Nearly everyone remembers the childhood tale of *The Wizard of Oz*. Four characters searched for something they believed magic alone could create, only to find that they already possessed it. The image of the Tin Man comes to mind, who believed he did not have a heart because he was made of, well, tin. Although his metal chamber lacked a physical beating heart, his metaphorical heart was larger than life.

In the hurried world of preparing regulatory submission documents, patient narratives may not always be top of mind for medical writers and those who perform quality control (QC). Often the focus on time and prioritisation resides with the body of the clinical study report (CSR). Although the CSR contains the all-important aggregated data that allow conclusions to be made, the narratives, in my opinion, are the metaphorical heart of the document. And just like the Tin Man’s heart, we may forget that it has been here all along. Reading these documents can bring the reader, and ultimately reviewer, closer to the study by sharing details of the courageous patients who gave of their time and entered the study with hopes of improving their health and furthering science. As noted in his book *The Gift of Participation*, Kenneth Getz hails the act of participation in clinical research as “a brave and selfless act.” Those who give of their time and information, anonymously without recognition or reward, deserve our utmost respect.

Part of my role is to train new editors how to conduct QC reviews of patient narratives. Our approach likens it to putting the pieces of a puzzle together and reviewing the narrative several times to focus on different items with each pass. One of these reviews includes simply *reading the story*. Why? By taking the emphasis away from the data, there is an opportunity to truly understand what the patient experienced.

When introduced to patient narratives years ago, my first impression was not glowingly positive. Frustration was felt as I scoured the trove of data sources in search of an informational nugget to validate the data. That changed one day while reviewing narratives about depression in children and how their illness affected, and sadly often ended, their young lives. I caught my breath while reading each new story. It was then that I realised how important it was to these patients and their families to share their stories, despite their pain and heartbreak, as a gift to further medical knowledge.

Those of us in the medical writing industry have a deep responsibility. In addition to applying our skills to translate complex information, we owe it to these patients to ensure their data, and their stories, are told correctly and reflected accurately. To comply with the new EMA Policy 0070, we also need to remember the sensitivity surrounding their data and treat them, and their data, with dignity.

In the recent EMWA workshop, *Patient Data Protection in the Clinical Trial Disclosure Era,* attendees were reminded to include only the amount of data needed. Protecting sensitive data was an overarching theme of the EMWA conference as the new policy goes into effect. Patient narratives are therefore a critical area where writers and editors need to remember and apply the policy’s guidance.

Just as the Tin Man realised that he had a heart all the while, we too can learn that our documents have a heart as well. I encourage everyone who writes or reviews patient narratives to apply our humanity to tell, hear, and feel the stories within the data.

**References**