

An interview with Kathy Giusti, Founder and Chief Executive Officer, Multiple Myeloma Research Consortium (MMRC)

Joining forces to beat multiple myeloma

By Mary Beth Nierengarten

In 1996, at age 37, Kathy Giusti, then a pharmaceutical industry executive, had just received a promotion at G. D. Searle & Company—a reward for her successful marketing and educational campaigns. But at the height of her professional life, Ms. Giusti received a devastating blow: she was diagnosed with multiple myeloma. At the time, the prognosis was poor and the research sparse. She was appalled to learn that her treatment options were not much different from those offered to her grandfather decades earlier when he contracted the disease. “We have ideas for new treatment,” one scientist told Ms. Giusti, “but not enough funding for research.”

That’s when Ms. Giusti, a graduate of Harvard Business School, swung into action. She recruited her identical twin sister, an attorney for Time, Inc., to form the Multiple Myeloma Research Foundation (MMRF). Their first fundraiser grossed nearly \$500,000. Since then, MMRF has raised more than \$50 million to support research at some 60 institutions around the world. In 2001, the organization teamed up with several leukemia and lymphoma groups to form a blood cancer coalition that advocates together in Washington.

Ms. Giusti has continued the push. In 2004, she founded the Multiple Myeloma Research Consortium (MMRC) to integrate research efforts, accelerate drug development, and expedite clinical trials. Seven leading institutions have joined forces under the aegis of the MMRC: Dana-Farber Cancer Institute, Emory University, H. Lee Moffitt Cancer Research Center & Institute, Mayo Clinic, Saint Vincent Catholic Medical Centers of

New York, University Health Network (Princess Margaret Hospital), and the University of Chicago.

We spoke with Kathy Giusti about what challenges the Consortium faces as it enters its second year and how community oncologists and their patients can become involved.

Community Oncology: You’ve certainly shined a light on multiple myeloma. Why wasn’t it enough just to raise money and fund research?

No matter how much we were funding, we still saw a tremendous need to integrate research across academic centers. A lot of the grants made by the MMRF were for individuals working on specific projects. All that was well and good. Things were moving in the right direction, but we believed that collaboration, especially in drug validation and clinical trials, could get us to a cure much faster, because we could move the compounds more quickly into the clinic.

So the Consortium was an idea that evolved?

It was a few years before I realized that no matter how hard we tried to put grants together that promoted collaboration, it wasn’t something that came naturally. It’s not that researchers are unwilling to collaborate; they don’t have the time. We needed to create a model that encouraged collaboration.

Tell us more about that model and the progress the Consortium has made since it began its work in 2004.

The first year was spent getting the central tissue bank under way. We’ve

accrued more than 500 samples of bone marrow aspirates and matching peripheral blood. We put data systems in place to facilitate information exchange, and we developed three scientific cores. The first is a validation core, which now has a 12 cell-line program and fresh patient tissue. The second core is clinical trials, chaired by Paul Richardson at Dana-Farber. Primarily, we are doing phase I and II trials, looking for the most promising therapies. And the third core is genomics, which is involved in quality sample collection. We’re collaborating with the Translational Genomics Research Institute and the Broad Institute of MIT and Harvard on a multimillion dollar project to map the myeloma genome. Because of our access to high-quality tissue samples, we are actually able to do incredibly good genomic work.

Where does funding for the Consortium come from? Is the National Cancer Institute involved?

The Consortium is funded entirely by philanthropic donations. No government money is involved.



Kathy Giusti

Will the Consortium include community-based groups, which recruit 60% of patients into clinical trials?

We started off with a lot of academic centers. However, as we broaden, we realize it's better to go to some centers that are more community-based so that we can reach more newly diagnosed, untreated patients. We focus on getting trials done as quickly as possible, and, sometimes, community-based centers are able to do that faster with us. Because we are running some of the most cutting-edge trials available, we certainly welcome referrals.

How do you recruit institutions?

We distribute a request for applications based on geography, as well as patient profile. We then select the strongest sites from the data received.

How can private doctors enter their patient tissue samples in your tissue bank?

They can refer the patient to one of the sites in the Consortium, the bone marrow is taken at that site, and then the patient returns to them.

Let's talk about the research itself. Give us an example of how it proceeds.

The Consortium is all about prioritizing the absolute best therapies. The joy of having such a strong steering committee is that we're working with the world's top experts in myeloma, who know a lot about these drugs and can prioritize them. Once we've identified the drugs, we reach out to industry partners and encourage them to come to us to get some of the validation work done and to initiate their phase I and II trials. Right now, we are working with five to seven industry partners.

Currently, we're running a phase I trial with Chiron on a kinase inhibitor; it's accruing very nicely. This year, we're evaluating between four and six trials in the queue that we could conduct with our new industry partners. We talk

with our partners at least once a month about the compound, protocol development, site selection, [institutional review board] approvals, and contracting. We really are a tremendous resource to industry, especially small biotech firms that need the expertise of our steering committee as well as myeloma trial management support.

This type of consortium seems quite unusual.

Definitely, it's very unusual and very cutting edge. But anyone could copy this model. You do need a strong business background to get it done. The staff here is very focused on all the business issues from program management to communications, fundraising, contracting—we get it all done for our scientists. All they have to do is concentrate on the research. I think that's what has made both the MMRF and the Consortium, which act synergistically, so successful.

So this model could be applied to other clinical areas?

Yes, I've done conference calls with 20 other organizations that want to know how to do this. It is a huge undertaking. But truly, the institutions that have come on board are very excited. Everyone wants to work where the opportunities are the strongest, and the Consortium is emerging in that way. People said we couldn't get institutions to sign membership agreements with us, but we did. People said we couldn't get institutions to bank tissue. Well, we did. People said pharma wouldn't join us, but they did. I think we've really proven ourselves, and now that industry is very willing to play a part, we can move things much faster.

By the way, do the institutions in the Consortium continue their own independent work on multiple myeloma?

Yes, definitely. We invite them to take part in certain Consortium proj-

ects. But at any given time they can have many other trials going on.

What do you see down the line for the Consortium? How big will it grow, and how much more involved will it become with community-based practices?

We probably won't go beyond 25 major centers because we can only make this so big and still manage it. But I still believe that within the 25 centers, we will have more focus on some additional community centers. I don't think we'll see individual private doctors applying to the Consortium. But say your patient is in Boston, and you know that Dana-Farber is a member of the Consortium. You can still take part in Consortium trials and donate tissue samples.

Tell us about your public outreach efforts.

We do that with our newsletter that goes out to more than 100,000 people every quarter, and we always communicate what is happening at the Consortium. If patients go to our Web site and indicate that they are newly diagnosed, we immediately flag them as someone who might donate tissue. We want patients to know they can help by sending bone marrow to our tissue bank and by enrolling in clinical trials.

Are you happy with how it's going so far? It's too early for the Consortium to have produced any tangible clinical successes, no?

For me, the hardest part was the first year-and-a-half, when we were putting all the business and operating plans into place and getting everyone to start tissue banking. But now that we've got that under our belt, we're off and running. We expect to have at least three very significant trials spearheaded at the Coalition this year.

For more information, go to www.themmr.org.