# Redesigning Research: A Blueprint for Patient–Sponsor Co-Creation and Collaboration Driving Science and Innovation in Clinical Trials

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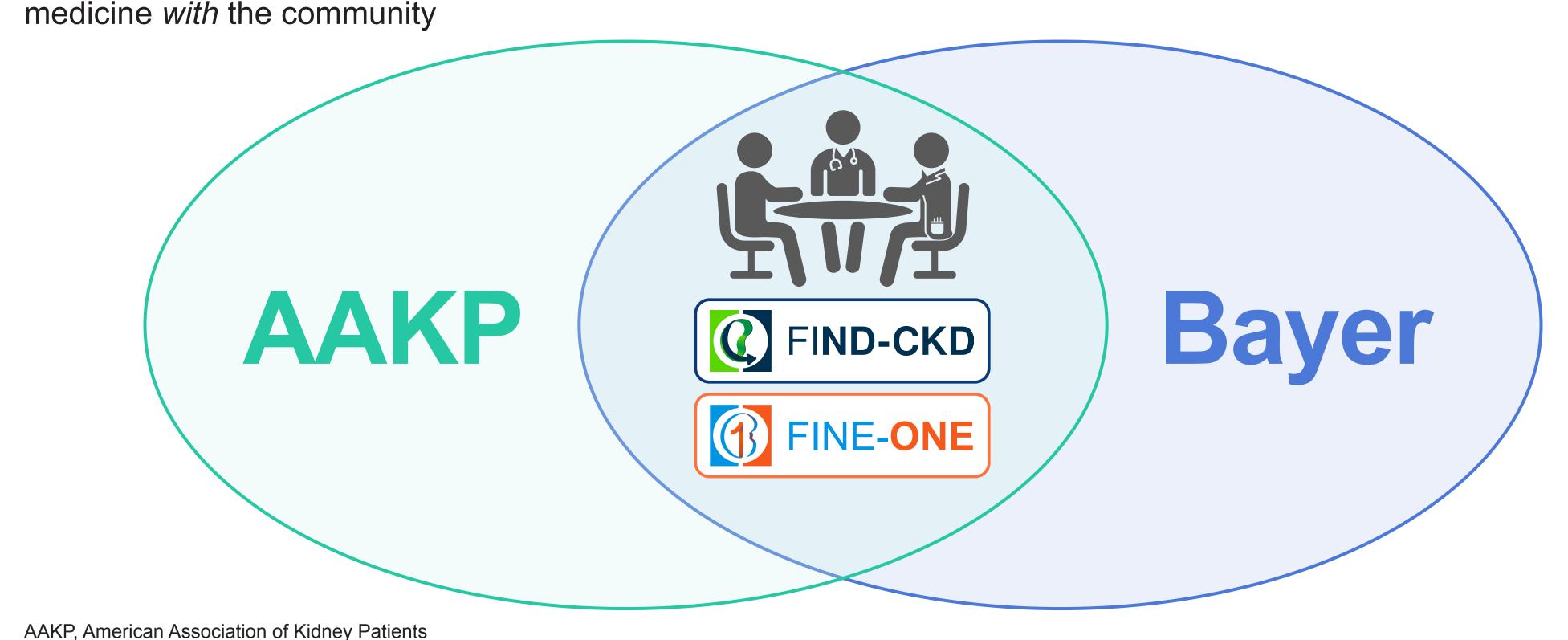
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# Why was the patient organization-sponsor collaboration initiated?

- Bayer aims to enroll patients into clinical trials such that the participant demographics are representative of the general patient population
- This can be challenging due to barriers including limited access to healthcare and scepticism towards trial participation<sup>1</sup>
- Patient organizations are uniquely positioned within their communities to identify these barriers
- Partnership between patient organizations and trial sponsors may therefore help to improve representation and diversity in CKD clinical trials<sup>2</sup>
- Here, we describe the successful initiation and development of a patient organization—sponsor relationship between the American Association of Kidney Patients (AAKP) and Bayer (Figure 1). The end result is a new approach to patient engagement, clinical trial design, and diverse trial recruitment that accelerates innovation and expands treatment choices for patients with CKD

**Figure 1.** AAKP–Bayer collaboration overview: Transitioning from making medicine *for* the community to making medicine with the community



# Establishing a patient organization-sponsor collaboration

## AAKP<sup>3</sup>

- AAKP is the largest independent kidney patient organization in the United States (US)
- It engages in kidney education, research, policy and advocacy, as well as playing a leading role in developing patient communities that amplify the independent patient voice and drive meaningful change
- It is active throughout the US and across over 100 other countries
- Launched in 2016, the AAKP Center for Patient Research and Education was created to connect patient experts with government agencies, academic institutions and pharmaceutical companies
- The Center has established expertise in:
- Social media outreach and large-scale engagement
- Clinical trial awareness and recruitment campaigns
- Patient advisory boards and technical evaluation panels
- Focus groups and patient surveys
- Clinical and public policy research
- Advising on effective and meaningful collaboration practices
- AAKP and Bayer formed their collaboration (Figure 1) to drive innovation and science in kidney health, increase care choice options for patients and improve long-term outcomes and quality of life

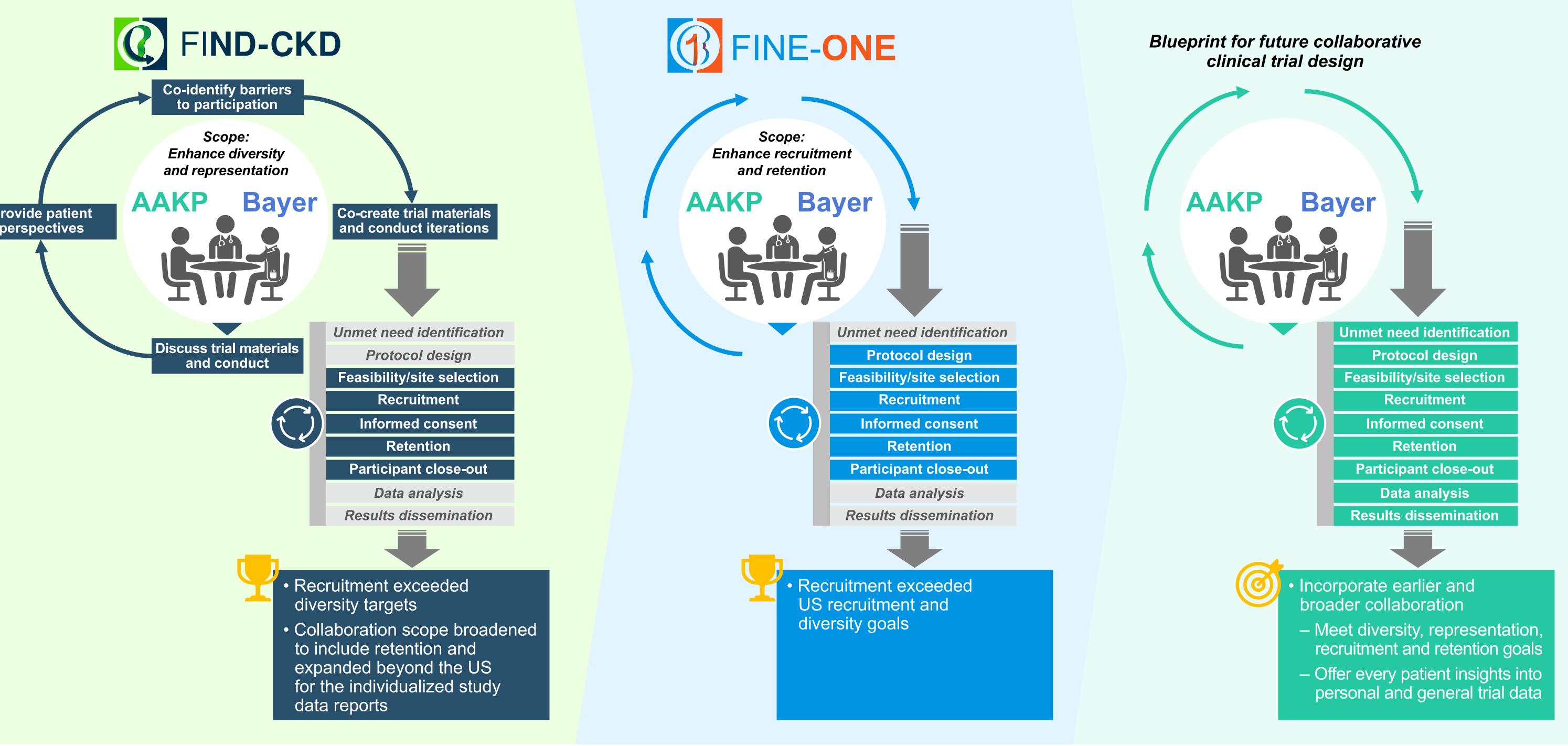
#### Forming the Standing Patient Councils

- The first AAKP Standing Patient Council (SPC) for Bayer clinical studies was established in November 2021
- The AAKP creates an SPC for each clinical trial and manages its ongoing monthly meetings and activities
- The SPC comprises individuals living with kidney disease who have knowledge or experience of clinical research, and are representative of trial participants
- The SPC provides expertise, lived experiences, and an innovative and strategic mindset to help optimize clinical trial conduct, analysis and data dissemination

# Refining the partnership model: Iterative creation of a blueprint for collaborative trial design

- The AAKP–Bayer collaboration has evolved and continues to evolve from when it was first initiated (Figure 2)
- Learnings, materials and practices developed in early iterations have been carried forward and strengthened in subsequent trials, ensuring consistency across study design, development and implementation
- This has resulted in the development of a new blueprint for future collaborative trial design
- This blueprint has co-creation and co-design at its core

Figure 2. Overview of the initiation and evolution of the AAKP-Bayer partnership: Establishing a blueprint for collaborative trial design



AAKP, American Association of Kidney Patients; CKD, chronic kidney disease; US, United States

#### Enhancing representation and diversity in FIND-CKD

• FIND-CKD (NCT05047263) is a phase III trial investigating the efficacy and safety of finerenone, a nonsteroidal mineralocorticoid receptor antagonist, in patients with CKD without diabetes<sup>4</sup>

Impact.

- The SPC for FIND-CKD, the first of the partnership, was formed soon after recruitment began
- In this trial, the initial focus of the AAKP–Bayer collaboration was to optimize representation and diversity by:
- Co-designing trial materials
- Co-creating patient recruitment and retention strategies
- Collaborating on tools to improve the participant experience

FIND-CKD

Besides allowing for diversity targets in the US to be exceeded,

Provided valuable input into a new initiative to provide

participants with an individualized study data report at

Supported excellent worldwide patient retention in the study as a whole

the FIND-CKD collaboration also:

the end of the study

### Key learnings, materials and practices from the AAKP collaboration in FIND-CKD

- The major outputs of the collaboration during FIND-CKD are outlined in Figure 3
- These co-created materials and strategies were designed with the patient perspective as their basis
- Patient-friendly language and key considerations that are important to patients when making trial enrollment decisions were included throughout
- New ways to recognize and communicate with trial participants were a focus, including the development of new trial awareness strategies
- Grassroots community ambassadors were key to co-ordinating awareness activities including distributing materials and organizing events
- Webinars about the trial, including the importance of diversity and representation, were important in providing information to patient populations the trial aimed to recruit
- Additional efforts included informing in the appointment of a Bayer consultant and Diversity Principal Investigator to support inclusive implementation

#### In FINE-ONE, AAKP was involved before the first patient visit Key learnings, materials and practices from the FINE-ONE AAKP collaboration (Figure 3):

A broadening role in FINE-ONE recruitment, design and conduct

earlier in subsequent studies and had a broader remit that stretched beyond diversity and

Following the success of the partnership model in FIND-CKD, AAKP involvement began

FINE-ONE (NCT05901831) is a phase III trial investigating the efficacy and safety of

- Review of study protocol
- Co-design of informed consent materials Co-interpretation of retention issues

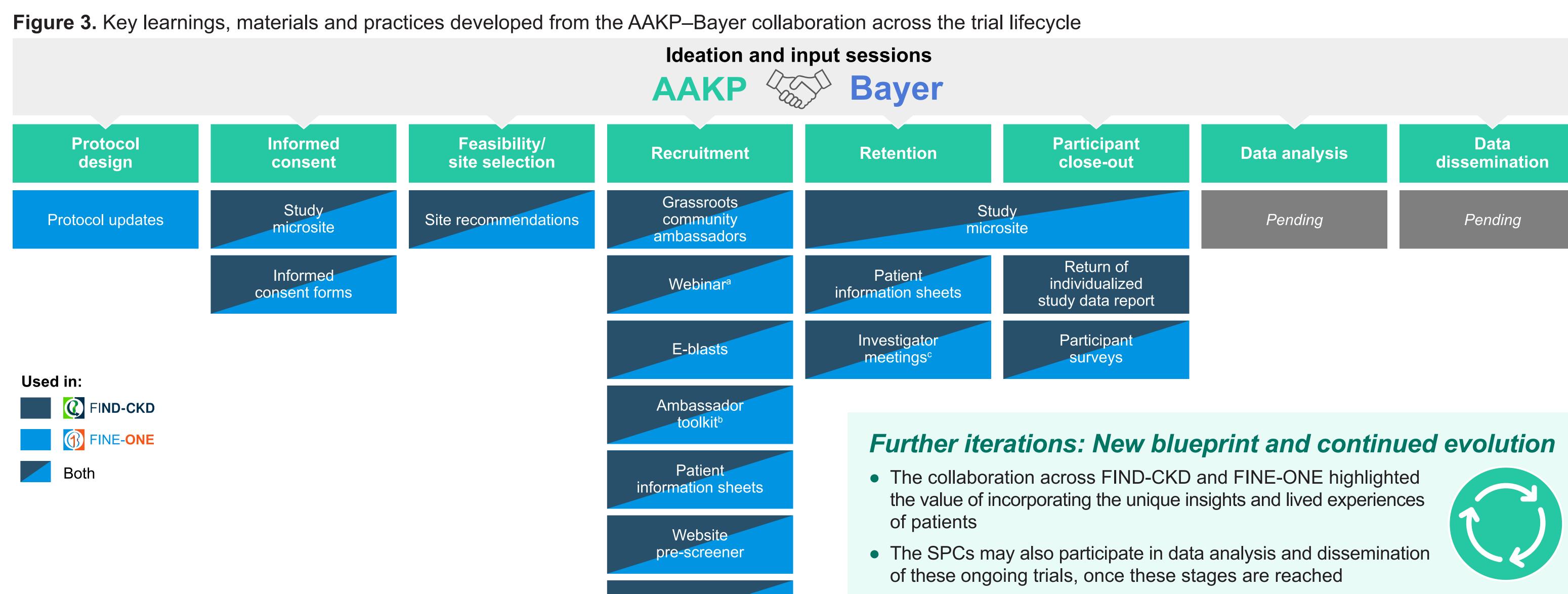
representation of the US population in trial recruitment

finerenone in people with type 1 diabetes and CKD<sup>5</sup>

- Informing on study design and trial conduct to include the patient voice, including trial site selection
- Inclusion of a patient representative on the scientific steering committee

- FINE-ONE exceeded US recruitment goals and diversity targets
- In the US, Black/African American participants and Hispanic participants comprise 18.8% (12/64) of those randomized versus a target of 10–15% and 3–6%, respectively, based on US demographics and Bayer's internal assessments
- FINE-ONE also mirrors longstanding US government goals for increasing patient insight data and lived experience within the product development lifecycle





aWebinars focussed on the clinical trials and included discussions of diversity and representation as important aspects. bIncluded institutional review board-approved materials, including trial FAQs, eblasts, leaflets and social media graphics, amongst other engagement resources. <sup>c</sup>AAKP presented at investigator meetings and provided motivational patient perspective videos AAKP, American Association of Kidney Patients

- The learnings, new materials and practices developed through this collaboration helped establish a new blueprint for trial design
- This co-creation model elevates the patient voice, putting it on a par with that of healthcare professionals in informing trial design and strategy
- Further iterations of this co-creation model are launching before phase II and expanding globally
- This has already led to the achievement of recruitment goals months ahead of schedule in another early-phase compound study

#### Conclusions

- Bayer successfully established a meaningful patient organization—sponsor relationship with AAKP, who have acted as a trusted ally for engagement with the patient community
- After accomplishing the initial aims of improving diversity and representation in the US, iterative development of the collaborative model has allowed earlier and broader input of the patient experience into improving trial design and conduct
- The onward achievements of this model include the enhancement of recruitment and retention in the US generally, resulting in global rollout of the model where appropriate
- Furthermore, exceeding recruitment goals could allow enrollment to be closed early, reducing trial running costs
- This model therefore offers a replicable path for ensuring continued, meaningful and substantive patient organization—sponsor partnership

#### References

- Alahamadi Z, et al. Kidney Med 2025;5:100594.
- 2. Byiringiro S, et al. Trials 2025;26:117.
- 3. The American Association of Kidney Patients. 2025. https://aakp.org [Accessed Sep 10, 2025].
- 4. Heerspink HJ, et al. Nephrol Dial Transplant 2025;40:308–319. 5. Heerspink HJ, et al. Diabetes Res Clin Pract 2023;204:110908.

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# **Disclosures**

PTC reports roles as AAKP Vice President and Chair of Policy & Global. MP, RL and MB are employees of Bayer AG. DC, EK and JB are employees of AAKP; DG is an employee of Bayer PLC. GM and MP are employees of Bayer US. SV is an employee of Bayer SA-NV. Poster INFO18-SA presented at ASN Kidney Week 2025, Houston, TX, USA, November 6–9, 2025