# Personal Journey into clinical trials Part 1

February 11, 2016 By Kimberly Morgan Bossley

Most recently I have been asked several times about my experience going into a clinical trial for a treatment to cure my hepatitis C. And most every time the first question was “How did you feel being a guinea pig?”

Here is my personal story and journey into the then unknown.

After finding out in March of 2012 that my then treatment of interferon and ribaviran was not working and that my doctor was pulling me off treatment, I was devasted. Here I was diagnosed with Stage 4 cirrhosis, a mother of 2 young children, and a business owner. To top it off, I witnessed first hand what this disease does in the final days after seeing my mom pass away with complications to liver failure. What was this expert telling me? Did he not think I could handle the side effects well enough? I begged and pleaded for him to keep me on this nasty awful regime. I wanted to live and back then this was the only hope I had and now he is telling me he is removing me from the medication? He said, “Kim, as much as I hoped this would work, I could keep you on for a year but knowing this medication as well as I do, your body will never respond and clear on this medication. It would only cause you to deteriorate and I won’t let that happen to you.” Silence and tears rolling down my cheeks at that moment. I felt as though the rug from under me just flung me to the ceiling and onto my back. I sat there in that room that once was my sancurary of hope only to be chilled to the bone.

Moments later my doctor returned and handed me a torn piece of paper with a name on it. To this day that paper is still in my wallet. That paper contained the name and phone number to what I didn’t know then was my miracle worker… Andrea. She was head of the hospital’s clinincal research department. Andrea was my doctor’s nurse in charge of the clinical trials he was conducting there at the University of Colorado Hospital. “Call this lady as soon as you can, let her know that you are a candidate for a few trials I have coming down the pipeline,” Dr. E. advised.

I don’t think I was in my car yet when I dialed her number and left a very long-winded voicemail. I remember holding the phone close to my every move, waiting and praying for her return call.

I don’t remember exactly when I got the call back, but she introduced herself and asked me lots of health questions pertaining to my hepatitis C. Without wanting to sound desperate I shared my condition, and that I was very eager to do anything to try to cure or stop this hep C from taking my

life.

It was about 4 months later Andrea gave me a call about a trial that had become available and recruiting people. I jumped at the opportunity. Going into the clinical trial office that first day was nothing like I anticipated. It was not the cold chemistry labratory I envisioned. While sitting in the waiting room, out came a petite lady, “Hi, I am Andrea.” I smiled at her with thoughts of my mom as I noticed she was about the same height as my mom was (4’10").

I was told that I would need several tests done to see if I qualified for the study. I’ve now forgotten what that particular trial name was or which drug it tested. I do know that the trials I did try for required various procedures ranging from endoscopy, MRI, CT scan, etc. I descibe trying to get on a clinical trial like a person trying to jump though small hoops with weights on. The process takes lots of time, lots of tests, lots of waiting and patience.

I will share that after all that I went through (my hoops so to speak) I failed to get on two different trials...one right after another. It was nothing I did but rather the drug companies’ strict protocols about patient’s medical status. If you miss the required mark by say 1 point either direction, they will deny particiapting in the trial. Each time was told I am a great candidate, filling me with so much hope only to sit in Andrea’s office and hearing that I was denied. I could tell it was just as hard for her to pass this news to me as well.

I learned after the first two I failed to get on, not to get my hopes up. It is not their way of saying “you are in, please go have a endoscopy ran”. It is... we want this and that is that. Going through all the requirements is no guarantee to anything in the clinical world of things.

I shed lots of tears in the year I failed to get on two trials. Then I got the call the 3rd trial was coming available. Of coarse I was eager to get down there to apply but my heart and stomach were not at that point of joyfulness. I went through much rigorous tests this time to get on this trial. I waited and waited until one day Andrea called and said “Kim, YOU are IN the trial.” Wait what? Seriously? For REAL? That day my daughter Megan and I drove down to what we knew was a true miracle in the making..

I was bursting at the seams with excitement while sitting in the room waiting for Andrea to come in. She sits down and says, “I am sorry Kim, you did not get the real drug this round.” My heart sinking to the ground, tears filling my eyes and a knot in my throat as big as a boulder. With my mind already foggy from the brain fog, I was not fully understanding what exactly she was telling me. Now I am no longer accepted? She proceeded to share that for 24 weeks I was randomly selected to get the placebo. Which means I come into the office 2-3 times a week for a month and then once a month after that for blood draws and tests as if I was really taking the medication. For those that have no clue just how long 24 weeks is..... it is eternity for someone with stage 4 liver disease. But my token was after the 24 weeks I should be guaranteed a spot for the real treatment. But wait ... That is not the end.

Coming up to the end of my 24 weeks I had to undergo all the detailed test again for the trial approval. Here is where I share -- don’t hold onto words, or numbers too tightly..things change

and Andrea had to explain that in my recent tests something in my liver pressure numbers changed out of the trials “requirement.” Meaning I no longer “FIT” into the trial protocol. Outraged, Andrea and Dr. E. went to bat for me calling Gilead and sharing that if they took my two tests and averaged them out, I still met the criteria. With the grace of GOD, they agreed.

I went in to Andrea’s office that beautiful morning in November 2013. Both Megan and I were filled with mixed emotions, scared but yet hopeful. Remember we learned not to count on anything until the “pill” was swallowed. I signed so many papers that morning to begin this journey to my cure. Finally Andrea, this lady whom has shared so many tears of diappointment and frustration with me, walked in with two bottles of unmarked pills. One filled with BLUE tablets and the other with YELLOW tablets. Her eyes now filling with tears as she handed me a small glass of water and two blue pills and 1 very pretty yellow pill. Shaking as I reached for them, my eyes could not keep the tears from flowing. The mascara on my face running in streaks. I could not believe my eyes... I finally was taking a medication that has the potential to cure me. I swallowed with hesitation as if I was to “FEEL” something miraculous right then and there. It was a day I will forever remember.

Stay TUNED as I share the final journey on my trial. As you can see it is not all simple easy but yet it can be if things fall into place. One thing I learned, never give up your hope. Don’t let any diagnosis, test, trial etc steal your hope for a cure. You MUST be patient and very very persisitant.

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