

Investigation of the functionality of electronic data capture and management systems for use in a
modern animal health industry

by

Ashlea Ellen Laporte

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Approved by:

Major Professor
Haley Larson, Ph.D.

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Abstract

Electronic data capture (EDC) systems work to supplement or replace traditional paper record documentation in many industries. Within both human and animal healthcare industries clinical trial studies serve to benefit from EDC for efficiency and cost perspectives. This allows for a faster timeline to new medicinal products being available to markets in both fields. The animal health industry has not adopted implementation of EDC as readily as some industries and lags behind human health industries which may be explained by an easier path to implementation based on infrastructure that is already in place within hospitals and doctors' offices. Animal producer industries, and the software available to those facets of the market, may be adapted or used to drive the use of EDC in clinical trials or other registration related animal studies. With focus on cattle producers a landscape analysis was performed to identify ranch management software available to the cow-calf industry. Using a search engine and application store search 23 EDC software programs were identified, analyzed, and further categorized based on their capabilities for technology integration, analytic options, and inventory features. Software capable of documenting relevant veterinary care aspects has the highest potential for crossover uses within the animal health industry. With the growth of infrastructure available to the animal health industry the implementation will only be delayed by the extrinsic nature of contract or external laboratory studies being commonplace. The benefits to EDC alone have not been enough to drive the animal health industry into full implementation. With further advancements within the human health industry, new software program availability for animal producers, and acquisition of software companies by animal health driven companies, this may eventually lead to improved implementation in the modern animal health industry in the future.

Table of Contents

List of Figures.....	vi
List of Tables	vii
Acknowledgements.....	viii
Chapter 1: Need for electronic data capture and management in the Animal Health Industry	1
Introduction to Electronic Data Capture.....	1
Electronic Data Capture to Meet Data Quality Standards	4
Role of Electronic Data Capture in Addressing Labor Shortages	6
Willingness to Adopt Technology	7
Chapter 2: Structured landscape analysis of cow-calf record keeping and data management	
software.....	9
Introduction.....	9
Methods	10
Eligibility Criteria	10
Search Strategy and Selection Process	11
Data Collection Process	12
Data Items	13
Results.....	16
Software Selection	16
Minimum Cow-Calf Operation Data	18
Technology Integrations	18
Data Features	19
Veterinary Care.....	20
Inventory Features	20
Discussion.....	21
Acknowledgements.....	22
Chapter 3: Juxtaposition of electronic data capture systems for animal producers vs. for	
regulatory or research applications.....	24
Understanding the Disparity between Animal and Human Health Industries.....	24

Research Industry Needs	27
Future of Electronic Data Capture in Animal Health	29
Conclusions.....	31
References.....	32

List of Figures

Figure 1. 1 Example of traditional paper data capture form used in clinical trials (adapted from AAI 840)	2
Figure 1. 2 ALCOA principles with distinction between ALCOA+ and ALCOA++ (adapted from McDowall, 2022)	7
Figure 2. 1 Identification of cow calf management software or ranch management software via Google search and Google Play Store.....	12
Figure 3. 1 Example of standard cow-calf record book (adapted from Valleyvet.com)	26
Figure 3. 2 Example of daily clinical trial observation form used in Animal Health studies.....	27

List of Tables

Table 1. 1 Percent cost reduction by clinical trial phase for electronic data capture vs paper records (adapted from Bart, 2003)	8
Table 2. 1 Categories used to define minimum cow-calf operation data during initial evaluations of software electronic data capture capabilities	14
Table 2. 2 Categories used to define technology integrations during initial evaluations of software electronic data capture capabilities	14
Table 2. 3 Categories used to define data features during initial evaluations of software electronic data capture capabilities	14
Table 2. 4 Categories used to define veterinary care during initial evaluations of software electronic data capture capabilities	15
Table 2. 5 Categories used to define inventory features during initial evaluations of software electronic data capture capabilities	15
Table 2. 6 Analysis of cow-calf operation software by feature categories for technology integrations, data features, veterinary care, and inventory features.....	17
Table 2. 7 Summary of included software, parent company name and location, and web address.	23
Table 3. 1 Welker's 12 barriers to Electronic Data Capture implementation	25
Table 3. 2 Makinde (et al.) barriers to Electronic Data Capture implementation in Canadian beef farms	26

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Chapter 1: Need for electronic data capture and management in the Animal Health Industry

Introduction to Electronic Data Capture

Electronic data capture (EDC) is the use of a computer system or program to document data facets as it relates to relevant information to a given process, typically associated with clinical trials in the human health industry. Emam et al. (2009) defines an EDC system as being capable of submitting data electronically into a database and allowing for reporting or some form of statistical manipulation within the system. Electronic Data Capture systems may include features that support many phases of a study starting with patient randomization and moving through final file transfer to the recipient of the data (Welker, 2007). Benefits of this type of system range from improved accuracy to reduced overall study costs and can include a reduction in timelines (Welker, 2007). The animal health industry appears to be lagging in implementation of EDC systems despite the demonstrated success within the human health industry (Sarasola). Within Animal Health, there are two sides to EDC implementation: (1) at the clinical stage and (2) within the manufacturing space. “Paper on glass” is an initiative in many production-based industries where original data capture happens within an electronic system to eliminate the need for transposing paper records into an EDC system. A Pharmaceutical Technologies (2021) article discloses that a given production plant can generate thousands of paper records every year which require an employee to complete the forms and up to 6 different employees to make manual entries or revisions per document. The “digital transformation” from paper records to EDC systems is becoming a continuous improvement project for many production companies globally. “Paper on glass” not only automates portions of the batch record documentation, it also

simplifies quality assurance review time of given documents. Figure 1.1 shows a traditional paper form utilized for data capture in an animal health clinical trial.

Figure 1. 1 Example of traditional paper data capture form used in clinical trials (adapted from AAI 840)

Study #: B1-121323 Date: 24 Feb 24
 Time: 1408 Study Day: 73

Daily Individual Animal Observations

Animal ID	Observation (normal / abnormal)	Comments
HYO-2	normal	
AXM-2	normal	
HGR-2	normal	
PUO-2	abnormal	lethargic and site swelling 3cm
RVX-2	normal	
YCZ-2	normal	
GAF-2	abnormal	diarrhea (no sample collected)
QMC-2	normal	
MBD-2	normal	
ASQ-2	normal	
TPG-2	normal	
ZUL-2	normal	
JSC-2	normal	
YFG-2	normal	
AJI-2	normal	

Assessed and Recorded By: [Signature] Date: 24 Feb 24
 Investigator Review: [Signature] Date: 26 Feb 24

Scanning and digitization of a data capture document may not always allow for easy legibility, as observed in Fig 1.1 in one line where the observer may have initially documented one result as “normal” then later added “ab” to the front of the word to indicate “abnormal.” Comments are also not standardized, and with often only a single line to document results, some

details may not be preserved. Electronic Data Capture allows for uniform entries and forces comments or justifications if an observer were to change a result that could impact the study findings. Aside from improved data control, improvements can range from searchable data fields to easily identifiable errors. Data regulation on paper records is widely understood, and while EDC regulations should be expected to follow similar requirements, there are some areas not covered by previously existing regulations. The Food and Drug Administration (FDA) updated the Code of Federal Regulations (CFR) 21 C.F.R. § 11 in 1997 to describe the added requirements around electronic records and electronic signatures, or ERES.

Animal producers in the industry may not require the level of control over data entries required by the animal health companies. However, the types of information captured at the clinical level overlap greatly between producers and companies. General animal condition scores, weights, categorization into a field or study group, and veterinarian interventions are all areas of overlap, regardless of data compliance requirements between producers and companies. Animal producers in the industry are especially interested in understanding implications of how EDC system data can be used for public health purposes. Clinical trial data can logically be leveraged to advance public health knowledge, and data and reports could be made available to regulatory bodies or the public depending on legal requirements. Producers have a different perspective. Data gathered by EDC on a producer's property may be voluntary. If data relating to diseases of interest was automatically provided to agencies that monitor potential outbreaks, what are the implications of providing said data in a data ownership argument? Ultimately the same software for EDC may be developed with a "One Health" goal in mind. This cross-sectional approach to total health improvement works in an interdisciplinary approach to share knowledge across all human and animal industries with any focus on health or environmental

factors (Filter et al., 2021). However, interests of companies, producers, consumers, and government agencies will need to be aligned first for a One Health application to be successful.

Electronic Data Capture to Meet Data Quality Standards

For an animal health product to be licensed or sold in any market, there is always a level of data capture required by the regulatory body as part of production or release of the product. With technological advancements in the last decade, coupled with the increasing improvements made to current good manufacturing practices (cGMP), the desire for electronic data capture (EDC) is growing. Efficiency of a given workflow is likely the easiest benefit to identify. For example, rather than writing out a description or a “Positive/Negative” or “+/-” as a result an analyst would select the correct identifier from a menu. An understated improvement would be consistency of reported information for improved study interpretation, and ease of review that saves the company time and money. The Food and Drug Administration (FDA) audits pharmaceutical companies on many aspects of production, including cGMP in various areas of the licensing process, which also includes clinical trials. An analysis of 300 warning letters issued by FDA from 2007 – 2018 identified data integrity and other regulatory compliance issues. Documentation and following procedures were significant contributing factors to clinical trial audit findings (Rogers et al., 2020). A suggested benefit of electronic data capture is automation and uniformity of documentation. Within the animal health space, clinical trials take a variety of shapes, meaning the variety of animals and distinct levels of care creates a need for specialized types of documentation in certain cases. Large animal studies have the potential for more veterinarian or caretaker interaction compared to small animals or customer owned animals.

Electronic Records; Electronic Signatures, 21 C.F.R. § 11 (1997) defines electronic records and record keeping expectations of the FDA. With the increase in EDC over the years, initiatives have been put in place to encourage software producers and consumers to have good data practices including validation approaches to software validation. The Lean Validation Approach (LeVA) has been promoted and supported in the industry as the best method to ensure compliance with all regulations. A standardized method of assessing computerized software provides a generalized list of aspects to review within the software.

With the growing need for technology within the animal health space, an established the framework for making that technology complaint, the only missing aspect needed for success is ensuring the software can keep up with the needs of the industry and has the agility to grow with a company. In 2016, USDA issued notice number 16-14 that allowed for electronic data to be submitted to the Center for Veterinary Biologics (CVB), as opposed to submitting paper records through the mail. This step shows the general acceptance even within regulatory bodies to support EDC within the animal health space. To encourage use of a modern approach to data submission, CVB published a list of benefits for using the portal: cost savings, ability to review when testing will be complete at the agency, pre-populated information to increase ease of entry, submission tracking with ability to see open or incomplete items, and streamlined communication with the agency, among other points (Rippke, 2020). Key stakeholder willingness to accept electronic data should encourage further development and use of EDC software within the industry. A Canadian research group that works within a Biosafety Level 3 and Biosafety Level 4 space sought out the benefits of electronic data capture purely from a biosafety perspective (Bente et al., 2011). The research group worked with laboratory animals to utilize a platform for data capture that emphasized data privacy. Their approach differed from

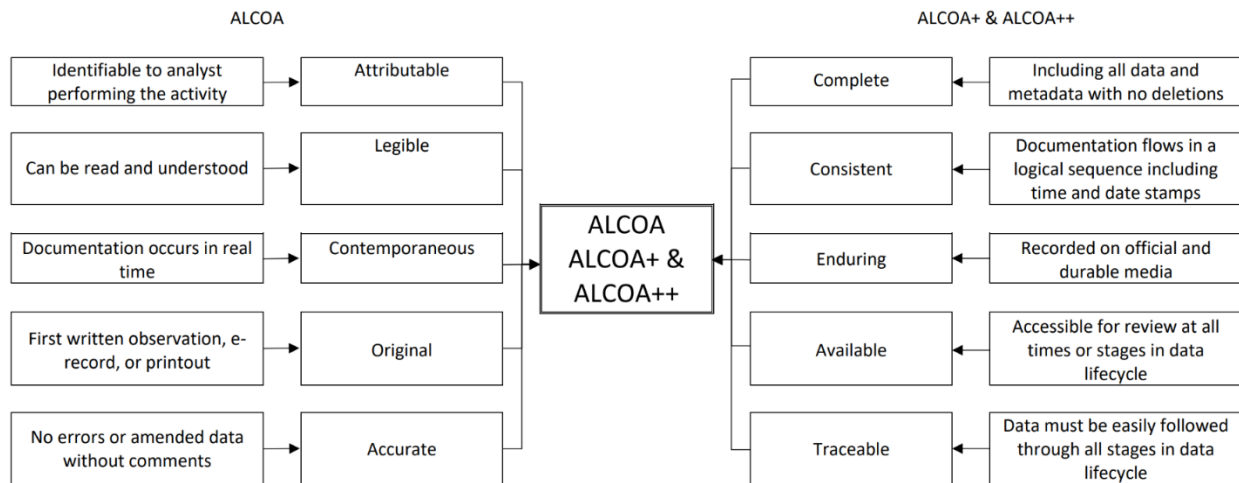
other examples presented in this chapter as they sought out to preserve biosafety and biocontainment of pathogens at those higher biosafety levels. The software evaluated, and many other platforms in the research space, are focused on laboratory animal care, rather than large animals used in clinical trials. Currently, large animal software is predominantly directed at producer use cases but overlap in functionality could allow for use by producers and companies alike.

Role of Electronic Data Capture in Addressing Labor Shortages

Labor shortages drive the need for efficiency, training, and availability of EDC improvements. Animal care itself can be a complicated process to manage when multiple individuals are responsible for the care of a group of animals. Electronic data capture steps in to fill the communication gap in an easily auditable format without need for a detailed shift change communication meeting. The adage “if it was not documented it didn’t happen” explains the necessity of compliant methods to document the care, experimentation, and results by both the producer and animal health companies. The “ALCOA+” principles define how documentation should be kept remaining compliant in many industries. Attributable, legible, contemporaneous, original, and accurate make of the basis of ALCOA. The plus was added to capture facets including completeness, consistency, enduring, and availability. While EDC can certainly improve some of the basic ALCOA principles, it can also build into improved “plus” facets by creating a stepwise documentation process and only allowing progression to the next field or form when the current file has been completed. Use of drop-down fields will drive consistency while the digitized format will improve availability and provide an enduring format because the data will always be a few keystrokes away especially if the program can be designed with report

building functionality. The ALCOA+ principles are clear guidelines to remind companies of regulatory requirements from various regulatory bodies both domestic and international.

Figure 1. 2 ALCOA principles with distinction between ALCOA+ and ALCOA++ (adapted from McDowall, 2022)



Willingness to Adopt Technology

Some animal food producer industries are more accepting of technological integrations, like the dairy industry, though some lags in implementation are still occurring. The advancement of technology as it stands will be impacted by industry willingness to adopt the technology.

Within the dairy industry adoption of EDC is viewed differently across age groups, which may explain why adoption has increased over time (Fadul-Pacheco et al., 2022). In general, within food producer and health industries, there appears to be a lack of awareness around proper data integrity with electronic data, and a lack of understanding of the control over data. In recent years, there has been an increase in requirements around cGMP, which impacts the amount of time, and money, that must be spent to ensure accurate and consistent reports. Clinical trials are costly, but EDC systems reduced costs more than anticipated in a 2003 study (Bart). Cost savings alone may be a large driving force to industries that have yet to adopt EDC systems (Table 1.1). With checks and balances able to be automated within an EDC system, the

improvements to be had over traditional paper systems can save as much as \$50 per query and can reduce queries for missing data from 48% down to 0% (Welker, 2007).

Table 1. 1 Percent cost reduction by clinical trial phase for electronic data capture vs paper records (adapted from Bart, 2003)

Clinical Trial	Budgeted Reduction ^a	Actual Reduction ^b
Phase I	12.9%	90.5%
Phase II	62.4%	94.4%
Phase III	79.9%	93.5%
Phase IIIb	76.7%	90.2%
The proposed reduction, or savings, and actual reduction in costs for switching from a paper record system to an electronic system demonstrate savings of 90% or more for all clinical trial phases.		
^a [Estimated paper model costs – Assumed EDC costs] / Estimated paper model costs		
^b [Estimated paper model costs – Actual EDC costs] / Estimated paper model costs		

Within this chapter as well as chapters 2 and 3, we aim to define the Animal health Industry’s need for data capture and the history of its development (chapter 1), discuss why producer data capture systems are leading implementation of EDC with data capture for clinical trials trailing implementation through presentation of a Landscape Analysis of cow-calf record-keeping and data management software (chapter 2), and juxtapose data capture systems for producers vs. regulatory/research applications to describe future developments needed to expand use case of data capture systems in Animal Health (chapter 3).

Chapter 2: Structured landscape analysis of cow-calf record keeping and data management software

Introduction

Data insights are paramount to enhancing globally sustainable agriculture. Good documentation, record keeping, and data standards enhance producer decision making, compliance, health monitoring, and traceability. The United States cow-calf sector of the beef industry is highly fragmented with no standardization and minimal adoption of robust record keeping and data practices. Beef Quality Assurance (BQA) provides systematic information to U.S. beef producers and beef consumers of how common-sense husbandry techniques can be coupled with accepted scientific knowledge to raise cattle under optimum management and environmental conditions. Three of the priority areas identified by BQA in their current mission statements include improvements to “cattle handling, facility management, cattle transportation, good record keeping and protecting herd health” (Beef Quality Association, n.d.).

The chapter will demonstrate the available computerized systems for record keeping, data management, and data analysis targeted for use in the cow-calf sector of the United States beef industry. Evidence will be provided through comparative overview of the market space. The findings of all research provided below are a tangible resource that can be referenced by multiple members of the cattle industry to promote the enhancement of record keeping practices in cow-calf operations. The conclusions herein will help strengthen BQAs efforts in defined priority areas and give ranchers an aid to get started with a record keeping improvement plan.

Although not a scientific systematic review, the project used guiding principles of the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) (Page et al., 2021), with the understood exception that the review period would not be over peer reviewed

articles or journals, but instead focus on the software as defined. The objective of the project was to perform a structured comparative landscape analysis of computerized systems for record keeping, data management, and data analysis targeted for use in the cow-calf sector.

Methods

Eligibility Criteria

During development of the comparative landscape, identified computer systems for record keeping, data management and data analysis were determined for inclusion based on predetermined eligibility criteria. Eligibility criteria to determine further investigation of the computer system were:

- product was actively marketed towards the “cow-calf” industry
- evidence of continued product support
- system captured multi-faceted data and was built for the purpose of operational data management (this criterion ensured no single purpose excel spreadsheets were evaluated)

Information Sources

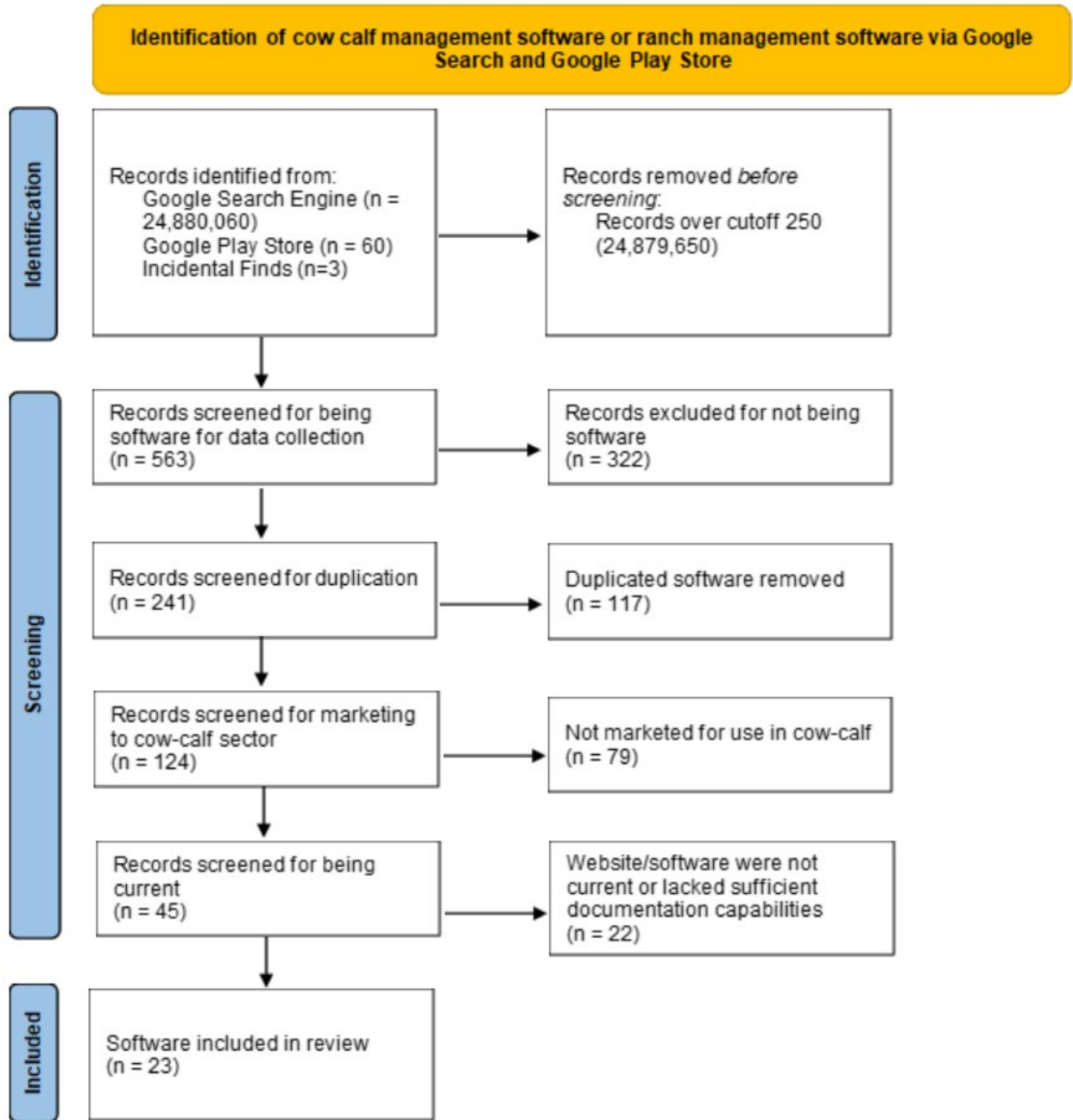
A publicly available search engine was used as the primary source for record identification (Google search engine, Google, Mountain View, California). Additional records were identified through search in an online store for mobile applications (Google Play Store, Google, Mountain View, California). Industry experts and published articles were used to assess completeness of records identified through the search engine and online mobile application store. Characteristics of each product were obtained through the product website and/or app description, through online demonstrations, and live demonstrations, when available.

Search Strategy and Selection Process

Two sets of search terms were used within Google search engine and Google Play Store occurring between March 2023 and May 2023. For each set of search terms, the first 250 records were evaluated for eligibility. The predetermined cutoff for the number of records evaluated was deemed by the authors to be a reasonable number of records to assess that would likely contain relevant results. A web-scraping tool was used to document the search engine results for the specific date and time each search was conducted (SEOquake, Semrush Inc, Boston, Massachusetts). The same search terms were used for the search performed in the online mobile application store. The first 30 applications returned by the search were evaluated, under the same considerations as records identified through the search engine. Using the search terms “cow calf management software” and “ranch management software” in the Google search engine and in the Google Play Store a total of 24,880,060 total records were returned (Figure 2.1). The protocol dictated that 560 of these records were to be inspected, plus three incidentally found products. Of these records including incidental finds, 241 were software with 124 unique software returned. Of the unique software, 45 were marketed toward the “Cow-Calf” industry. The number eligible for analysis was 23 true software, not a formatted excel workbook download, that had updated copyrights and provided some form of software support.

Products identified through interview with industry experts, through published articles, or were incidentally found were also included in the study to ensure completeness of the searches defined above.

Figure 2. 1 Identification of cow calf management software or ranch management software via Google search and Google Play Store



Data Collection Process

For eligible products, the website and/or informational materials for each product were reviewed. Additionally, recorded demonstrations were used when available. The companies

supporting each product were also contacted for interview and live demonstration, when available. A record of all software and applications was maintained in an electronic database (Excel, Microsoft, Redmond, Washington).

Data Items

Each software had the following data recorded:

- Software or application name and parent company name
- Data field descriptions and data types
- Analysis features
- Technology integrations
 - RFID Scanning, etc.
- Identified key features and limitations

The main categories of interest for the software were further described by dividing them into differentiated levels of complexity or features. Authors predetermined characterization levels for minimum cow-calf operation data (Table 2.1), technology integration options (Table 2.2), data features (Table 2.3), veterinary care (Table 2.4), and inventory features (Table 2.5). Levels were used to guide discussion of each products' functionality for cow-calf producers.

At a minimum, all the reported software could document an animal ID of some kind, a date of birth or age, a history of weights for the animal, and a history of lineage at some capacity. An identified reoccurring theme amongst programs evaluated was software being available to document in real time, in the field to capture events as they occur (Table 2.1). As a result, many of the software have access via a phone application or through any web browser on a tablet or cellphone.

Table 2. 1 Categories used to define minimum cow-calf operation data during initial evaluations of software electronic data capture capabilities

Minimum Cow-Calf Operation Data	
Level	Description
1	Any software with additional features for entry, like the ability for data entry to occur on handheld personal computers
2	Detailed genealogy tracking, data fields and inventorying for artificial insemination and embryo tracking or links to national breed associations

Electronic Identification (EID) tracking and the ability to connect to Bluetooth wands and digital scale heads are some of the basic technology integrations available to many of the software assessed (Table 2.2). Scale head connectivity is used by some software for animal weights and feeding metrics.

Table 2. 2 Categories used to define technology integrations during initial evaluations of software electronic data capture capabilities

Technology Integrations	
Level	Description
1	Both EID tracking and scale head connectivity
2	GPS and mapping of farms
3	Specialty integrations (ex: high frequency tags and readers)

Data Features range from report building to advanced data visualization (Table 2.3).

Table 2. 3 Categories used to define data features during initial evaluations of software electronic data capture capabilities

Data Features	
Level	Description
1	Pre-built or customized report generation without offering built in graphical representations of the data or interactive data tools
2	Basic visualization packages, offering graphical representation of the data without the option for customization, -more complicated data grouping, and interactive data tools
3	Advanced data visualization, interactive dashboards, and more customizable views of data

Veterinary care, treatments, and general health tracking of animals varied from basic notation of vaccination events to withdrawal tracking, one software program went as far as

integrating with Veterinarian access to further support animal health at the farm level (Table 2.4).

Table 2. 4 Categories used to define veterinary care during initial evaluations of software electronic data capture capabilities

Veterinary Care	
Level	Description
1	Basic recording of treatment or veterinary events
2	Recording of health events, veterinary product inventorying and costs, and slaughter withdrawal compliance
3	Software with further feature enhancement that allows for veterinarian interaction within the software including uploading of veterinary protocols and veterinary user profiles

Inventory features broke out into two main categories, animal inventory and consumable inventory (Table 2.5). Other software offer additional tracking related to the cost of animal production such as feed costs or medical treatments that are accounted for as part of event entry in the given system. More advanced features for inventory center around managing financial records to aid in tax preparation or tracking consumable inventory to the level of nutritional impact to the animal.

Table 2. 5 Categories used to define inventory features during initial evaluations of software electronic data capture capabilities

Inventory Features	
Level	Description
1	Only offers inventory or financial tracking of animals or an inventory option for consumables
2	Offers both animal inventory and consumable inventory offerings allow for a better idea of cost of production
3	Offers financial tracking in a way that can be used in tax preparation. Level 3 also describes software developed with the feedlot software from the same companies and offers features for feeding tracking. This allows for an analysis of costs by the herd or batch mixes as well as a cost per head of cattle

Once the initial search was done, a list was generated of all software and applications that would be reviewed. A general script was composed to drive the interview and research portion of this analysis. For consistency, the following topics were reviewed for each software: minimum

cow calf record book data, technology integrations, veterinary care documentation, analytic features, financial and inventory features, and other information. The accumulated research data was then used to summarize into comparative tables a quick summary with the classification for each of the assessed categories.

Results

Software Selection

At the end of the screening process, 23 software products met the final eligibility criteria for inclusion into the comparative landscape analysis (Figure 2.1). Performance Livestock Analytics software (Performance Livestock Analytics, Performance Livestock Analytics, Ames, Iowa) was initially included as being marketed towards the cow-calf sector but during a demonstration with a sales representative it was stated that there was a planned cow-calf extension of the software that had not been released as of the date of the research. Cow Records (parent company information unable to be determined, <http://cowrecords.com/>) software was unable to be accessed even though the website shown gave the appearance of an actively supported software. Livestock Analytics (Livestock Analytics, Livestock Analytics, Hermosillo, Sonora) did not appear to be available in English since all demonstration information available was in Spanish, though they do offer an English translation for their website. A total of three products were found through industry experts or incidentally found: HerdX (HerdX, Boerne, Texas), Critter Works (Critter Works, Unknown), and CalfDex (Kansas State Univ. College of Veterinary Medicine, Manhattan, Kansas).

Table 2. 6 Analysis of cow-calf operation software by feature categories for technology integrations, data features, veterinary care, and inventory features

Product	Tech Integration Options ^a	Veterinary Treatment Tracking ^b	Analytic Options ^c	Inventory Features ^d
AgriERP	2	1	2	3
AgriWebb	3	2	3	3
Animal Record Management	1	3	2	3
bioTrack Plus	1	2	3	2
BoviLog - Cattle Management	-	1	-	-
Breedr	1	2	3	3
Calf Book	-	2	1	1
CalfDex	-	1	-	-
Cattle360	-	-	1	1
CattleMax	2	2	1	3
Cattylitics	1	2	-	-
Cow Herd Appraisal Performance Software (CHAPS)	1	-	1	1
CowSense	2	2	2	-
Critter Works	-	-	1	3
DigitalBeef	-	-	2	3
Farmbrite	-	-	3	2
FarmRexx	-	-	1	3
HerdX	3	2	3	1
Navfarm	-	1	1	3
Ranch Manager Open	-	-	1	2
Ranchr	-	1	-	1
VacApp - Livestock management	1	2	-	-
Vaquitec WEB	-	1	3	3

The numbers above denote the classification defined for each software for the given category. A dash indicates that the software does not have the feature defined.

^a1 = Both EID tracking and scale head connectivity; 2 = GPS and mapping of farms; 3 = Specialty integrations (ex: high frequency tags and readers)

^b1 = Pre-built or customized report generation without offering built in graphical representations of the data or interactive data tools; 2 = Basic visualization packages, offering graphical representation of the data without the option for customization, -more complicated data grouping, and interactive data tools; 3 = Advanced data visualization, interactive dashboards, and more customizable views of data

^c1 = Basic recording of treatment or veterinary events; 2 = Recording of health events, veterinary product inventorying and costs, and slaughter withdrawal compliance; 3 – Software with further feature enhancement that allows for veterinarian interaction within the software including uploading of veterinary protocols and veterinary user profiles

^d1 = Only offers inventory or financial tracking of animals or an inventory option for consumables; 2 = Offers both animal inventory and consumable inventory offerings allow for a better idea of cost of production; 3 = Offers financial tracking in a way that can be used in tax preparation. Level 3 also describes software that appear to have been developed in conjunction with the feedlot software from the same companies and offer features for feeding tracking. This allows for an analysis of costs by the herd or batch mixes as well as a cost per head of cattle

Software included in the assessment can be found in Table 2.7 and further summarized based on the categorization performed in Table 2.6. All software included are marketed towards the Cow-Calf industry and capture the minimum required information that was defined Table 1.

Minimum Cow-Calf Operation Data

The main data requirement for including software in the analysis was of the ability to document the same information contained in the standard Cow Calf Record Book by Gallagher. There were several software or excel sheet options for calculating breeding timelines, but capturing growth of individual animals and birth records with additional details allows for better operation management. In addition to basic data entry of minimum cow-calf operation data, some software offered technology integrations such as handheld Personal Computer scanners like CowSense (Midwest MicroSystems LLC, Lincoln, Nebraska) and HerdX (Table 2.6). AgriWebb (AgriWebb, Surry Hills, New South Wales), Ranch Manager Open (White Mountains Livestock Company LLC, Snowflake, Arizona), BioTrack Plus (AgSights, Elora, Ontario), Cowsense, Calfbook, CattleMax (Cattlesoft Inc., College Station, Texas), Animal Record Management (Telus, Vancouver, British Columbia), DigitalBeef (DigitalBeef, LLC, San Antonio, Texas), Breedr (Breedr, Austin, Texas), Vaquitech (Agritec Software, Wheatland, Iowa), and AgriERP (AgriERP, San Mateo, California) all had the identified facets as a focus of their recorded information, in addition to minimal requirements.

Technology Integrations

Software that use more common technology integrations like EID and scale head connectivity were a fairly common identified feature, and included BioTrack Plus, Cattlytics, VacApp (Equinox.one, Barcelona, Barcelona), CHAPS (North Dakota State University, Fargo, North Dakota), and Breedr (Table 2.6). CattleMax, Cowsense, and AgriERP go a step farther to

include GPS mapping options for better vitalization and tracking of tasks within the farm.

AgriWebb has the previous integrations in addition to an option for tracking water levels in tanks by partnering with other software companies that make specialized farm monitoring devices for things like tank water levels. HerdX, though they currently do not have scale head integrations, fully developed their own line of high frequency ID tags and readers in addition to the link on their webpage specifying all the companies they have partnered with as part of their technology integrations.

Data Features

Though Ranchr (Ranchr, Dixon, California), VacApp, BoviLog (VET Inc., Unknown), and CalfDex did not offer any data features for analytics within the application there is an option to export data to an Excel or .csv file for a producer to perform their own analytics. The only software to not offer exporting of data was Cattylitics (Folio3 Software Inc., Belmont, California). CattleMax, Cattle360 (Cattle 360, Smithton, Pennsylvania), Navfarm (Prudence Technology Pvt. Ltd., Belmont, California), CHAPS, and Calfbok offered data reporting options in a table format. Ranch Manager Open and Farmrexx (FarmRexx, Gulgong, New South Wales) additionally offered expense report options (Table 2.6). DigitalBeef, Cowsense, Animal Record Management, and AgriERP offer built in reporting and basic visualization. Animal Record Management did state that additional visualization options are currently under development for future versions of the software. Farmbrite (Farmbrite, Hyfiene, Colorado), AgriWebb, BioTrack Plus, Breedr, Vaquitech, and HerdX all offer advanced data visualization packages with more pre-built data filtering options based on grouping of animals.

Veterinary Care

Farmbrite and Ranch Manager Open both use custom or free entry fields to document health tracking of animals, but were not classified since they are not functionally designed to work for health tracking or veterinary care. CHAPS does not allow for any tracking of treatments to animals, but does allow for capture of body scores during weighing events and to provide medical reasons for culling events. Ranchr, NavFarm, AgriERP, BoviLog, and CalfDex do allow tracking of disease status and treatments. Vaquitech additionally is capable of tracking withdrawal times, but is a very basic field of entry (Table 2.6). CattleMax, CowSense, AgriWebb, BioTrack Plus, Breedr, Calfbook, VacApp, Cattylics, and HerdX all offer further details to be recorded when it comes to treatment of animals. Many of the software programs offer the option to build in contacts, so that the individual administration of the treatment can also be recorded in real time. Animal Record Management allows for Veterinarian interaction within the software and can track protocols to maintain compliance. This function appears to be a novel feature to Cow-Calf industry software and allows for the veterinarian to see all animal details for any farm they work with as well as serving as an avenue for virtual care offerings.

Inventory Features

Some software, like CowSense, offer the option to generate a cost of production report, but each item or expense would need to be manually added to each animal, and is not factored into normal entry and logging in the software. HerdX only offers inventory features for consumables tracking. Cattle360, Ranchr, CHAPS, Calfbook, all offer features for animal inventory only (Table 2.6). Farmbrite, Ranch Manager Open, and BioTrack Plus, all offer at least some features for both animal and consumables inventory. CattleMax, Animal Record Management, AgriWebb, NavFarm, Farmrexx all appear to offer both of the more advanced

inventory options. Animal Record Management offers unique options for tracking and sharing animal inventory information in the form of QR codes accessible to individuals without software. Digitalbeef, Critter Works, AgriERP, Vaquitech and Breedr can track financials for animal costs and inventory, but does not track anything related to consumable inventory.

Discussion

The final analysis is accurate based on the date of review (March 2023 – May 2023) with current software, details described in Table 2.7. Software changes daily and many companies stated that new features are being planned and developed currently to support the market need for growing technological demands. Summaries and data provided are not intended to provide endorsement to any given software but rather to provide a comparative landscape analysis of software currently available to the Cow-Calf industry.

AgriWebb appears to have more advanced options in the categories summarized within analysis, with additional features included in AgriWebb Academy. The online database of training tools sets AgriWebb apart because it implies a focus on ensuring users can use the software to its full capability. The calendar and planner views were another beneficial attribute for functionality within the software to aid in scheduling of routine or more rare tasks within the operation. Animal Record Management from TELUS also was a standout in comparison within the analysis with subtle touches like built in QR code generation that can be applied to an animal or operation and shared with others outside the software system for information sharing at feedlots or at the point of sale. Animal Record Management also allows for transfer within the software to buyers with their own operation account. Enhanced sharing of data was a unique feature not identified in other products. Breedr is a software that is relatively new to the United States but is a well-rounded application with features that appeared easy to operate within the

phone application and desktop version of the software. The efforts of HerdX to develop their own technology within the industry to increase the range at which an EID can be captured from an electronic tag, helps their EDC system stand out in the market space. Improved EID tracking is beneficial to herd management in the normal sense of gathering animals for treatment or weighing but is further desired for large scale operations to determine if an animal has visited a water or feed station within a period and allows notification of such events (if requested) in the system. Integrations for feeding and water stations are advanced and useful features for determining a multitude of attributes related to overall animal health. CattleMax offers a feature with an interactive map of the production process for the operation that provides insights at each step within the process. AgriERP uniquely offered equipment maintenance and inventory in addition to consumable inventory. CowSense offers many features at some level, but the most striking feature was that many of the features were add-ons, which allows the user to determine which features are needed for their day-to-day operation.

Limitations of the presented summary were tied to information available at the time of review and were dependent on the accuracy of marketing materials provided on individual websites. Additionally, information provided through direct contact with the companies varied in level of response.

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Table 2. 7 Summary of included software, parent company name and location, and web address.

Software	Parent Company	Location	Website
AgriERP	AgriERP	San Mateo, California	https://agrierp.com/livestock-management
AgriWebb	AgriWebb	Surry Hills, New South Wales	https://www.agriwebb.com/cow-calf/
Animal Record Management	TELUS *Formerly HerdTrax	Vancouver, British Columbia	https://www.telus.com/agcg/animal-agriculture/cow-calf-producers/products/animal-record-management
bioTrack Plus	AgSights	Elora, Ontario	https://agsights.com/livestock-record-keeping-software-system/
BoviLog - Cattle Management	VET Inc.	Unknown	https://play.google.com/store/apps/details?id=com.vet.bovilog
Breedr	Breedr	Austin, Texas	https://www.breedr.co/en-us/
Calf Book	Calf Book	Unknown	https://www.calfbook.com/
CalfDex	Kansas State Univ. College of Veterinary Medicine	Manhattan, Kansas	https://play.google.com/store/apps/details?id=com.ksu.CalfDex&hl=en_US
Cattle360	Cattle360	Smithton, Pennsylvania	https://www.cattle360.com/
CattleMax	Cattlesoft Inc.	College Station, Texas	https://www.cattlemax.com/
Cattlytics	Folio3 Software Inc	Belmont, California	https://play.google.com/store/apps/details?id=com.folio3.cattlytics
Cow Herd Appraisal Performance Software (CHAPS)	North Dakota State University	Fargo, North Dakota	https://www.ndsu.edu/agriculture/ag-home/impact-stories/ndsu-extension-releases-updated-cow-herd-appraisal-performance-software
CowSense	Midwest MicroSystems LLC	Lincoln, Nebraska	https://midwestmicro.us/cowsense_livestockherdmanagementsoftware
Critter Works	Critter Works	Unknown	https://critterworks.com
DigitalBeef	DigitalBeef, LLC	San Antonio, Texas	https://www.digitalbeef.com/cowcalf/
Farmbrite	Farmbrite	Hyfiene, Colorado	https://www.farmbrite.com/solutions/cattle
FarmRexx	FarmRexx	Gulgong, New South Wales	https://www.farmrexx.com/
HerdX	HerdX	Boerne, Texas	https://herdx.com
Navfarm	Prudence Technology Pvt. Ltd.	Belmont, California	https://www.navfarm.com/livestock
Ranch Manager Open	White Mountains Livestock Company LLC	Snowflake, Arizona	https://www.ranchmanageropen.com/cattle-software.html
Ranchr	Ranchr	Dixon, California	https://www.ranchr.ag
VacApp - Livestock management	Equinox.one	Barcelona, Barcelona	https://play.google.com/store/apps/details?id=com.mateuyabar.vacapp
Vaquitec WEB	Agritec Software	Wheatland, Iowa	https://www.agritecsoft.com/en/

Chapter 3: Juxtaposition of electronic data capture systems for animal producers vs. for regulatory or research applications

Understanding the Disparity between Animal and Human Health Industries

When registering a new product with a federal agency, clinical trials and other registration related studies within the animal health industry are often required to be performed in the target animal species of the product. In human health, the infrastructure for documenting the equivalent study types is already available, thanks to software and other types of EDC used in the healthcare industry by hospitals and doctors' offices around the world. While there are more stringent regulations around human health products than animal health products, parallels can be drawn between the two industries when it comes to clinical trials and general data capture concerns. By drawing a parallel between these two industries, and leaning on One Health principles, it would make sense that EDC software used by animal producers could be adapted for use by companies in the animal health industry. As general scientific understanding of animal health grows, there is a need or desire to monitor more facets of a study than previously done. With relation to clinical trials, or even product release quality testing, in the animal health industry, the main benefit gained from gathering further information is an improvement in understanding of safety relating to a product. The FDA, and other agencies, have also increased requirements for data capture over the last several years to ultimately benefit safety of consumers. The human health industry is held to a higher standard, which could be a driver for why EDC is more prevalent in the human health industry compared to the animal health industry.

Implementation of EDC systems has been a phased approach even within the producer segment of the industry. Variety of animals and differing production goals have led some industries to be more willing early adopters of the technology. Within the cattle industry, the two

main EDC user groups can be categorized as producers in the dairy industry and producers in the beef industry. In many countries, it has been seen that the dairy industry has an increased willingness to accept new technological approaches to support daily operations. Differences in technology acceptance around the world is most likely tied to farming practices and requirements of each region (Makinde et al., 2022). For example, in Canada the use of RFID ear tags is a regulatory requirement, while operations in Sweden have only a 1% use of the same technology.

Welker (2007) identified 12 common barriers to migrating from a paper record system to an EDC system within clinical trial studies, shown in Table 3.1.

Table 3.1 Welker's 12 barriers to Electronic Data Capture implementation (Welker, 2007)

1	User input
2	Technical support
3	User motivation
4	Regulatory requirements
5	Communicating with users
6	Timing of implementation
7	Software installation
8	Graphical user interface
9	Identification of bridgers
10	Patient participation
11	Availability of technology
12	Costs

The first three items on Welker’s list emerge as most pertinent regarding EDC implementation, because they heavily depend upon the end user. Specifically, the barriers of interest for EDC are user input, technical support, and user motivation. To put this in the perspective of the animal producer, specifically cow-calf producers, the buy-in to be needed from the end user is less because the end user is invested in the success of company or farm. As stated in chapter 2, for animal producers, the minimum information needed is what would be documented within the “Cow-calf Record Book” (Valley Vet, n.d.) as shown in Figure 3.1. In order to replace existing

documentation processes the EDC system must provide solutions to some of the labor-intensive portions of the producer’s workload, which also makes it an enticing alternative.

Figure 3. 1 Example of standard cow-calf record book (adapted from Valleyvet.com)

Cow No.	Tag Color	Cow Wt.	Date Bred	Sire No.	Calf No.	Calf Sex	Calf Birth Date	Birth Wt.	Wean Wt.	Remarks

Animal health companies would also benefit from saving time and money in labor costs, but often animal health pharmaceutical companies are not performing their own studies. Companies are paying other contract laboratories to conduct the research trials. It is more difficult to influence change across organizational barriers than within your own company or management hierarchy, making implementation of EDC systems a challenge unless contract laboratories are targeted specifically. Makinde (2022) identified other barriers to EDC implementation (Table 3.2). The identified barriers predominantly revolved around different costs and the return on investment, as well as the relevance of the software to the given operation.

Table 3. 2 Makinde et al. (2002) barriers to Electronic Data Capture implementation in Canadian beef farms

	Barrier	No. of responses (of 19 surveyed)
1	Technology Cost	10
2	Return on Investment	9
3	Training Cost	2
4	Training Complexity	2
5	Set-up Time (to Install/Train)	4
6	Technology Relevance	5
Survey of 19 Canadian cattle Farmers’ responses to “what are the barriers stopping you from automating or using technology to help manage the operations?”		

Many barriers for implementation could be overcome by utilizing software trial periods and taking advantage of customer support during infrastructure set up, particularly with regard to the support needed at the farm level to maintain the EDC system.

Research Industry Needs

Electronic data capture systems need to capture all of the information captured within a paper record for a clinical trial. Figure 3.2 shows a generalized example of information a clinical trial may capture daily.

Figure 3. 2 Example of daily clinical trial observation form used in Animal Health studies

Study #: _____ Date: _____
 Time: _____ Study Day: _____

Daily Individual Animal Observations

Animal ID	Observation (normal / abnormal)	Comments
HYO-2		
AXM-2		
HGR-2		
PUO-2		
RVX-2		
Y CZ-2		
GAF-2		
QMC-2		
MBD-2		
ASQ-2		
TPG-2		
ZUL-2		
JSC-2		
YFG-2		
AJI-2		

Assessed and Recorded By: _____ Date: _____
 Investigator Review: _____ Date: _____

The example includes animal identification number, animal “condition,” and a free form comments section. Benefits of EDC include entries’ time and date stamp, as well as tracking the individual performing the data entry. The interface can also be developed to include a requirement to capture comments or further information for any unexpected entry in one of the fields. Data validation or checks greatly improves study outcomes and saves time when undergoing Quality Assurance review (Sarasola et al., n.d.).

A benefit may not be apparent if animal observations were recorded for only a single day however, majority of trials in the animal health industry compound data collection over the life of the study. Electronic data capture has the capability to automatically link results together for a given animal on the trial to allow investigators to observe trends early and easily. The described benefits appear to far outweigh the implementation hurdles.

From a regulatory perspective, a hurdle to adoption that many animal health companies experience is the need for Computer System Validation, or CSV, testing over a variety of topics (Babre, 2011). The process includes defining user requirements to ensure the software can document all relevant information. Other specifications for function and system design must be defined prior to implementation as well. Installation qualification, operational qualification, and performance qualification must all be documented to demonstrate that the system can operate in a controlled environment. Further, a plan to test all requirements and specifications must be formulated into a validation protocol that when executed will document testing of the system and will be provided as a validation summary report.

With appropriate system validation in place, an EDC system captures minimum study requirements with the added benefit of labor efficiency. The systems can also be used to track animal care protocols, patient randomization studies, inventory management, and custom

notifications based on data inputs (Loyo & Browner, n.d.). Mid-study reports and summaries can easily be prepared and all reports, both interim and final, and data will be increasingly uniform coming from EDC systems. Software and custom reports can be formatted to align with regulatory requirements, making a more streamlined licensure submission and pathway to market.

Future of Electronic Data Capture in Animal Health

The COVID-19 pandemic changed the world in many ways; one of which includes rapid adoption of telehealth technologies. Telehealth adoption confirms that this type of technology change within both human and animal health can be made, and made quickly, when the right drivers are in place. Telehealth had been available prior to the COVID-19 pandemic but was not utilized in the capacity that it is today. Another common experience resulting from the COVID-19 pandemic was the use of websites or electronic forms to capture pharmacovigilance data, particularly data from those who had received the mRNA antibody treatment. Companies like Prelude already utilize a similar reporting system to document health outcomes in client owned animals. Even prior to telehealth and digital self-reporting options, the human healthcare system had used at least some form of EDC for years. A typical doctor's office visit will include a check-in procedure where patients work with a less specialized individual to document arrival and other health or insurance items. Then when a patient is seen there may even be a technician or practitioner to gather vitals and document additional health related questions before being seen by the actual physician. At each stage there is typically an electronic entry, or a paper form that is then digitized at some point, which is then provided back to an insurance company or the patient for payment of health services.

Telus Animal Health recently purchased the EDC software company HerdTrax and rebranded the system under the new name Animal Record Management. This acquisition has created a software solution that spans the animal health industry in addition to the feedlot and cow-calf sectors for animal producers (Bauermeister, 2023). Telus also has a strong background in data acquisition as seen in the innovative features incorporated into the company's EDC system. While other software available to cow-calf producers also includes feedlot integrations, Telus takes this feature a step further to allow veterinarian interactions within the system and has built in data sharing to integrate into buyer and seller data systems. The unique dynamic brought to the table by this Animal Health company seeking to make improvements to the producer sector may lead to advancements in clinical trial software that is available for large animal studies. This would combat some of the barriers of implementation by showing the success of an EDC system in field use, while also showing that a uniform solution could be used in multiple fields to encourage adoption of this type of EDC solution.

Ultimately a company that offers "Software as a service" (SAAS) would be the fastest way for a company with no EDC integrations currently in place to convert to an EDC solution. Purchasing the software or even a hybrid of SAAS and owning the data system are also viable options (Sarasola et al., n.d.). The real benefit to SAAS is that the software vendor would be responsible for owning the data structure and providing portions of the CSV testing. Larger companies, or those with established CSV departments, would likely choose the purchase or hybrid options to have more control over the data ownership. Realistically, larger companies would also have more to gain from implementing EDC solutions due to the larger potential for efficiency related savings.

Conclusions

The Animal Health industry has lagged behind other industries when it comes to accepting and adapting to the use of Electronic Data Capture solutions. Clinical trials stand to have the most to gain in terms of cost and time savings by implementing EDC systems, upwards of 90% cost savings over a traditional paper record keeping process. Improvements to study accuracy and reducing errors, and the need for error correction, are added benefits when considering the updated data and documentation requirements from regulatory agencies over the years. Parallels can be drawn between Animal Health and Human Health industries where healthcare systems provided the infrastructure to support EDC within clinical trials. Some of the difficulties with Animal Health infrastructure include the variety of animals and types of studies needed within the industry, whereas in Human Health all the software is centered around one species – humans. From this perspective, it stands to reason that within the animal producer industry there may be software available to adapt for use within in a research or clinical trial setting. The cow-calf producer industry is yet another area where implementation of EDC has lagged behind other industries, though at least 23 software are currently marketed to that industry and are currently capable of documenting the minimum information required by that field. Regulatory and validation requirements around EDC are one of the first hurdles a company would need to overcome to support this implementation and additional difficulties to implementation revolve around stakeholder support. Some Animal Health companies have seen the benefit to EDC and see path to driving their own solutions by acquiring software companies and reimagining these programs to incorporate more veterinarian interactions. Hopefully, these types of acquisitions and software improvements will drive change within the industry and show a path to implementation that is enticing to other companies.

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