



The Exon 20 Group at ICAN

Summer, 2021

The Exon 20 Group (<https://exon20group.org>) was created as a special initiative of ICAN, International Cancer Advocacy Network, to combat two lethal genetic mutations that cause a rare form of cancer. There are two types of exon 20 insertions—one is an EGFR insertion, the other is a HER2 insertion. These gene mutations are diagnosed in 2% of Non-Small Cell Lung Cancer patients. Exon 20 insertions have also been found in 24 other cancers so far.

The Exon 20 Group was founded in March, 2017 by ICAN’s EGFR exon 20 insertion patient, Kevin M. Hanlon, an entrepreneur and President/CEO of ComSource, Inc., headquartered in Syracuse, New York, and by his brother, Robert T. Hanlon, PhD, a Senior Lecturer at MIT. Four years later, the Exon 20 Group has become a widely respected global working group and multi-stakeholder coalition serving 54 countries. Comprised of patients, care partners, families, thoracic/medical oncologists, physician-scientists, cancer biologists, and molecular pathologists, the Exon 20 Group also includes pharmaceutical companies, biotech companies, and molecular profiling laboratories. After Kevin’s passing in 2019, Bob Hanlon continues to serve as Chairman. Marcia K. Horn, JD, serves as the Executive Director of the Exon 20 Group, in addition to her role as President and CEO of ICAN.

Both ICAN and the Exon 20 Group specialize in one-on-one direct patient navigation, molecular profiling matching services, clinical trials matching services, and expanded access matching services. Vitally interested in reducing health disparities and promoting international health equity, the Exon 20 Group at ICAN recently initiated three projects: ICAN Match-Africa, ICAN Match-Middle East, and ICAN Match-Nepal to bring research advocacy, molecular profiling, clinical trials, and expanded access programs to South Africa, Zimbabwe, Nigeria, Kenya, and Ethiopia; to Middle Eastern countries including Iraq, and to Nepal.

ICAN, International Cancer Advocacy Network (<https://askican.org>) is a 501(c)(3) patient advocacy and research advocacy organization (EIN 86-0818253) specializing in helping late-stage cancer patients find clinical trials and other novel treatments. Headquartered in Phoenix, Arizona, ICAN was founded by attorney Sidney Rosen. Since its founding, ICAN has helped nearly 15,000 cancer patients in all 50 states and in 54 foreign countries.

ICAN is led by Board of Trustees Chair Sherry Weinstein and has received *GuideStar* Platinum ratings and *Great Nonprofits* Top-Rated Health Care Nonprofit Awards since the inception of those rankings. Robert Tamis, MD, is Chairman of the Physicians Council, and Scott M. Kahn, PhD, is Chairman of the Biomarkers Council. G. Robert Pettit, PhD, long known as one of the most prolific anticancer drug discoverers (the bryostatins, dolastatins, auristatins, and the combretastatins, etc.), served as Chair of ICAN’s Scientific Advisory Council until his retirement from Arizona State University’s Department of Biochemistry in 2020. ICAN named Dr. Pettit Chair Emeritus in December, 2020.

The Exon 20 Group’s services for its multi-stakeholder membership and network—now numbering more than 1200 members—include these 21 commitments for 2021:

1. Direct navigation of the patient’s exon 20 insertion mutation case and help with an expedited strategic plan going forward at each decision point so no time is wasted.
2. Second opinion referrals to leading thoracic oncologists and other specialists—at community oncology practices and comprehensive cancer centers.
3. Assignment of an “Angel Buddy” for patients and care partners throughout the patient’s treatment on each drug to help mitigate side effects as a member of our highly individualized EGFR Exon 20 Support Group or our ERBB2/HER2 Exon 20 Support Group.
4. Insights on collateral medications that can help mitigate side effects, including ***The Exon 20 Group’s Guide to Collateral Medications*** that will be distributed to patients, medical oncology teams, and biopharmaceutical companies in the coming months.
5. Review of the patient’s comprehensive biomarker testing reports and molecular profiling matching services for EGFR Exon 20 and ERBB2/HER2 Exon 20 Patients.
6. Clinical trials matching services.
7. Expanded access (“compassionate use”) matching services for EGFR Exon 20 insertion and ERBB2/HER2 Exon 20 insertion patients.
8. Review of next therapeutic options, in the event of conflicting opinions, by our ad hoc molecular tumor boards.
9. Participation in the Exon 20 Group’s social media sites, with closed groups organized for each exon 20 drug to protect patient privacy.
10. Patient and care partner Virtual Meet-Ups, with leadership opportunities in the U.S. and abroad on our Exon 20 Council.
11. Opportunities to participate in Real World Evidence projects and initiatives of our Exon 20 and Rare Cancers Communities.
12. Updates regarding the cutting-edge research we have funded at leading laboratories focusing on exon 20 issues, from discovery to resistance mutations. For example, the Exon 20 Group has funded grants at the MD Anderson Cancer Center at the University of Texas and at the Broad Institute at MIT.
13. Projects promoting international health equity, comprehensive biomarker testing, clinical trials, and expanded access in Africa, Iraq, and Nepal.
14. Participation in our public policy initiatives to accelerate patient access and personalized medicine at the state and federal levels.
15. Training via our Speakers’ Bureau to become an effective patient or care partner presenter or citizen lobbyist in the patient’s country.
16. Collaborations with partner organizations on national, global, and country-by-country sequencing and profiling campaigns to identify exon 20 insertions and point mutations on diagnosis.
17. Knowledge Bank collaborations with leading oncologists, medical centers, and industry members on projects involving biological sample collection and the curation of insights to better inform the sequencing of therapies.
18. Updates on all lung cancer and pan-tumor conferences featuring Exon 20 insertion mutation presentations.
19. Referrals to organizations that work to reduce the financial burdens associated with treatment.
20. An invitation to the Exon 20 Group’s Annual Summit (December, 2021—Virtual) covering all the issues for EGFR Exon 20 insertion patients and HER2/ERBB2 Exon 20 insertion patients.
21. *Perhaps most important: the knowledge that we will never give up on any exon 20 insertion patient, and we will never leave the patient stranded.*

The Exon 20 Group's New Initiative:

The Exon 20 International Research Consortium

Since its founding, the Exon 20 Group has actively engaged with leading researchers in basic science and drug development for the benefit of exon 20 patients. To accelerate our efforts, we are pleased to announce the launch of the Exon 20 International Research Consortium (Ex20-IRC). This consortium will add new participants from the broader medical, oncological, and research community to the group of existing researchers devoted to exon 20. The Ex20-IRC will bring these disparate minds together and hold focused regular sessions to discuss new results, share ideas, and collaborate on the challenging set of scientific questions related to exon 20 insertion mutations.

Our goal is to determine what factors are holding back drug discovery and development and to accelerate the process. To quote our Ex20-IRC leadership: "Why don't we have hundreds of drugs for exon 20 that work far longer and with less toxicity than the drugs currently in the pipeline?" By bringing together out-of-the-box thinkers, we are hopeful that we can usher in a new era of smarter, rational, faster, and more productive drug development. This project is designed to not only directly augment the exon 20 drug pipeline, but also to help all other rare mutation patient populations who are contending with drug pipelines which could be greatly accelerated.

We think that a multidisciplinary team of cancer biologists, chemists, physicists, computer scientists, molecular modelers, data scientists, and others with common interests in the exon 20 problem, will inspire new ideas, novel team-building, and creative solutions to this very difficult challenge. We also think that a multidisciplinary team focused on a specific targeted condition will be more successful than a broad-brush approach.

The Ex20-IRC will develop a knowledge bank and make its findings publicly available because we believe our progress in this area will hold lessons for fighting other rare diseases. If successful, this consortium could be a model for other specialized conditions.

The Exon 20 Group is delighted to have Stephen B. Baylin, MD, Afshin Beheshti, PhD, and John W. Lawson, PhD, as co-chairs of the Exon 20 International Research Consortium.


The Ex20-IRC was announced in *USA Today's* Mediaplanet Lung Health Supplement (reprinted below).

The announcement also features a profile of Exon 20 Group Founding Chair Kevin Hanlon. His determination to defeat this disease continues to guide all of us at the Exon 20 Group. Your participation and support of the Exon 20 Group will see Kevin's vision soon become a reality.

Thank you!

For more information on the Ex20-IRC, please contact:

Ex20consortium@askican.org

A photograph of a family of five standing outdoors in a wooded area. From left to right: an older man with grey hair wearing a blue jacket, a young woman with long blonde hair, a young man with dark hair wearing a blue shirt, a young woman with long brown hair, and a young woman with long dark hair. They are all smiling and looking towards the camera.

Kevin Hanlon with daughter Lilly, son Mark, wife Denise, and daughter Ellrose

A New International Research Consortium to Battle Two Rare Cancer Mutations

In April 2016, Kevin Hanlon, an entrepreneur from Syracuse, New York, was diagnosed with an EGFR exon 20 insertion-mutated lung cancer. There are two types of exon 20 insertions, the other is a HER2 insertion. Both are rare gene mutations diagnosed in two percent of non-small cell lung cancer patients. Exon 20 insertions have also been found in 24 other cancers so far. Many of the patients diagnosed with these mutations are, like Hanlon, never-smokers in excellent shape.

Hanlon came to [International Cancer Advocacy Network](#) (ICAN) for help navigating his complex case. Patient advocates help in a variety of ways: Suggesting questions to ask a physician; recommending that comprehensive biomarker testing gets ordered; translating test results in understandable language; making referrals to top doctors for second opinions; encouraging patients to discuss challenging or unusual side effects with their medical team; and numerous other services designed to help patients ensure that no stone is unturned in the battle for life.

To marshal all possible resources against this relatively unknown disease, Hanlon and his brother, Robert T. Hanlon, PhD, a senior lecturer at MIT, co-founded the [Exon 20 Group](#) as an ICAN project. Their goal was simple. To turn this lethal disease into a manageable and survivable condition.

Just four years later, the Exon 20 Group is a global coalition and advocacy organization representing 1,200 stakeholders, including patients, care partners and families, medical oncologists, molecular pathologists, scientists, and molecular profiling labs, as well as a growing number of pharmaceutical and biotech companies developing exon 20 drugs.

The Exon 20 Group provides 21 different services for patients in 54 countries, including direct patient navigation at each pivot point of the patient journey; numerous social media sites including closed groups to protect privacy; referrals to molecular profiling services; clinical trials matching services; assistance with requests for compassionate use of drugs; and everything else that a full-spectrum patient advocacy organization provides.

Tremendous progress is being made by researchers and drug companies. We've gone from no FDA-approved drugs for exon 20, to an outstanding drug approved in May, and at least one more promising drug that is very likely to be approved in late autumn.

We believe even more can be done, so the Exon 20 Group is creating a new working group to improve the drug development process. The Exon 20 International Research Consortium (Ex20-IRC) will have two goals. The first is to determine what factors impede or delay drug development, and then to expedite clinical trials that combine promising drugs in the pipeline with other currently-approved drugs so that the cancer can be attacked more effectively.

The Ex20-IRC brings together exon 20 researchers and scientists from related disciplines for regular sessions to discuss new results, share ideas, and collaborate on the challenges posed by exon 20. We believe this team of cancer biologists, research oncologists, chemists, physicists, computer scientists, and others will inspire creative solutions and also be a model for combatting other diseases. All results will be shared throughout the broader cancer and disease community.

As often happens, the founder of an organization did not live to see all the progress he inspired. When Hanlon passed in 2019, he left behind a strong and energized base. This new and exciting multidisciplinary effort owes much to his passionate and focused efforts against exon 20 insertions and his continuing inspiration for all of us. When this challenging disease is defeated, Kevin will deserve much of the credit.