

NCI Community Oncology Research Program (NCORP): Precision Medicine in the Community



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Dr. McCaskill-Stevens discussed the participation of NCORP in precision medicine research.

NCORP is part of the NCI Clinical Trials Network (NCTN) and was formed to engage community oncologists in research, allow them access to cancer trials, and train them in cancer prevention. NCORP is an academic and community partnership that participates in clinical trials for cancer control and prevention, comparative effectiveness, and screening; accrues to NCTN treatment and advanced imaging trials; conducts cancer care delivery research to develop clinical practices that achieve optimal clinical outcomes; and incorporates cancer disparities research into clinical trials and cancer care delivery research.

NCORP is a large network with 34 community sites and 12 minority and underserved sites, including more than 4000 investigators. Since beginning in 2014, NCORP has enrolled about 18,000 patients in clinical trials. Enrollment of minorities is 21% overall, with 15% in community sites and 53% in underserved and minority sites. NCORP sites have enrolled 37% of the patients in the ALCHEMIST precision medicine trial and 44% in the MATCH trial. Patients are enrolled from very different environments, from Manhattan to the fields of Montana.

Precision prevention is an important area for NCORP. We have identified six opportunities/priorities in this area: immunoprevention, HPV vaccine, overdiagnosis, pre Cancer Genome Atlas, surveillance, and tomosynthesis(3D) versus digital (2D) mammography. NCORP has undertaken a large screening trial of 165,000 women with the primary aim of comparing the rates of advanced breast cancer in women undergoing screening with tomosynthesis vs. digital mammography alone. This is the first time tissue has been collected concomitantly from both benign, premalignant and malignant cancers in a screening trial. The goal of this study is to provide information that will help individualize screening recommendations.

Another area of focus for NCORP is precision medicine in symptom science. Symptoms are important to patients, particularly cardiovascular disease, cognitive impairment, cancer pain, fatigue, and peripheral neuropathy. Studies are planned for these areas. In the area of cancer care delivery research, opportunities related to precision medicine include financial toxicities (cost of tests and medications, lost work, travel, etc.) and current practices in the community setting such as biomarker testing and genetic counseling.

Challenges for NCORP include the avoidance of disparities in outcomes from benefits of precision medicine, identifying the best funding model for investigators, identifying strategies to engage oncology stakeholders at the sites, appreciating the complexities of presenting a new generation of trials and communicating results, and engaging patients and non-oncology partners as “we” work to implement advances and improve the quality of cancer care.

Audience Questions and Answers

- *The definition you cited of precision medicine included a psychological component, which I've not seen in other definitions. Could you give examples of where this is used?* The paper in which this definition appeared was looking at the broader perspective as we introduce precision medicine to the community. One example is how patients might feel when they see a precision medicine treatment on television, but when their tissue is sequenced, they don't have that mutation and therefore don't receive that medicine. They may feel like they are not getting state-of-the-science care. Another example is that patients might have a mutation for which the significance is unknown. This can have a psychological impact. Without data, patients have ambiguity.
- *People are often excluded from clinical trials because the protocol is not available in their language or the quality of life component in clinical trial has not been validated. What does it take to get groups to make this a priority and is NCORP the vehicle for looking at this issue?* In terms of quality of life, the protocols now must include quality of life tools for which there are translations. Many of the classical tools are translated. Now the translated versions must be referenced in the protocol so that investigators can find them easily.
- *How are you able to recruit patients so efficiently for your trials?* The trials are often designed so that they can be implemented efficiently and are of interest to the communities. However, not all trials recruit at a high level.
- *We need to be careful about specifying eligibility criteria that is not appropriate because it excludes patients who have actionable mutations and want to enter the trial. Patients may be devastated. I agree that eligibility criteria are important to carefully consider. This has actually been under discussion for decades. Many parties come together to generate these criteria and we need to be sure that the trials are sensitive to all stakeholders.*
- *With regard to the coverage of NCORP, what is the overlap between local oncologists and NCORP, and how many patients have access to trials like you are discussing?* We are attempting to determine this. In some areas we might have an NCORP site with a defined catchment area, but this doesn't take into account competitors or referral patterns. There is significant coverage but it's dynamic. There are also some areas of the US that are untouched, such as New England and several southern states. If you overlap the cooperative group sites with the NCORP sites, the US is pretty well covered, but there are still some patients who don't have access.
- *NCORP has a consistent group of recruiters and I wondered if you have considered lessons learned from those places like metro Minnesota and Southeast Clinical Oncology Research because something they are doing could inform other NCORP sites and academic centers?* Our staff tries to share best practices, but the truth is that there are cultural differences across the country. In some places, people are willing to drive great distances, whereas in others places, people don't want to walk several blocks. Investigator passion, institutional support, and trial features all play a role. We

do hold conference calls to discuss best practices and common issues; for example, insurance coverage barriers were a common problem for which we now have an organized approach.

- *I noticed that for the TMIST trial you only showed 4 sites currently open. How do you decide how many sites ultimately need to open and did you undertake testing at those sites to see if they could meet the accrual rates?* This trial requires engaging radiologists in research, many of whom are not rostered within the system. This trial also requires significant training and we are currently developing a video to aid in this. We do have more than 50 people in the cue, but it takes time for the enrollment to be processed.