TUTORIAL

Approach to High Volume Enrollment in Clinical Research: Experiences from an All of Us Research Program Site

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Clinical trials and cohort studies are required to meet target recruitment of study participants within stipulated timelines, especially when the priority is to include populations traditionally unrepresented in biomedical research. By the third quarter of 2019, the University of Arizona-Banner Health Provider Organization (UA-Banner HPO) has enrolled > 30,000 core participants into the *All of Us* Research Program (*AoURP*), the research cohort of the Precision Medicine Initiative. The majority of enrolled participants meet the criteria for individuals under-represented in biomedical research. The enrollment goals were calculated based on a target of 20,000 as set by the National Institutes of Health and our health provider organization achieved enrollment numbers between 17% and 86% above the targeted daily enrollment. We evaluated enrollment methods and challenges to enrollments encountered by the UA-Banner Health Provider Organization into the *AoURP*. Challenges to enrollment centered around the need for high-touch engagement methods, time investment necessary for stakeholder inclusion, and the use of purely digital enrollment methods especially in populations under-represented in biomedical research. These challenges occurred at the level of the individual, provider, institutions, and community, and cumulatively impacted participant enrollment. Successful strategies for engagement and enrollment leveraged provider partners as advocates for the program. For high-volume enrollment in clinical research, it is important to engage leaders in the healthcare setting, patient providers, and tailor engagement and enrollment to potential participant needs. We emphasize the need for precision engagement and enrollment methods tailored to individual needs.

Study Highlights

WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?
☑ Many clinical trials and research cohorts fail to achieve enrollment targets and in large disease agnostic studies enrolling diverse populations, there is limited evidence on which enrollment strategies are successful.

WHAT QUESTION DID THIS STUDY ADDRESS?
☑ This review addressed how high-volume enrollment can be achieved in clinical research cohorts especially individuals under-represented in biomedical research.

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?
☑ Our findings add to the body of empirical evidence on successful strategies for enrollment in clinical research stressing the importance of engagement of healthcare leadership, providers, and study participants.

HOW MIGHT THIS CHANGE DRUG DISCOVERY, DEVELOPMENT, AND/OR THERAPEUTICS?
☑ This study provides the opportunity to replicate successful strategies in high-volume enrollment. In enrolling a diverse population in precision medicine, it is important to tailor engagement and enrollment strategies to individual needs.

Cohort studies and clinical trials face the challenge of meeting enrollment targets within stipulated timeframes especially if the priority is to enroll individuals in groups under-represented in biomedical research.[1,2] This challenge is compounded in disease-agnostic studies with large sample sizes.[3–5] The *All of Us* Research Program

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(*AoURP*) is a national cohort program that plans to enroll one million or more core participants to serve as the research platform for precision medicine studies.[6] The core participants are individuals who enroll into the baseline cohort, undergo physical measurements, provide urine and blood specimens, complete several questionnaire modules (participant provided information), and agree to be followed longitudinally.[6,7] The goal is for about 50% of the national cohort of *AoURP* core participants to be individuals under-represented in biomedical research.[8]

The University of Arizona-Banner Health Provider Organization (UA-Banner HPO) is one of the regional academic medical centers charged with enrolling 100,000 individuals into the *AoURP*. Of these 100,000 participants, the UA-Banner HPO plans to enroll at least 50% of participants from Hispanic/Latino origin and 10% from other race/ethnicities. Of the 6.07 million Arizonans in our *AoURP* catchment area, ~ 60% (3.64 million) receive their health care from Banner Health. All Banner Health facilities utilize *Cerner* for their electronic health records. In addition to the metropolitan areas, our health provider organization serves patients from geographically remote populations in the Sonoran Desert, border towns, and farming communities.

There is little data available on recruitment and retention strategies into large population cohorts that are disease-agnostic and hypothesis-free.[9] This is especially challenging when long-term recruitment and engagement of participants (healthy or diseased) are needed and when there are no evident or immediate benefits or interventions being proposed at the time of enrollment. We present the strategies, methods, and challenges involved in the recruitment of over 30,000 participants into the UA-Banner *AoURP* over the first 2 years.

METHODS

Overview of the AoURP

To become a core participant in the *AoURP*, an individual first needs to consent to the research program and then sign a separate consent to share electronic health records. Subsequently, individuals' complete electronic surveys (basic demographic data, lifestyle, and health), physical measurement assessment, and donation of biospecimens (urine, blood, and/or saliva).[7] On average, a full enrollment lasts 90–120 minutes. Enrollment can be done entirely on-site or in a combination of on-line, pre-visit, and on-site assessment of physical measurements and collection of biospecimens. **Figure 1** illustrates the pathway to becoming a core participant through the UA-Banner HPO. **Figure 2** shows the steps involved in the enrollment process for the *AoURP*. We obtained institutional review board (IRB) approval from the central IRB of the *AoURP*.

We commenced by enrolling healthy volunteers during an initial alpha phase between June 20, and July 5, 2017. In the alpha phase, we enrolled a maximum of six participants per day. This phase was a period focused on testing and refining protocols and systems from the biorepository at Mayo Clinic in Rochester, Minnesota, and Data and Research Center at Vanderbilt University in Nashville, Tennessee. The subsequent beta phase of enrollment allowed for further program expansion into the healthcare arena by testing and

improving processes, providing additional training, and consolidating our operations.[6] **Figure 3** shows our targeted vs. actual enrollment over the first 18 months.

Building and maintaining infrastructure needed for high-volume enrollment

The ideal populations for engagement and enrollment for the UA-Banner HPO were adult patients (18 years and older) from Banner Health facilities. Banner Health is one of the largest nonprofit health systems in the United States with > 400,000 patients (located across 29 sites in Arizona, Colorado, Nebraska, Nevada, Wyoming, and California).

Geographic distribution of enrollment sites. Our strategy was to focus on hospitals in the Banner Health system located within central and southern Arizona, with the desired demographics of individuals under-represented in biomedical research. Our initial enrollment centers (*n* = 3) had the following characteristics: (i) academic centers with commitment to research; (ii) access to inpatient and outpatient populations; (iii) resources of space and equipment; and (iv) the presence of provider champions and partners on site. Provider champions are high profile medical leaders who are visible in the healthcare arena and promote the *AoURP* in their healthcare facility. Provider partners work in a dyad with the coordinator team and are involved in the day-to-day enrollment of participants.

The UA-Banner HPO currently comprises 14 enrollment sites serving the populations of Arizona and Colorado. Enrollment sites are located within Banner medical centers (*n* = 10), University of Arizona facilities (*n* = 3), and an approved Federally Qualified Health Center in Nogales, Arizona (*n* = 1).

Establishment and implementation of an enrollment center. Prior to starting an enrollment site, the *AoURP* program leadership engaged both academic and hospital leadership in the University. We partnered with the health establishment, ensuring that we clearly defined shared goals, expectations, and responsibilities of each entity, and how to return value to involved parties. Following this, we arranged meetings with key stakeholders (academic faculty, physicians, nurses, and healthcare staff) from units in the healthcare facility. Once the IRB and National Institute of Health (NIH) approved potential enrollment sites, we identified suitable working spaces, allowable signage (location, size, and other details), and created opportunities for familiarization of the healthcare teams with *AoURP* research staff.

Establishment of enrollment units within clinical centers. The characteristics that made a location ideal for participant enrollment included: (i) a safe space for participants and staff; (ii) proximity to where the individual receives health care; (iii) high patient flow and regular influx of new patients; and (iv) ability to establish partnerships with healthcare team. Enrollment spaces were temporary or permanent depending on the availability for use for the *AoURP* teams. Our location and spaces were designed with the convenience of the participant in mind. The use of mobile enrollment carts (self-contained roll-along luggage with all items needed for biospecimen collection
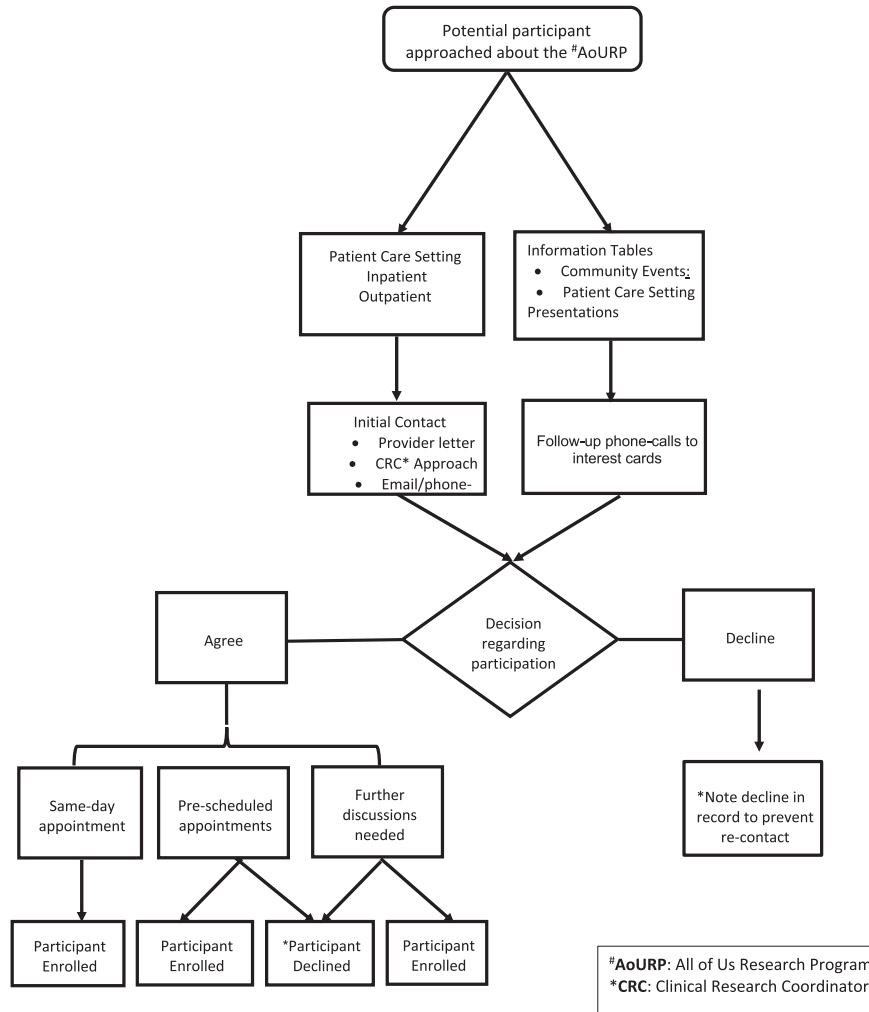
Figure 1 Schematic showing the approaches to participants in the University of Arizona-Banner Health All of Us Research Program.

and physical measurement assessment) containing necessary supplies, facilitated enrollment of participants in this setting. Enrollment units had to be located close to a laboratory processing space to allow for timely delivery of biospecimens according to the processing time requirements in the *AoURP* protocol (minimum of 30 minutes and a maximum of 4 hours).

Communication tactics for large research teams. There were > 90 clinical research staff working for the UA-Banner HPO across the 14 enrollment sites. GroupMe, Slack, and WhatsApp texting were part of the initial communication channels tested. Research teams later transitioned to using Microsoft Teams for internal communications. These instant communication channels allowed for timely change in strategy (i.e., movement of additional staff to high volume enrollment areas within hospitals and clinics), to communicate needs for assistance with enrollments, and also provide a means for broad dissemination of key program information or changes for immediate implementation.

For overall oversight for the UA-Banner HPO communications, we hired a local communications manager as the liaison to the national *AoURP* communications team and was responsible for all external and internal communications and adequate signage at the clinical sites.

Staffing models. To estimate the number of staff needed to accomplish a daily enrollment of about 100 core participants, we considered the following factors: (i) conversion rate (proportion of individuals enrolled into cohort as a percentage of those approached); (ii) time to enroll participant (90–180 minutes depending on participant needs and language, with an allowance of additional time to enroll Spanish speakers and persons with low digital literacy; (iii) number of work days/ year (≈ 247 days); and (iv) low enrollment secondary to inclement weather days (summer months in Arizona plagued with excessive high temperatures, monsoon rains, and dust/ozone warnings, which will limit outings of the team members).

Staff training. We developed a structured program for training of newly hired individuals under the oversight of a specialized training team. This team, comprised of a
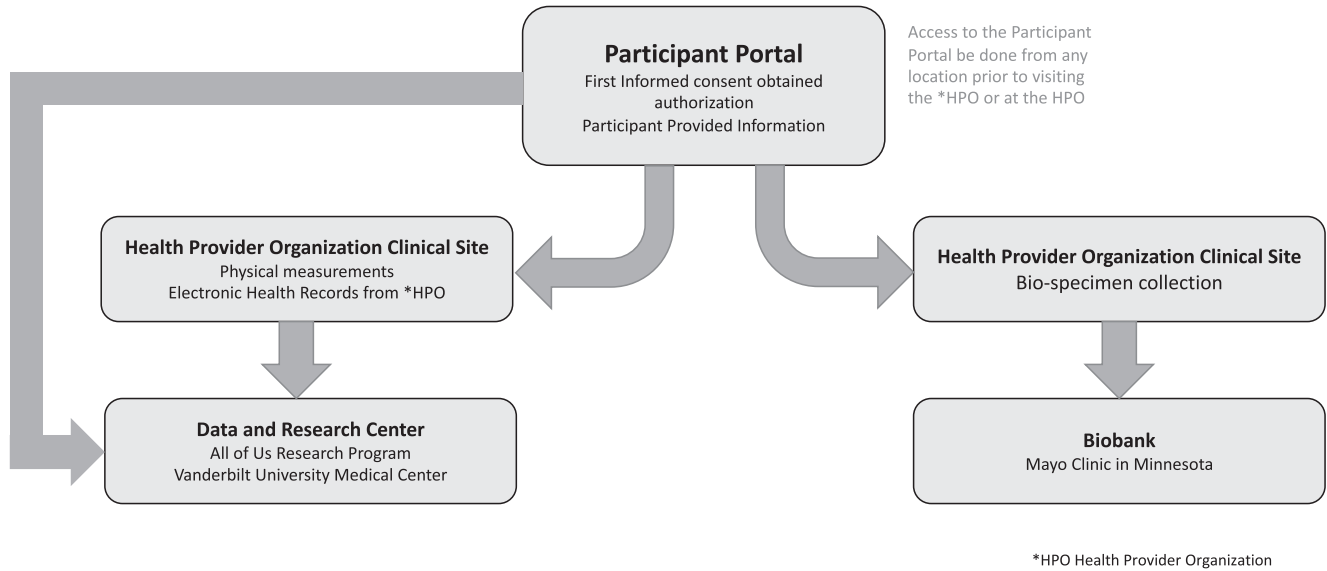
Figure 2 Per quarter actual vs. target enrollments in the All of Us Research Program, University of Arizona-Banner Heath, Health Provider Organization (June 2017–December 2018).
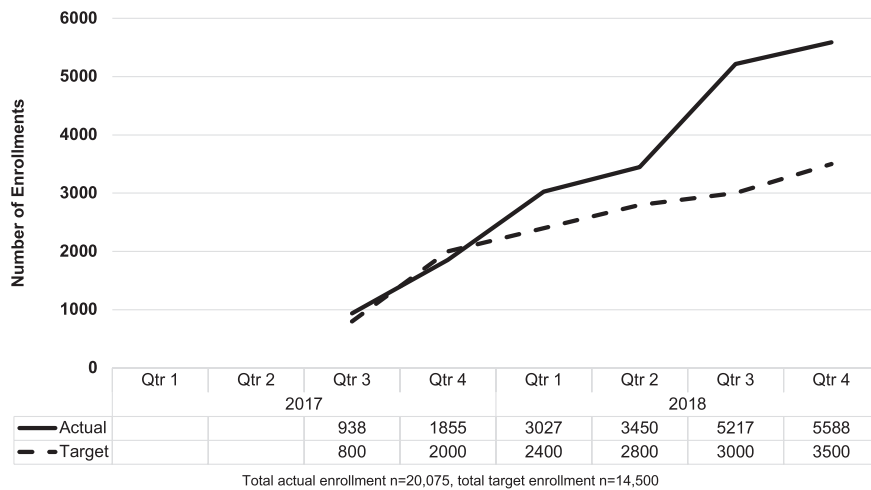

	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
		2017				2018		
Actual			938	1855	3027	3450	5217	5588
Target			800	2000	2400	2800	3000	3500

Total actual enrollment n=20,075, total target enrollment n=14,500

Figure 3 Enrollment process in the University of Arizona-Banner Health All of Us research Program.

clinical research manager and senior clinical research coordinators, was primarily responsible for the training and on-boarding of the over 90 clinical research coordinators, 20 engagement coordinators, and support staff. We developed and used training modules consisting of general onboarding information, human subjects' protection, research compliance certification, *AoURP* protocol, data entry at the health provider organization level for scheduling and management (Research Electronic and Data Capture (REDCap)), other data platforms for data collection by *AoURP* and cultural competency. Emphasis on rapport building and training about eye contact, body posture, and vocal cadence were keys to success for the program staff and equipped them to be the "face of the research program." The training program also ensured program staff

had the tools to engage, educate, and enroll participants at all levels, while ensuring a first-rate participant experience to establish a long-term partnership with the *AoURP*.

We ensured that our workforce was culturally and linguistically congruent with the population of Arizona. Of our > 90 research staff, 45% were bilingual in English and Spanish. Our engagement team comprised of 20 engagement coordinators and Spanish *promotores* who are trusted members of the Hispanic/Latino community with specialized training to provide education/information on precision health to members of their communities and create awareness about the *AoURP*.[10] About 88% of the engagement coordinators were bilingual in English and Spanish and of Hispanic/Latino origin. All team members underwent rigorous cultural sensitivity training.

Enrollment strategies

Physician champions and physician partners. Provider-patient relationship built on trust is a key predictor of health outcomes as well as a predictor for successful recruitment of patients as research participants.[11] Provider-patient rapport is an asset for engagement and enrollment of research participants in the healthcare setting. By identifying provider champions, we were able to disseminate information about the program to other providers and staff in the hospitals and clinics. Provider champions formed a conduit for other physicians or providers who were interested in participating in the program. They also provided opportunity for the active engagement of provider partners. Provider partners are classified as active partners (discuss *AoURP* with their patients) or passive partners (simply provide the *AoURP* team access to their patient population). We educated provider partners to familiarize them with the *AoURP* and provide them with answers to commonly asked questions about the program.

Our approach to provider engagement in this research program was to emphasize the benefits of participation in the *AoURP* for patients and future participants: (i) increased patient satisfaction by being invited to participate in research; (ii) future return of value (for example, pharmacogenomic results) to core participants in the *AoURP*; (iii) coordinating participant enrollment visits before or after clinic visits thereby decreasing "no-show" rates and reducing transportation burden to participants; (iv) enabling providers to identify future research opportunities; (v) ongoing access to multimedia educational materials and continuing medical education opportunities[12] (for example Test2Learn to enrich provider knowledge about pharmacogenomics); and (vi) updates on metrics and milestones of the *AoURP*.

Outpatient enrollment: Physician-coordinator dyad. Potential provider champions may be academic faculty with a relatively small clinical footprint or providers with a large clinical practice. *AoURP* medical directors would initiate discussions with providers and foster relationships between provider partners and the *AoURP* research team. The methods of navigating engagement and enrollment in the outpatient setting could follow any of several paths: (i) provider gives brief presentation of the *AoURP* to patient with hand-off to the research team (this demonstrates the highest conversion rate); (ii) provider asks patient if *AoURP* research staff could speak with them; or (iii) clinical research coordinators may send IRB-approved invitation letters from the *AoURP*, signed by the provider, to patients prior to appointment time (**Figure 1**). Research staff made follow-up calls to patients who received the signed *AoURP* letters and answered additional questions about the program. Research staff recorded a refusal to participate in the research program REDCap and Cerner, to prevent re-contact of those persons who declined participation. Interested participants were ideally scheduled on the same day or close to their future appointment with the provider as per their convenience.

Inpatient enrollment: Nurses and doctors as provider champions. Early in our program, we recognized the importance of partnering with physicians and nursing staff in the inpatient setting. Therefore, we established partnerships with physician leadership in the hospitalist groups. Our initial workflows had provider partners approaching patients on the inpatient service and informing them of the goals and objectives of the *AoURP*. However, this approach proved too cumbersome and impractical for busy clinicians. The current workflow, now utilized across our inpatient enrollment sites, uses the physicians as passive partners (allowing access to patients) and nurses as active partners. Nurses guide the *AoURP* research team on which patients are appropriate to approach based on the protocol and current medical status and informing the research team of an ideal time to approach based on the level of acuity of the patient, reason for admission, and the schedule for the patient. Only when the patient's nurse confirms that the patient can be approached to discuss participation in the *AoURP*, does the clinical research coordinator approach the patient, introduce self, job title, and ask for permission to discuss the *AoURP*. If the patient refuses to participate, the decision is noted in REDCap and Cerner (**Figure 1**). If the patient decides to enroll, the entire enrollment process can be conducted in the patient's room using iPads and mobile enrollment carts.

Patients may also opt to defer their enrollment visit until after hospital discharge. In that case, our team would contact the patient 2 weeks after discharge to discuss participation and to schedule an enrollment visit that ideally coincides with a subsequent healthcare visit to reduce the transportation burden on the participant. Using our electronic medical records, we are able to indicate which individuals were approached and the outcome of the approach which could be: (i) enrollment; (ii) decline; or (iii) needing further conversation.

Information tables: A participant walk-in and real-time scheduling strategy. Tabling involves a table emblazoned with *AoURP* signage, strategically situated in high traffic areas within the healthcare facility (hospital or clinic lobby). The audience for this activity could include patients; patient's family members/friends; general passers-by; facility staff; and providers. Possible outcomes from tabling activity include: (i) real-time enrollment of the participant for a walk-in visit (a backup *AoURP* staff member is contacted to accompany the potential participant to the on-site enrollment unit); (ii) engagement and scheduling of an enrollment visit for a future date; (iii) completion of an interest card so contact can be made with the individual at a later date to provide more information; or (iv) lack of interest in participation (see **Figure 1**).

Community engagement activities. We identified activities, such as community fairs, health fairs, health-related professional societies and advocacy associations, lectures, and community events (suggested by our participant engagement board) and obtained permission for the *AoURP* information tables and program literature to be shared at such events. The engagement team generated multiple opportunities for engagement within groups of individuals under-represented in biomedical research

and established community partners, such as community service agencies, churches, community centers, schools, and family resource centers. With a limited budget for purchased media, our health provider organization took advantage of earned media, press releases, public service announcements, TV, radio interviews, and social media to publicize *AoURP*.

Since the protocol development and initial launch, no recruitment efforts have focused on American Indian or Alaska Native individuals or tribes. Nationally, the leadership of the *AoURP* and American Indian or Alaska Native tribes are engaged in bidirectional and culturally sensitive discussions to develop collaborations between the *AoURP* and American Indian or Alaska Native. The UA-Banner HPO held a 2-day conference in 2017 with the tribal leadership titled, "Regional American Indian/Alaska Native Tribal Dialogue Conference on the All of Us Research Program on Precision Medicine," the first of its kind in the *AoURP*. We continue to support efforts of the *AoURP* at the national level in the discussions and collaborations with the tribal leadership. Locally, we have an American Indian or Alaska Native working group assisting in our supportive efforts to build awareness. A unique barrier to enrollment and engagement is mistrust because of historical transgressions. It is important to note that issues related to (i) tribal sovereignty and consent, (ii) governance, (iii) culturally sensitive engagement, and (iv) ethics and IRB oversight specifically pertaining to biospecimen storage and access need to be addressed in the discussions with American Indian or Alaska Native sovereign nations. Having American Indian or Alaska Native representation in the governance of the *AoURP* at national and health provider organization levels is one crucial step for future meaningful collaborations between *AoURP* and tribal nations.

Presentations. To introduce the *AoURP* in our immediate community, we presented to various groups within the healthcare facilities. The audience included leaders and stakeholders within the institutions ranging from senior hospital administration to physicians and nurses as well as community leaders (e.g., Hispanic Chambers of Commerce). One outcome of these educational opportunities was the ability to engage and enroll interested members of the healthcare team, allowing for firsthand experience with the program. These individuals often went on to be unofficial ambassadors for the *AoURP*.

Digital and print enrollment strategies. We used a series of digital enrollment strategies targeted at individuals who could utilize a digital platform for engagement and enrollment. Prior to the start of the program, we designed a pre-interest website for persons interested in the program to provide contact information that would be used at a later date. Other digital strategies include the AllofUsAZ. org website and a *URL* unique to the UA-Banner HPO. We utilized IRB-approved emails to Banner Health facility staff informing of the local launch of the *AoURP* and provided contact information so that interested individuals could learn more about the program. These emails stressed the voluntary nature of the research program and contained language and disclaimers to avoid the potential for coercion.

DISCUSSION

In the new era of large prospective cohorts, it has been suggested that process expertise is as important as scientific rigor; therefore, developing and testing cost-efficient and effective methods of high-volume enrollment and retention becomes vital.[13] Globally, there are more emerging cohorts with large recruitment and enrollment targets for example the United Kingdom Biobank has already enrolled 500,000 individuals.[13,14] The added challenge of enrolling individuals from under-represented groups in biomedical research makes it crucial to ensure tested, cost-effective strategies are identified, such as those we report in this paper.

Pure digital enrollment strategies were not as effective as in-person enrollment strategies.[15] We found the highest enrollments among our population from in-person approaches on the inpatient service, outpatient clinics, and *AoURP* staffed information tables as opposed to pure digital approaches. Although access to digital technology is increasing among various age groups, there is decreased access to the internet and information technology among racial and ethnic minorities, persons with disabilities, rural populations, and individuals with various levels of socio-economic status. This is known as the "digital divide" evidenced by data that blacks and Hispanics are less likely than the national average to own a computer, have internet access, and have access to the internet at home.[16,17]

As part of our strategies to reduce the digital divide, our enrollment sites became "hubs" for guiding and assisting participants with digital technology, such as navigating the use of iPads. Research coordinators provided support to participants for registering and creating accounts in the *AoURP*. We made adjustments in our workflow to accommodate the additional time needed for individuals who were not accustomed to using digital devices. At the national level, the use of phone numbers in the registration process as opposed to only emails also helped in the registration process for individuals who were not accustomed to email use. Where needed, and based on participant preference, we used desktop computers for older participants because it was easier for them to navigate. Digital literacy continues to be an ongoing challenge that needs further attention and research in individuals who are under-represented in biomedical research.

The barriers to enrollment we encountered include reluctance of participants to enroll due to concerns about data security and privacy, questions surrounding the potential impact on employment and health insurance, and general lack of knowledge of precision medicine (**Table 1**). Previous studies have shown that there is a high level of suspicion and mistrust among minority populations participating in medical research.[18,19] We used strategies such as educating participants on precision medicine, hiring and training a diverse workforce to whom participants were able to relate, meaningful community engagement, and educating participants on our certificate of confidentiality to mitigate mistrust and build participants' confidence in the program (**Table 1**). Our team members exemplified qualities, such as flexibility, adaptability,

Table 1 Barriers, challenges, and solutions to high-volume enrollment in clinical research studies

Barrier/challenge to high volume enrollment	Solutions to the challenges
High touch methods needed for general population, especially under-represented minorities in medical research	Use high-touch strategies for engagement and enrollment, invest in staffing, and training
Building infrastructure	Invest the funds and time in building infrastructure, use best practices
Physician engagement	Invest time, resources, and personnel in physician engagement
Leadership and stakeholder engagement	Invest time, resources, and personnel
Staff retention and satisfaction	Training, career development trajectories, culture, and values
Digital enrollment	Training participants, invest time
Data and security concerns of participant	Train staff on talking points around data security Emphasize data security measures
Mistrust of clinical research	
Time for enrollment and avoiding interruption of the clinical workflow	Piloting various iterations of the research workflow to ensure minimal interruption to the clinic workflow

compassion, rapport-building, and cultural competence, necessary for participant engagement and enrollment.[20]

Horowitz *et al.* reported findings similar to our experience, that community involvement by project staff may be more crucial in the retention of African Americans and Latinos than the initial recruitment.[21] Other barriers to enrollment identified by previous studies include the provider referral in introducing and explaining clinical trials, group-specific barriers, which may be present in various cultural and heath beliefs within various racial or ethnic groups, socioeconomic status, and institutional factors, such as organizational buy-in, size, and staffing.[22–28]

We experienced similar findings to Joseph *et al.*[29] who show that there are institutional barriers to recruiting minorities to cancer clinical trials. These barriers include a lack of engagement by the providers or hospital leadership, the organizational climate of a healthcare institution, including clinic space, structure, hours, methods of patient assignment, and research-specific resources, such as staff, funds, and availability of appropriate linguistic and literacy resources.[29]

Damashek *et al.* in their study highlighted the importance of flexibility and the ability to tailor programs to participant needs in engagement and retention.[30] Part of an individualized experience is making enrollments as convenient as possible for participants enrolling in different arenas within the healthcare setting. The ability to enroll within the clinic helps to reduce the burden of the research visit on the participant and linking appointments to clinic or other healthcare visits helps to reduce the burden of multiple visits.

A complex interplay of individual, provider, program, and community factors synergistically affect participant enrollment, engagement, and retention.[30] Failure at any of these levels could result in failure of meeting enrollment targets. Precision medicine is geared at tailoring medical treatment to the needs of the individual; in practicing precision enrollment, it is important to tailor strategies to the individual subpopulations and geographic areas.

A review of 114 clinical trials in the United Kingdom shows that less than a third of the trials (31%) met recruitment targets.[4] This is also problematic in longitudinal cohorts, as exemplified in the National Children's Study.[31] Part of the lessons learned from cohorts, like the National Children's Study, is that it is

necessary to clearly define recruitment strategies *a priori* especially within specialized populations. However, there are very few randomized control trials testing recruitment strategies and fewer in individuals under-represented in biomedical research. Our findings add to the body of empirical evidence and will provide the opportunity to replicate successful strategies in future high-volume enrollment studies. To our knowledge, the *AoURP* is the first time in the United States that such a high-volume of research participants would be enrolled on a daily basis.

Our research program was able to exceed enrollment goals in the first 2 years because of the successful engagement of the highest level of leadership of the University of Arizona and Banner Health, engagement of local leaders at the different Banner Health facilities, and the engagement of our healthcare team partners. Additionally, we respectfully leveraged the physician-patient relationship to create an atmosphere of rapport and trust for the UA-Banner *AoURP* team in the clinical arena, and by building a team of clinical research and engagement staff who are committed to the vision of the research program.

Aside from the large number of participants, there are other unique characteristics that differentiate the *AoURP* from other longitudinal cohort studies. Participants agree to (i) ongoing accessibility to health records by participating and sharing electronic health records on a continuous basis, (ii) providing biospecimens for laboratory and genetic testing (DNA samples), and (iii) use of mobile health technology to gather geospatial and environmental data.[6,32] Most longitudinal cohorts are considerably smaller, lack diversity, and do not possess comprehensive phenotypic and genetic data.[6] The *AoURP* is disease agnostic and is currently enrolling all disease types and all health status. Although we anticipate the return of genetic and other laboratory results in a portion of participants in the future, at the current time, there is no immediate short-term benefit to participants. The perceived lack of a short-term benefit (aside from immediate return of physical measurements at the time of enrollment), poses a unique challenge in enrolling potential participants. Coupled with the additional challenge of participants consenting to sharing their electronic medical records on a continuous basis, with no

specific end-date, research coordinators have to provide potential participants with additional explanations and education on why it is important to participate.

Faced with these peculiar characteristics of our research program, we tested known strategies of enrollment in clinical research. The leading approaches that successfully enrolled individuals traditionally under-represented in biomedical research were strategies involving the use of information tables, physician-coordinator dyads, and engaging provider champions on the inpatient and outpatient settings. Considering participants' preferences on where and how enrollment occurred was also an important feature of our enrollment process.

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