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and SCCE/HCCA Board Member

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by Kelly M. Willenberg, MBA, BSN, CCRP, CHRC, CHC

Chicken before the egg?

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A challenge for research sites is the interface of a myriad of IT systems within an institution. In working with clients daily, many are asking, “What do we really need?” Considering there are Clinical Trial Management Systems (CTMS), electronic health records (EHR) hospital billing systems, and eRegulatory systems to choose from, bridging the communication between them is an ongoing exercise. The more systems a site has to intersect, the more workflow is necessary. Because there is no turnkey option, what must you consider when purchasing any system?

Whether you have an EHR you like and use for research, or a CTMS already implemented, you have to consider research patient identification within both. Some choose a CTMS to enhance their EHR. Some use an EHR to manage trial subjects exclusively. Data, though, needs to flow from one to the other, but is it the “chicken before the egg or the egg before the chicken”? Interconnection of research documents, charge entry, financial services, and coding can be tricky. You must store documents compliantly and track accounts receivable, too. It sounds easy. Right?

Because document storage is also a high priority, you also must consider validation within the FDA regulations under 21 CFR Part 11 for electronic records and signatures. Where does this sit in your process?

One figures out quickly—flowing from system to system—and how you manage that data will not only help you, but can make your life much easier. How do you get there?

Where can these systems intersect, or can they? A CTMS can manage study information, an EHR-hospital billing system can logistically help manage study information and patient/study association within the study calendar for billing compliance. What can help the other? Some CTMS can process invoices and help with accounts receivable, but some facilities already have a process in place for that. An eRegulatory system can integrate a document solution, if needed. Look at the choices you have at your fingertips!

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If you are in the market, look at many types of software systems. Evaluate project and patient management, compliance with government regulations, financials and accounting, regulatory document storage, and compliance. Remember, compatibility with other systems will either make things easier or make things harder. If you do not consider all of the above, you will be walking on eggshells.

Wait, we are back to the chicken before the egg, or the egg before the chicken! Either way, you do not want egg on your face when using IT systems to achieve compliance. ☐