SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

Get to Know the SME: Lew Fredane

1. **Were you always interested in neurology? If not, what did you originally want to be and why?**

   Not at all – I wanted to be a surgical oncologist in medical school. If you told me at that point I'd become a neurologist, I would have laughed myself silly. But I attended Haverford College, which had a freshman requirement called the Freshman Interview where you spill your guts to peers and faculty members so they can advise on your path to success, or whether you need time off for some soul-searching. The big idea I got from this interview is that the purpose of education is to give you as many choices as possible at any decision-making point in your life, so I became more open to absorbing things and change.

2. **Tell us how you made the transition from surgery to neurology.**

   I was working in a surgical research lab, where the head of the lab was a neurochemist working on animal models for multiple sclerosis (MS). I also met the head of research programs for the National Multiple Sclerosis Society, who became a mentor and encouraged me to apply for an MS research fellowship through the society, which landed me at Yale's immunology lab. My mentor there was a brilliant guy with a great, creative imagination.

   While at Yale, I was invited to a neuroimmunology conference and connected with Allen Roses, who was the head of neurology at Duke. He recommended that I pursue a neurology residency if I wanted to take my career in the direction of MS, since I only had one year of experience in surgery. I ended up interviewing for a neurology residency and got accepted into the program.

3. **What made you shift from practicing neurologist to the clinical research side?**

   After nearly 20 years in practice – both in private practice and at hospitals – a family acquaintance who worked at a CRO asked me if I knew any neurologists who would be interested in becoming their neurologist for clinical research. I literally said, "Well…how about me?" I spent about two years there before moving on to work for one of the CRO's sponsors, where I spent a few years running seasonal rhinitis trials, of all things, while working in pain management and supporting a key, marketed, anti-convulsant.

4. **Can you share a short story about a time you found your work rewarding?**

During my time working in epilepsy, one of the major medications the company had brought to market was the best anti-epileptic drug that had ever come out because it was initially thought to be very safe, and there was no need to monitor blood cells or liver enzymes because there were no adverse effects during its development.

It was fascinating to go into child neurology meetings and meet parents of children who were about to go through epilepsy surgery but were placed on the drug and no longer were candidates for the brain surgery. Hearing this message of relief from parents was wonderful, but they expressed concerns that because of intervening issues with safety that did occur during the early years of use, resulting in a boxed warning, that the company would cease to support and produce the drug. I was able to assuage their concerns by indicating that the company would continue to produce the drug into the future. In fact, the medication is still in production today.

5. **You've applied your neurology expertise to support drug development for nearly two decades. How has the industry changed since when you first started?**

Things are much more complicated now because of the pandemic. We already knew that putting technology in the hands of study participants was becoming important. There had been an early clinical study for a skin condition that enabled the use of patients' own devices, so we saw things heading in that direction. COVID-19 pushed that even more – how can we start to conduct remote visits or decentralize trials with the tech we have on hand?

Beyond wearable sensors, there are smartphones and even sensors that can be placed bedside to detect breathing during sleep. Signant's Dan DeBonis recently engaged with a company that can capture simplified parts of the Parkinson's exam on video so that AI algorithms can analyze movement, speed of movement, and rhythmic vibrations. There is also software for detecting signs of Parkinson's or ALS from aspects of voice before physical symptoms show! More and more, we will leverage what's available to improve the science.

6. **Can you share a current project you are working on that you're excited about?**

We are supporting a study for Farber disease, which causes external nodules over children's joints that make mobility difficult and painful. Eventually, these nodules accumulate in the respiratory tract and cause death. These kids are not only suffering with progressive loss of mobility, but also with growing pain.

We know that to some degree, these diseases are reversible, so Signant is working with

a company that is searching for a cure and helping to provide continuity from the prior original study. We've adapted a special tool to measure nodule size, even in difficult to reach spaces between the fingers. The training uses 3D printed model hands that are very costly, so we also had to figure out what material the models were printed with, what could be used to draw on them, and how to clean it off completely without damaging the model hand. Then, we developed a methodology to train raters live and in-person, and then mail a clean hand model to their site for further testing of the raters.

We must fulfill an obligation to do the best we can to carry through progress from the original study, so that the new company can conduct a successful trial for the sake of these children.

7. When you're not working, what do you like to do?

I enjoy helping to raise my granddaughter and seeing the world through her eyes. What does it mean to the mind of someone who's seeing something for the first time? I also enjoy travel and photography. One of my best memories stems from our family trip to visit our daughter while she was studying abroad in Prague, I used to get up early in the morning with my camera and walk about to capture the city's beauty and history.

Want to meet our in-house experts? Interested in having Lew's invaluable expertise on one of your upcoming studies? Contact us today.

Signant Health

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