

# Beyond the Value of EDC— The eClinical Paradigm Shift

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You can almost hear the readers' groans as you begin to write a paper like this. Not *another* piece lauding the benefits of electronic data capture (EDC)! If you have read this far, rest assured that this paper is *not* about the wonders of EDC. Ever since PhaseForward really opened up the EDC floodgates in 1997,<sup>1</sup> a deluge of companies has come and gone, saturating the market with messages about efficiency, speed, and reduced cost to the point where EDC's advantages have become a given.<sup>2</sup> In fact, some companies are now beginning to regard EDC as a commodity offering, and are thus subjecting vendors to reverse auctions.<sup>3</sup> EDC adoption was its own paradigm shift in thinking and has gained so much momentum in the marketplace<sup>4</sup> that its U.S. adoption rates are projected to have increased from 24.2% during 2005 to 45.2% at the end of 2007.<sup>5</sup> (See Figure 1.)

This paper is about a new, somewhat quieter, but no less revolutionary paradigm shift that is under way—beyond EDC and towards eClinical, with the inclusion of clinical and operational metadata.<sup>6</sup>

Differentiating between EDC and eClinical is sometimes difficult, as the industry on occasion uses the terms interchangeably. Here are the definitions from the *Applied Clinical Trials* glossary 5.0 (2006):

- **EDC**—The process of collecting clinical trial data into a permanent electronic form. (Note: “Permanent” in the context of these definitions implies that any changes made to the electronic data are recorded via an audit trail.)
- **eClinical**—Clinical trial in which primarily electronic processes are used to plan, collect (acquire), access,

exchange, and archive data required for the conduct, management, analysis, and reporting of the trial.<sup>7</sup>

In the context of this piece “eClinical” will be used to refer to a system that enables a clinical trial under one technology umbrella. When well executed, eClinical represents a paradigm shift beyond EDC.

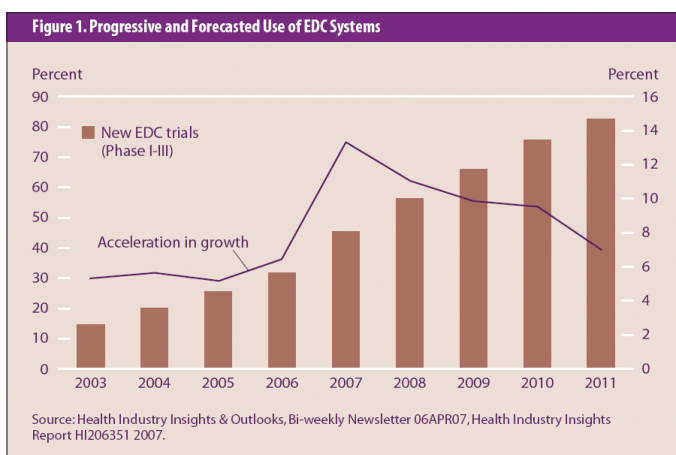
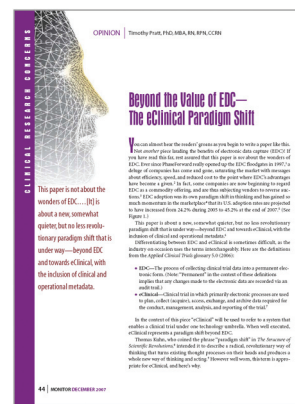
Thomas Kuhn, who coined the phrase “paradigm shift” in *The Structure of Scientific Revolutions*,<sup>8</sup> intended it to describe a radical, revolutionary way of thinking that turns existing thought processes on their heads and produces a whole new way of thinking and acting.<sup>9</sup> However well worn, this term is appropriate for eClinical, and here's why.

## Where We Have Been

It's often of value to reflect on the past to understand the present, especially with technology. Historically, EDC was preceded by remote data entry (RDE)— basically a locally distributed set of software, often on a dedicated special computer, that people would use to enter data locally, and then “sync up” with the sponsor database via modem (or in the really early days, by sending the whole computer back to the sponsor). Although some degree of dynamic edit checks were incorporated to make the data a little cleaner than paper, there were limitations and major problems of “immediacy”; after all, the dataset was complete only when everyone synced up on schedule (which rarely happened) or if someone didn't spill coffee on the computer or steal it (which often happened).

Then came EDC at about the same time as the Internet really took off in the late 1990s. Early versions of EDC were simply web-enabled RDE systems and carried with them some of that early technology baggage; they would work only on particular operating systems or required certain software (usually those operating systems were MS-DOS, which morphed into Windows), and often the browser required was Internet Explorer, so users of FireFox, Netscape, Linux, or a Mac were precluded from using these systems.

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Eventually, some of the major EDC players began to gain traction in the marketplace. They were great solutions for their time, and much effort was put into market development: better, cleaner, faster, cheaper—the classic EDC mantra. These early systems were paradigm shifts compared to paper methodologies, but the dark side of the technology has only just begun to emerge as the eClinical revolution gains traction.

### Where We Are Now

The first mover/adopter in any new technology always has to deal with somewhat unsophisticated, limited functionality. When companies invest heavily in early technology, they are typically unwilling, and in some cases unable, to change fundamentally and take advantage of newer more flexible technologies. The U.S. railway system and the land line telephone system, for example, use outdated and outmoded technologies anywhere from 80 to 120 years old, and the companies using them are too heavily vested to change (and thus have lost business to highway transportation and modern digital cell phones).

For our purposes, EDC has become focused on selling their product because of their heavy investment in it, rather than meeting the evolving need—and there is a subtle, but rather large, difference there. For a classic analysis of this phenomenon, see Levitt's "Marketing Myopia,"<sup>10</sup> in which he uses the U.S. rail tycoons of the late 19th century as examples of people who thought they were in the railway business, but in fact were in the *transportation* business and had invested so much in the rail network that they were unable or unwilling to move with the times. Too many companies fall into this same trap.

So the dark side for some companies is that their technology is fundamentally predicated on outdated and inflexible platforms/architecture. Ten years is a multi generational lifetime in software/PC development; can you imagine still doing your work on an old 486 PC or working in a DOS command line environment? Does anyone remember (or want to remember!) how hard that was? A reliance on inflexible architecture carries with it the baggage of inability to extend effectively beyond the EDC space, other than buying other standalone applications and attempting to integrate them into the offering. Thus, many EDC companies now advertise that they have an "integrated" or "suite" offering.

Is integration an acceptable road to eClinicals? The term "integration" itself is somewhat of a misnomer in these situations. Most people would agree with a definition of "integrate" along the lines of "to form, coordinate, or blend into a functioning or unified whole."<sup>11</sup> The difference in this type of software approach is that the products are never truly integrated at all; what you have is a series of standalone

applications joined by what programmers call application programming interfaces (APIs). The key word is "interface," and it is akin to a bridge between applications. For the bridge to function, the applications must always remain static, which makes it very difficult to enhance functionality or performance. Most of those applications were never designed to have APIs in the first place, so building reliable ones is problematic indeed. Such integrated systems have been described as made up of "islands of automation"<sup>12</sup> joined by bridges which periodically get clogged up with traffic or fall down.

### Where We Are Going

As the allure of EDC begins to wane simply because it is becoming the standard *modus operandi*, early movers in the technology attempt to extend into a comprehensive eClinical offering with CDMS and CTMS functionality. This is a perfectly logical and seemingly simple extension of the original EDC concept, but no less revolutionary for its simplicity. The problem is that early architecture-based products are often forced to attempt this in a manner that is fundamentally predicated on integration of dissimilar elements. Some, stuck with a system that cannot be anything other than integrated, will attempt to persuade clinical professionals that it has to be that way—that advanced technology cannot perform, say, honoraria/reimbursement or CTMS functions in addition to EDC.<sup>13, 14</sup> Is it true? No. Articles have previously been written about systems that are not bound to this technology vector, and indeed can accommodate those elements.<sup>15</sup>

What does an integrated system mean to you, the clinical professional? Probably a lot of frustration with inflexible technology that simply will not do what you need and a lot of difficult bridge maintenance work for your IT personnel if your organization has licensed the technology. There is a reason why some older systems cannot do simple things like parent-child conditional branching, and why relatively minor change requests take a very long time and a lot of money to execute.

On a broader note, heaven help you if an "integrated" component like the randomization system fails. Yes, that has happened, and it did cause the trial to fail, and the pharmaceutical company involved did have to redo the trial at great expense.<sup>16</sup> Worse yet, the nature of the integrated system in this case was such that the problem was not realized until the trial was over.

The market is beginning to turn against these integrated models. A leading industry observer said recently that small to mid-sized pharma and similarly sized CROs are indicating their frustrations with "integrated" systems that do not work as advertised. The requirements for ongoing, high-burden maintenance have such firms actively seeking single system

solutions.<sup>17</sup> Such solutions will come in the form of a single database, single application system with everything residing within the one structure and instantly accessible without batch processing or constant attention to the interfaces (the bridges) for day-to-day activities.

## The Paradigm Shift

So we arrive at a paradigm shift that takes us away from EDC and integrated multisystem eClinical offerings and toward single-system eClinical solutions that are designed with significantly newer and more flexible technology.

Imagine a system that is entirely homogenous in nature and can do everything you need it to: visit scheduling, recruiting, phone logs, honoraria, clinical inventory, monitoring, interactive flexible workflow, documents tracking, IRB/EC approval/renewal tracking, auditing, conditional branching, PRO, IVRS, and much more (and EDC, too). Such a system can accommodate multiple trials and facilitate CTMS functions, allow customization, and never has to rely on unstable interfaces. The possibilities are still being explored by various vendors, but the potential exists to make many of today's systems completely obsolete and to usher in a whole new way of conducting clinical research.

Beyond EDC, true eClinical systems represent as radical a shift in thinking and impact on the clinical professionals as the original early forms of EDC did compared to paper-based methodologies. Just like those CROs that were slow to adapt to EDC, companies that are slow to adapt to the next wave of eClinical run the risk of sinking into obscurity. As Kurzweil maintains, "Technology is accelerating and its powers are expanding at an exponential pace. . . . It starts out almost imperceptibly and then explodes. . . ."<sup>18</sup> Paradigm changing technology is like that: It comes in a slowly gathering, tsunami-like wave that quietly gains momentum before sweeping all before it.

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