Eileen M. O'Reilly, MD
Associate Director for Clinical Research
David M. Rubenstein Center for Pancreas Cancer
Memorial Sloan Kettering Cancer Center
Professor of Medicine
Weill Cornell Medical College
New York, New York

The Precision Promise[SM] Initiative: What Is It Designed to Achieve?

Hi, my name is Dr. Eileen O'Reilly. I am going to outline what is happening with regard to medicine, with Precision Promise[SM] in pancreas cancer, and with the topic of clinical trial design in pancreas cancer. There has been a lot of reflection over the last couple of years recognizing that the best tools we have, only have had modest impacts on this disease, and there have been many phase 3 studies that have been conducted that have not moved the bar. Bringing up other ways that we can do trials differently that might lead to an earlier identification of a signal, might spare a lot of patients exposure to drugs which are not going to hit a benchmark and maybe to allow more patients to access trials and to do this in a more efficient way. I think that is a very important topic in difficult-to-treat diseases, and there has been a recognition now by the NCI, by advocacy organizations, by patients and families, and the academic community that we need to change how we do business. Incorporating novel trial designs is of critical importance, in my opinion, for moving the bar forward in pancreas cancer. Examples of how we might do things better are really being very rigorous in terms of valid scientific hypothesis and focusing in on the genetic underpinning of this disease, for example, and picking something that is important biologically. I am trying to ask and answer that question in a very efficient way, having surrogate endpoints that allow us to get to that endpoint more quickly and being able to learn as we go, so using adaptive trial designs which are certainly more complex and not ones that the whole community is familiar with. For example, Bayesian statistical designs using more phase 2 and then going onto phase 3 designs as a certain signal is identified and incorporating biomarkers and testing biomarker-based hypothesis, all of these I think will allow the field to move forward. An example where many of these possibilities are going to be incorporated is in the Precision Promise[SM] series of trials that will open in the later part of 2017. This is a very large and wide ranging opportunity that has been developed by the Pancreas Cancer Action Network (PanCAN) in collaboration with academia and in collaboration with industry and patients. It will have a series of rolling treatment arms, in part to evaluate it against the control arm, with every patient undergoing deep genomic sequencing,

RNA sequencing, immune profiling, and collecting all of this information prospectively. Each patient will then have the opportunity to go from a first-line to a second-line trial, with early decision points in terms of efficacy and safety signals, that will again hopefully move the field forward in a more timely way, compared to traditional approaches. This is one of several examples of large scale efforts that are about to commence in the pancreas cancer world, Precision Promise[SM] being the initiative in North America, and a parallel trial design approach in the UK called PRECISION-Panc. I think the whole community is very excited to see these hopefully come to fruition soon and see how this can move the field forward.

For more information on trial design and clinical trial sites visit
https://www.pancan.org/research/precision-promise/locations/