include identifying useful biomarkers, relating subphenotypes to mechanisms of disease progression and therapeutic candidates, and leveraging subphenotype to understand genetic risk. Several steps must be taken to address these challenges, including developing preclinical and *ex vivo* models of disease subphenotypes and embedding specimen collection into clinical trials with longitudinal sample collection.
- Drug development is expensive and inefficient, but phenotypic and target-based screening can ease bottlenecks associated with the process. Gene therapy is strategically and logistically challenging because each mutation requires a unique treatment development path. Using methods such as cell painting to identify disease phenotypes and potential treatment effects and targeting the regulators that affect multiple mutations might be more effective ways to develop treatments. Similarly, identifying single compounds with multitarget activity simplifies and de-risks drug development.

Session 3: Preparing the Precision Trials Toolbox

Speakers provided an overview of precision trial design components, including biomarkers, trial design, and laboratory programs for trial screening and monitoring. During the presentations and subsequent question-and-answer session, the speakers and participants highlighted the following clinical gaps and research opportunities.

Research Gaps and Opportunities

- New therapies for kidney disease are promising, but high residual risks for treated patients remain. These risks can be due to low treatment response and off-target effects of the therapies.
- Traditional biomarkers, such as albuminuria, might be ineffective at predicting individual drug responses because patient responses are highly variable and the biomarker is not specific to the drug mechanism of action. However, at the population level, average treatment effects on the same biomarker can differ significantly between responders and nonresponders.
- Future challenges will involve assessing existing biomarkers more precisely and discovering and validating more accurate response markers that match the kidney disease pathophysiology and drug mechanism of action.
- Laboratory programs from the National Cancer Institute serve as examples for precision clinical trial programs. A central laboratory hub may include a very small number of sites (e.g., five or

fewer) using common laboratory procedures, including the same assays, instruments, and analysis pipelines with required agreement (e.g., more than 99 percent). An alternative model is the External Designated Laboratory Network, which uses a network of selected highest-quality laboratories with demonstrated performance characteristics confirmed in the application and selection process. This includes some "full-service" laboratories and some specialty laboratories for unique assays.

Session 4: Perspectives from Regulatory, Industry, and Patient Advocacy

Speakers shared perspectives on precision medicine trials from the U.S. Food and Drug Administration (FDA), pharmaceutical companies, and the American Association of Kidney Patients (AAKP). Moderators, panelists, and other participants identified the following gaps and research opportunities.

Research Gaps and Opportunities

- Precision therapeutics are most relevant for drugs with narrow therapeutic indices and variable responses and conditions in which a solid understanding of the disease pathophysiology and drug mechanism of action are present.
- Reducing biological heterogeneity (i.e., implementing precision approaches) can increase trial benefits by identifying likely responders and can decrease risk by avoiding populations either unlikely to respond or more likely to experience adverse drug reactions.
- Evidence necessary to consider a precision medicine approach from a corporate perspective might include confidence in the biomarker (e.g., predictive performance, intrinsic variability), the nature of the disease (e.g., morbidity, mortality, available treatments), therapeutic properties (e.g., magnitude and nature of treatment benefit, toxicities, dosing approach), and the business case.
- Precision approaches can be complex. Companion diagnostics require distinct development procedures and inclusion of a specific patient subgroup (population enrichment) that might limit the pool of eligible participants for an individual trial.
- Drug development activities might leverage regulatory incentives (e.g., rare pediatric disease designation and priority review vouchers).
- FDA staff are available to consult on addressing clinical trial study designs and development plans for devices and diagnostic assays.
- Advocacy organizations have developed powerful platforms to engage patients in the process of scientific discovery. Trial recruitment strategies are likely to benefit by leveraging existing brand trust, patients as expert research partners, and tools that advocacy organizations have developed with their populations. Patient populations that are not incorporated into existing advocacy organizations might require the development of unique advisory boards.
- From the patient advocacy perspective, patients are organized and well equipped to be at the center of science from the earliest stages of study question consideration through the full cycle of trial completion to communications with representatives of the payer communities. Early and ongoing patient engagement is essential for treatment development.
- Patient surveys have highlighted the priorities of patients, including learning about the purpose of a study and the qualifications of the study investigators, understanding the potential risks to their overall health, and helping reduce the burden of kidney disease for others. More than 90 percent of kidney patient survey respondents have never been invited to participate in a clinical trial.

- Patients and their advocates should be engaged as early as possible regarding proposed therapeutics and their potential effects, trial design, study burden assessment, and patient-facing materials. Patients want to know about the purpose of trials, the qualifications of those running the trial, and the logistical aspects of trial participation.

Session 5: Precision Medicine Trial Program Exemplar

An expert clinical trialist provided an overview of a precision medicine trial exemplar, Investigation of Serial studies to Predict Your Therapeutic Response with Imaging and molecular AnaLysis 2 (or I-SPY 2 TRIAL). During the session, the following best practices and research opportunities were identified.

Best Practices and Research Opportunities

- The I-SPY TRIAL platform was developed to improve breast cancer outcomes. It was launched with the belief that treatment approaches and outcomes could be improved and an understanding that there is uncertainty in discovery. Investigators were certain that continuing with the historic standard of care would not improve the health outcomes for high-risk patients.
- I-SPY TRIAL is a platform to conduct multiple clinical trials and continually improve study methods (e.g., patient stratification, monitoring, treatment response, treatment progression) and study operations and to integrate clinical trials with clinical care.
- The Bayesian study design incorporated disease heterogeneity prospectively, identified earlier endpoints during care, and recognized screening signals by disease subtype.
- The I-SPY 2 TRIAL was a Phase 2 platform adaptive trial to identify agents to improve pathological complete response (pCR) in combination with standard chemotherapy in high-risk breast cancer. The I-SPY 2 TRIAL randomized and graduated therapeutic agents based on receptor subtypes, leading to a response-predictive subtyping schema that better predicts patient responses in the modern treatment landscape. As new drugs and mechanisms are discovered, they are added to the schema and validated in new trials or trial arms.
- The next-generation trial—I-SPY 2.2 TRIAL—has been initiated. The goals are individualized care within the trial and using better classifiers to achieve pCR in 90 percent of patients without standard chemotherapy. The trial design includes sequential treatment blocks with built-in opportunities for treatment escalation or de-escalation as needed. Toxicity and efficacy have been integrated into a single endpoint to identify superior treatment strategies. Data capture is integrated into the clinical workflow and involves minimum essential data sets, built-in decision support, and electronically recorded patient outcomes.
- The new gold standard for trial design involves a standing platform, a master protocol with many therapeutic agents, performance-based accrual, and Bayesian analysis approaches. Efficient trials integrate research and care into the same system, utilize point-of-care data collection as a source for primary endpoints. They include electronic patient-reported outcomes in clinical and trial environments, focused safety reporting, a central institutional review board, and dashboards for trial oversight and dashboards with decision support and forms returned to the electronic health record (EHR) for trial-generated data.
- Patients have been included in I-SPY program development and operations, including participating in each of the 14 active working groups.
- In partnership with the central institutional review board and patient-led efforts, the study consent form has been shortened and is supported by an educational treatment guide. New virtual consent methods are being developed.

Session 6: With a Little Help from Our Friends

Presenters highlighted the value of collaborations and inclusion of colleagues beyond nephrology researchers. During the session and the following moderated discussion, speakers and participants identified the following research gaps and opportunities.

Research Gaps and Opportunities

- Public–private partnerships (e.g., academic–industry collaborations) can strengthen the assessment of the evidence related to disease mechanisms, drug targets, biomarkers, and the potential efficacy and safety of candidate therapeutics.
- Trials for precision medicine might focus on developing novel drugs or improving the selection, dosing, efficacy, and safety of existing therapeutics. Drugs with narrow therapeutic indices or with wide interpatient efficacy or safety variability especially might benefit from precision trials.
- Genetic influences play a significant role in interpatient variability, and populations with diverse continental ancestry must be included in clinical trials. For example, prodrugs might be metabolized differently in patients with varying genotypes. Trials focused on pharmacogenetics have substantially changed clinical care in many therapeutic areas.
- Patients' knowledge of their genetic status and associated health risks—without additional interventions—can improve health outcomes. Trials that provide genetic results, such as the Genetic Testing to Understand and Address Renal Disease Disparities Across the United States (or GUARDD-US) study, have been well received in patient communities.
- The National Cancer Institute (NCI) Molecular Analysis for Therapy Choice (or NCI-MATCH) program demonstrated that using biomarkers to match patients with a range of rare tumors can be conducted efficiently and effectively on a national scale. This program has evolved into a robust set of platform trials that readily add matching biomarkers and protocols to the NCI-sponsored matching toolbox using novel trial designs and ongoing interactions with the FDA.

Breakout Session 1: Assess Current State of Kidney Precision Trial Preparation and Opportunities for Advancement

Presenters reported on discussions in their breakout sessions, which focused on the topics of patient and clinician community; disease mechanisms, biomarkers, and endpoints; defining evidentiary thresholds for precision trial activation; and what is currently known and through which methods. The following points were raised.

Patient and Clinician Community

- The key considerations for recruitment and consent to participate in precision medicine trials were highlighted by patient advocates in attendance, who emphasized the importance of defining the scope and goals of the trial, diversifying recruitment, and understanding participants' reasons for joining the trial. Building trust between patients and clinicians is critical to both recruitment and participation.
- A cultural change is needed to substantively engage community members in the design and conduct of AKI trials—the relationship between academic and community practices must center what is best for the patient. AKI trials can be difficult to recruit for, but researchers could learn from colleagues in emergency medicine, who have experience enrolling patients without long-standing relationships.

- Increasing the workforce in pediatric and adult nephrology, including improving its diversity, is a challenge for the advancement of kidney precision medicine clinical trials. Other challenges include the need for protected time, plans to manage the turnover of study coordinators, and advanced biomarker development.
- Researchers should ensure that all participants understand the informed consent process. Many participants join trials for altruistic rather than monetary reasons, and these patients often want to see their results. Study burden can be minimized by shifting more tasks to home settings and reducing visits to the trial site.
- Primary care providers and engagement with local nephrologists were considered underutilized opportunities. Partnerships with these trusted providers must be developing through such strategies as the inclusion of consent to share patient trial status with local providers and the use of a memorandum of understanding (between the trial site and the local providers) to codify the co-management of the trial candidate from the point of trial referral, through the study, and after the patient's trial participation is complete
- Group members suggested that NIDDK host a webinar on patient advisory boards and include an increasing number of patients as research partners and patient advocates in subsequent meetings and trial design efforts.

Mechanisms, Biomarkers, and Endpoints

- Candidate diseases, mechanisms, and biomarkers were discussed for genetic, glomerular, acute, nondiabetic, and diabetic CKD in adults and children, as well as the transition from acute kidney disease to CKD.
- Precision medicine trials might support the selection of single versus combination therapy.
- Researchers must distinguish disease-initiating mechanisms from disease-stabilizing and terminal CKD progression mechanisms and identify targets for intervention that might change over the course of a disease.
- As mechanisms of disease may change over time, trials should be specific about targeting primary disease versus chronic disease, and biomarkers will be needed to identify the relevant disease mechanism (aligned with the candidate therapeutic) to help match a precision trial to the relevant population.
- Precision trials in nephrology might also address CKD complications.
- Precision medicine approaches can be de-risked by optimizing the use of preclinical models, existing databases, biorepositories, registries, and cohort studies, as well as data and specimens from completed clinical trials.

Defining Evidentiary Thresholds for Precision Trial Activation

- Many types of expertise are needed to evaluate the strength of evidence for clinical trials, and collaboration is key for successful evidence review.
- Evidence is needed to address the following aspects of a precision clinical trial:
    - Mechanism of the disease of interest
    - Prioritization assessment of actionable targets (e.g., druggable, genetic, and nongenetic intervention)

    - Relationship of the disease mechanism and drug target to the proposed study population (i.e., subgroup), including the phase of the disease (e.g., initiation, maintenance, late-stage kidney failure) and relationship to health outcomes, such as progression of kidney disease or selected complications
    - Pharmacologic profiles of the candidate therapeutic (i.e., intervention characteristics, such as mechanism of action, toxicity assessment, potential for interpatient heterogeneity due to pharmacogenomics, dose selection)
    - Biomarker characteristics (e.g., relevance to human disease mechanism, relevance to intervention mechanism of action, assay performance characteristics)
    - Natural history of the selected trial population
    - Endpoint selection and feasibility by trial stage
- Potential sources of evidence include the following:
    - Model system data with strong potential for translatability to humans, such as kidneys on chips, organoids, and robust animal models
    - Preclinical toxicology studies
    - Pharmacogenetic/pharmacogenetic simulations
    - Human disease registries, databases, biorepositories, and prior clinical trials
    - Clinical trial emulation studies
- Areas of expertise for evidence review team members might include the following:
    - Bioinformatics
    - Biomarker selection
    - Biostatistics
    - Clinical nephrology
    - Clinical trial design
    - Differentiation between druggable and nondruggable target assessment
    - Epidemiology and natural history of population subgroups
    - Laboratory assay performance assessment
    - Model systems
    - Pharmacogenetics
    - Pharmacology
    - Regulation of drug, device, and companion diagnostic development
    - Translation from mechanism to trial
    - Trial technical and operational expertise

- Opportunities to improve evidence for review and progression to kidney precision medicine trials include the following:
    - Improve animal models or select models that closely represent specific acute, chronic, or kidney disease subgroups.
    - Advance the understanding of molecular drivers of kidney disease.
    - Use comprehensive databases and preclinical models to help strengthen the evidence in support of precision trials.
    - Leverage registries, cohorts, repositories, and past clinical trials as a foundation for building a learning system for a series of clinical trials.
    - Develop and implement *a priori* strategies to design, conduct, and support toxicity assessments applicable to adults and children within a timeline that accelerates precision therapeutics development.
    - Improve workforce training related to the evidence needed for nephrology clinical trial preparation, design, and implementation.
    - Include regulatory support in trial readiness assessment and implementation infrastructure.

Breakout Session 2: Identifying Opportunities and Potential Challenges to Kidney Precision Medicine Trials

Presenters outlined discussion points from the breakout groups, which focused on defining opportunities and potential challenges to kidney precision trials. The following discussion points were identified.

AKI Precision Trial Teams, Components, and Capacity

- Biomarkers (beyond serum creatinine) and data science currently are supporting the identification of patients within clinical subgroups and at risk for AKI progression in clinical settings. EHR systems that are inclusive of clinical phenotyping and biomarkers can be leveraged for AKI trials.
- Clinical AKI subgroups are not sufficiently precise to align with a specific biological mechanism for treatment targeting.
- Trials focused on moderate AKI with a risk for progression could be a useful subgroup for precision medicine trials.
- Artificial intelligence/machine learning and dynamic phenotyping provide opportunities for AKI precision medicine platforms. Current challenges with real-time analytics using EHR data must be mitigated for time-sensitive AKI trials.
- New response biomarkers that predict major adverse kidney events 90 (or MAKE90) outcomes would be beneficial to the drug development community.
- Trials will need to consider the timing of intervention in the individual AKI experience, the subpopulation of relevance for a specific intervention, and the proximity of the biomarker to the disease and intervention target mechanisms.
- Community engagement is likely to benefit from a broader definition of community to include people with a history of AKI, current AKI, and at risk for AKI; clinical providers, such as primary care physicians, cardiologists, hepatologists, intensivists, and oncologists; and payers.
- Even small requests to perform activities can be demanding for patients with acute illness.

CKD Precision Trials Teams, Components, and Capacity

- Ensuring that vulnerable patients remain involved in precision medicine initiatives for CKD is important, and researchers must ensure that innovations reduce, rather than enhance, disparities in care. The kidney community has identified a need for training that is focused on community engagement and collaboration.
- Clinical research and clinical care should be integrated into a single process for precision trials in nephrology.
- Chronic kidney, genetic, glomerular, and vascular-access diseases were suggested as good candidate conditions for precision medicine trials. Research on the biological mechanisms underlying these conditions already is being conducted in NIDDK-sponsored studies.
- EHRs are a useful tool to identify patients for precision medicine trials, and contemporary patient registries could be leveraged. Data sharing is key for these systems to be effective for national efforts.
- Researchers should capitalize on the opportunity to overlay biomarkers and genetic analysis with clinical, demographic, and environmental data.
- A small group of champions—inclusive of strong patient partnership—could identify near-term candidates to launch a kidney precision trial initiative.

Drug and Dose Optimization

- Although high-quality drug screening libraries and high-content imaging are not ubiquitous, these resources exist in academic and private sectors.
- Opportunities exist to optimize the safe and effective use of treatments available today, as well as novel therapies under development.
- A false perception exists that genetic evidence levels need to be significantly higher than those for other biomarkers, but genetic testing is a laboratory test.
- Collection of genetic data and dose-response data from Phase 1 and Phase 2 trials is important so that concurrent or retrospective analysis can be conducted to evaluate subpopulations.
- Any knowledge of small molecules, pathways, or pharmacogenetics needs to be incorporated within inclusion criteria and might require stratification.
- Precision therapy development and clinical trial teams will benefit from including expertise in clinical pharmacology, genetics, pediatrics, data science, bioinformatics, histopathology, and implementation science.
- Education is needed around currently available resources to support good kidney precision trial development focusing on drug and dose optimization, including the following:
    - Existing high-throughput drug screening programs
    - Exemplar clinical pharmacology cores, which provide expertise in other disease areas and in pediatrics, advance the understanding of relationships between drug exposure and pharmacodynamic response, and might be available to support or provide examples for kidney precision trial development and conduct
    - Pharmacokinetic and pharmacodynamic modeling resources
    - Pharmacogenetics approaches and expertise

- Current studies are providing significant information about identifying kidney disease mechanisms, candidate drug targets, and so forth, but challenges exist in terms of infrastructure, funding, and the diversity of diseases that require precision therapeutic development.

Conclusion

People with kidney disease are eager for timely, effective, and safe therapies to preserve kidney function. When they have been equipped and empowered with information, patients and their advocates are ready to contribute to the success of kidney precision medicine trials. Precision therapeutics development will be accelerated by coproduction between patients, families, and all academic, federal, industry, and regulatory partners. Whether within individual trials or trial platforms, precision clinical trials will require the use of a strong biologic mechanism foundation, innovative clinical trial designs, and outcome assessment measures that are fit for the trial purpose—ultimately leading to the right treatment at the right dose for the right patient at the right time. Progress in kidney precision medicine will require the spirit of innovation, willingness to launch trial programs amid uncertainty, and a strong foundation based on science, collaboration, and a willingness to learn together.

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