Table of Contents

Introduction 3

The Mounting Data Pressure of Modern Clinical Trials 4

Transforming CDM for Today's and Tomorrow's Trials 6

The Three Pillars of Intelligent CDM 8

Skill Sets Needed E e T 11

Summary 12

References 14

Copyright 2021 Medidata Solutions, Inc., a Dassault Systèmes company

I d c i

C i ica ia a e bec i g e c e a d a c e ce f f ce i c di g he g i g COVID-19 a de ic, g ea e e ha i a ie e e ie ce i c ea i g c c e i a d eci e a e diffe e ia i i acce e a i g hi c e i . T ia ha e e ed i c de a e e -e a di g a a f da a ce i c ea ed da a e a d eci i , dece a i ed c i ica ia (DCT), a d ada i e de ig .

The e e i e a a d i d cha ge ha e ed ig i ca da a a age e cha e ge beca e c i ica da a a age e (CDM) ech gie a d ce e ha e g e ed a he a e b eak eck eed. F he ech g ec e a e f e b i i h a i f di a a e ha a e h eg f diffe e e d , a d he i di id a c e ack i e e abi i . C e e ia da a i a ge a aged i h a d ce e ha a e ab e e e a d ada a he eed e i ed he ea i ie f he e e -cha gi g de c i ica ia .

The i e f ad a ce e i CDM i . I i c e bei g de i ed b if i g da a a d k a c d-ba ed a f . Thi i a f i g CDM be ca ab e, e ib e, i e ige , a d i e e ab e i h a a ie f hi d- a e ha i ca ai d g de e e i he f e. Tha f e i c de e DCT de ig he e i i a e i ed e e d g a e hi ed a ie , da a i ca ed di ec f a ie ega d e f ca i , a d a da a c ea i g a d a f a i cc i ea -i e i gi e ige a d a a ed digi a e igh e e .

The be e f if i g da a a d k a c d-ba ed a f i c de a agg ega ed ie f a ie da a, e i i a i f d ica e da a e a d ec ci ia i , a d ea i ed ce e . I h , a i ed a f e ec i e ide he ece a f a e k eeded achie e he eed a d ca e e i ed f de ia de ig i c di g:

fa e d a - (h gh e a d c ia ce a age e f e ab e ib a ie),

fa e ef cie d c d c , a d

ea i ed da a aba e ck .

U i a e , i ed a f i ca b he a e diffe e ia i f e d g de ice b de e i g a e c ehe i e e f h a ie a e affec ed b d g a d di ea e. The i a ce f hi i heigh e ed i da ' e i e he e akeh de ac he hea hca e e e i e eg a , a e , a d a ie a e aci g g ea e e ha i a ie -ce ici a d a e de a i f e he a ie .

Thi hi e a e ide a b ief a f h CDM ick ada he i g da a e e i de c i ica ia . Ne , i di c e he h ee i a ha f he f da i fa de i e ige CDM a f ha i eeded cceed i a i c ea i g c e c i ica ia d. La ca e die a e ided; he e high igh h i i g da a i a acci e ega- ia a de ec ed i ea ea -i e ia i e ige , a a ed da a- e ie ech g , a d he ec d de c ibe h ega i e a ie c e e e a e ed b aki g a h i ic a ach a ie da a ca e a d i i g.

C igh 2021 Medida a S i I c , a Da a S e c a

Thi e di acce e a i g, gi e he a de ic a d g ea e e ha i a ie -ce ic a ache e i e. The f e ha b ed he de a d f DCT a d i a i a i i hi ia , eadi g a ha i e i he ad i f digi a hea h ech gie (DHT), i c di g e a d ea ab e , f he acce e a i g he a ai ab e e f high- e, high- e ci , high- eci i ea e e . Thi i a ici a ed i c ea e, i h 70% f ia jec ed e DHT i he e fe ea a e (M hk , 2019) ca e b h bjec i e (e.g., e / ea ab e) a d bjec i e (e.g., ePRO) da a ea ha c e e each he a d ig i ca e ha ce e ide ce ge e a i . T ge he , he de h a d b ead h f da a f a f he e ce ha e cha e ged he i d a h he h d a d c d be ed ide he adi i a da a c ea i g a d ec ci ia i ac i i ie .

A e i ed, CDM hich i c de h da a i e ie ed, c ea ed, a d cked ech g a d ce e ha e g e ed a he a e ace a i a i i da a ca e. C e , i e da a ce a e agg ega ed i e f h ee a :

The a e f ced i e ec ic da a ca e (EDC) e e age e ie a d c ea i g a ai ab e i h e i ed e . Thi c e i h a a age e e head i hi he EDC e , ha i e a ed he eCRF, a d f e i e fe e i h he i e da a ca e f hich he a e de ig ed.

The a e a a c ida ed b g a e i h i e a aged i ead hee , e ai , a d he high a a ce e i h i e acki g echa i .

O ga i a i de e hei be ke i agg ega e a d a age da a. The e c e a a e e e high de e e c , e i e c a ai e a ce, a d gg e kee i h he cha gi g d f da a ac i i i . Addi i a , he a e he e ce f he da a a d he d i e e abi i i h e ide he ga i a i .

A f he e agg ega i echa i a e b i e a d ca ab e, e a high a a ce ha i f e e - e, a d ha e a acce ab e deg ee f a e c .

F he , e e a i e f e ide ce ha e ai ed e i ega di g he effec i e e f addi i a da a e ie ce e ; a gge i g ha da a cha ge e i e af e i i ia e .

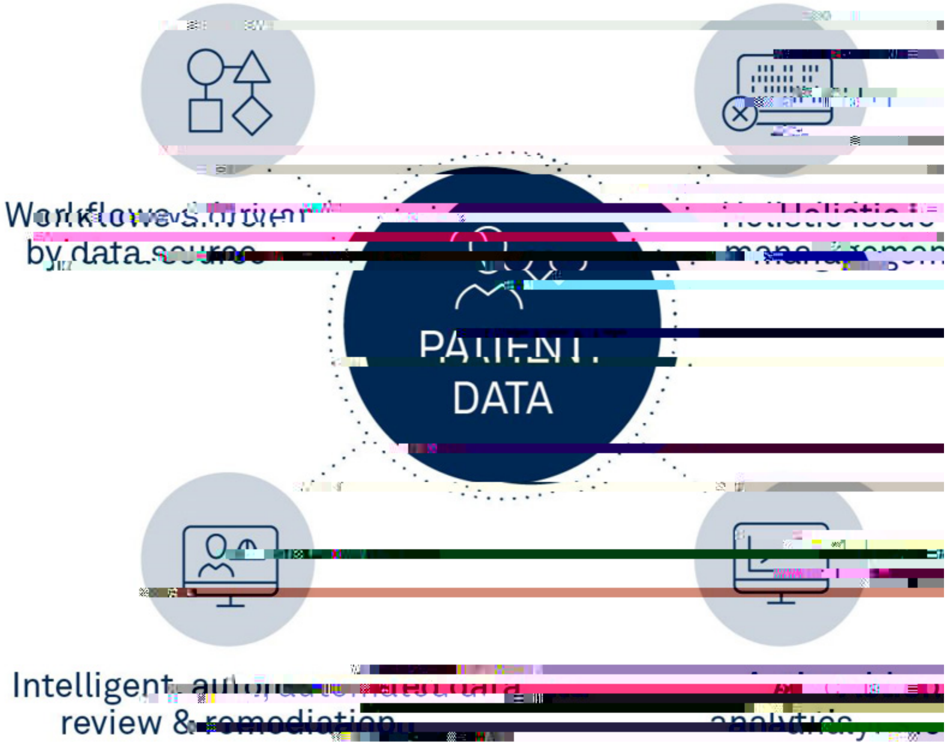
F i a ce, e a a i h ed ha , a e age, 3.7% f da a e e ed i eCRF a e cha ged af e e i EDC e , i h 2.6% f cha ge a ib ed ce da a e i ca i (Shee , 2014). Addi i a , S k a e a . (2021) e ed hei a a i f die c i i g e ha 20,000 a ici a ea 50 i i da a i , a d e ha 1.9 i i e ie . The f d ha hi e he e a e a e a 3.9% (i c di g i di ec a d i f a i e di ca i), fe e ha ha f f he e e ie e ed i a da a cha ge, affec i g e ha 1.7% f e e ed da a. Gi e he i i ed i ac f he e e d eff ha g i ge e a i ed e -ba ed da a c ea i g, he a ic e c c ded ha i d e c ib e i a he ai f he a da aba e ed f a a i . The a h , he ef e, ec e d e di g he c e e e ce c ec e f c i ica da a i Pha e III die a d aci g g ea e e ha i a d ech i e ha he ide if e ici e i he da a c ec i ce .

M de CDM a f i be ab e ea i face a d a f da a f i a i a i a d a a e . Thi i c de ea e c bi i g di c e e, high di e e, a d e e hi ica da a e , a i g f ike- - ike c a i be ee diffe e da a de ck he f a e f di e e da a ea .

The f i g ec i a i e he ke e e e f de i i g CDM ee he ia de a d f da a d .

C igh 2021 Medida a S i c , a Da a S e c a

Figure 2: M[illegible]de[illegible] CDM de[illegible] a[illegible] d[illegible] ca[illegible] a[illegible] e a[illegible] data [illegible] ac[illegible] e[illegible]e[illegible] d a d[illegible] a[illegible]e [illegible]da[illegible]a[illegible]e[illegible] [illegible] a[illegible] a[illegible] e c[illegible] e [illegible] f[illegible] e WHOLE [illegible] d de[illegible]. T[illegible] e [illegible] e[illegible] e[illegible] e [illegible]a d a [illegible] a[illegible]ed [illegible] a d [illegible]. [illegible] a d a [illegible]e e [illegible] e e ce[illegible] a[illegible]ca [illegible] e a[illegible]e[illegible] [illegible] e c[illegible] [illegible]e[illegible]e[illegible] d a d[illegible] a[illegible] e [illegible]da[illegible]a[illegible]e[illegible], a [illegible] c[illegible] f [illegible] ce.


Workflows driven by data source
Holistic issue management
PATIENT DATA
Intelligent, automated data review & remediation
analytics

C[illegible]igh[illegible] 2021 Medida[illegible]a S[illegible]i[illegible] I[illegible]c., a Da[illegible]a[illegible] S[illegible] e c[illegible]a[illegible]

The Three Pillars of Intelligent CDM

Copyright 2021 Medidata Solutions, Inc., a Dassault Systèmes company

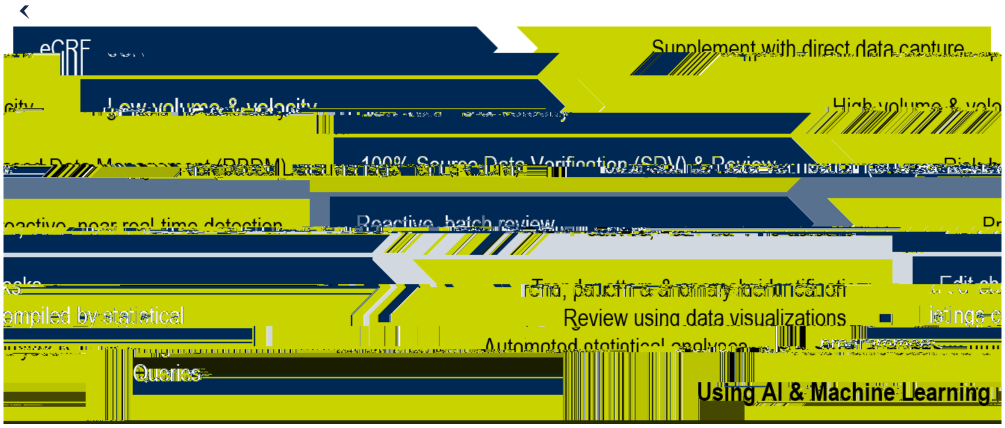
RISK-BASED DATA MANAGEMENT

A e i a ed 4% f da a d e cha ge af e e , hi e 80% f edi check a e igge ed. M de i k-ba ed da a a age e f c e high-i ac da a i a d e ie i e ige a a ic (Fig e 3). Thi i beca e e e da a i i e a , a d h e i h he g ea e i ac h d be i i ed. P ac i e, c i e ie i a ea -i e a i e be e ed bef e he bec e a e ic be ha ca i e ia g e a d de a da aba e ck.

> **be e fec . E e da a e a , a d e d e da a a a e e e ac**
>
> Wa e Wa ke , SVP P d c , Ra e P a f Tech g (Medida a)

A i k-ba ed da a a age e a ach ha bee h ed ce edi check b 20% 40% a d a f a a i g 50% 55% f da a e ie . Whi e adi i a da a e ie , c ea i g a d ec ci ia i ac ice ha e ea ha he a da aba e ck ha ake a be f eek , e be ie e de i ed CDM ca acc i h hi i h da . O g i g i e ige a d i c e e a a k c e i ea e fe e a k c e e af e a a ie , a i i .

F e 3: R -Ba ed A ac f M de CDM. T ad a Me d D N Sca e.


eCRF
Supplement with direct data capture
Low volume & velocity
High volume & velo
100% Source Data Verification (SDV) & Review
Reactive, near real-time detection
Reactive, batch review
Trend, pattern & anomaly identification
Compiled by statistical
Review using data visualizations
Automated statistical analyses
Queries
Using AI & Machine Learning

CASE STUDY: IDENTIFYING DATA ISSUES IN VERY LARGE DATA SETS

I a ece eg a ia de ig ed i e iga e he afe a d ef cac f a e a i-SARS-C V-2 acci e, a i e ige a d a a ed a a ica a f a de ed de ec de e i g f ad e e e (AE) i a ea -i e. De i e he eg a ia a id e e a d high e a d e ci f da a c ec i , he ech g cce f ide i ed i i g AE da a. The ech g igge ed a ig a he e dee e a a i h ed ha i i g AE da a a d e i c e e eCOA dia e ie . Si ce he i i g da a e e ide i ed i a ea -i e, he e e ick ec i ed a d he a abe a id c i i g he a i ica e f he d.

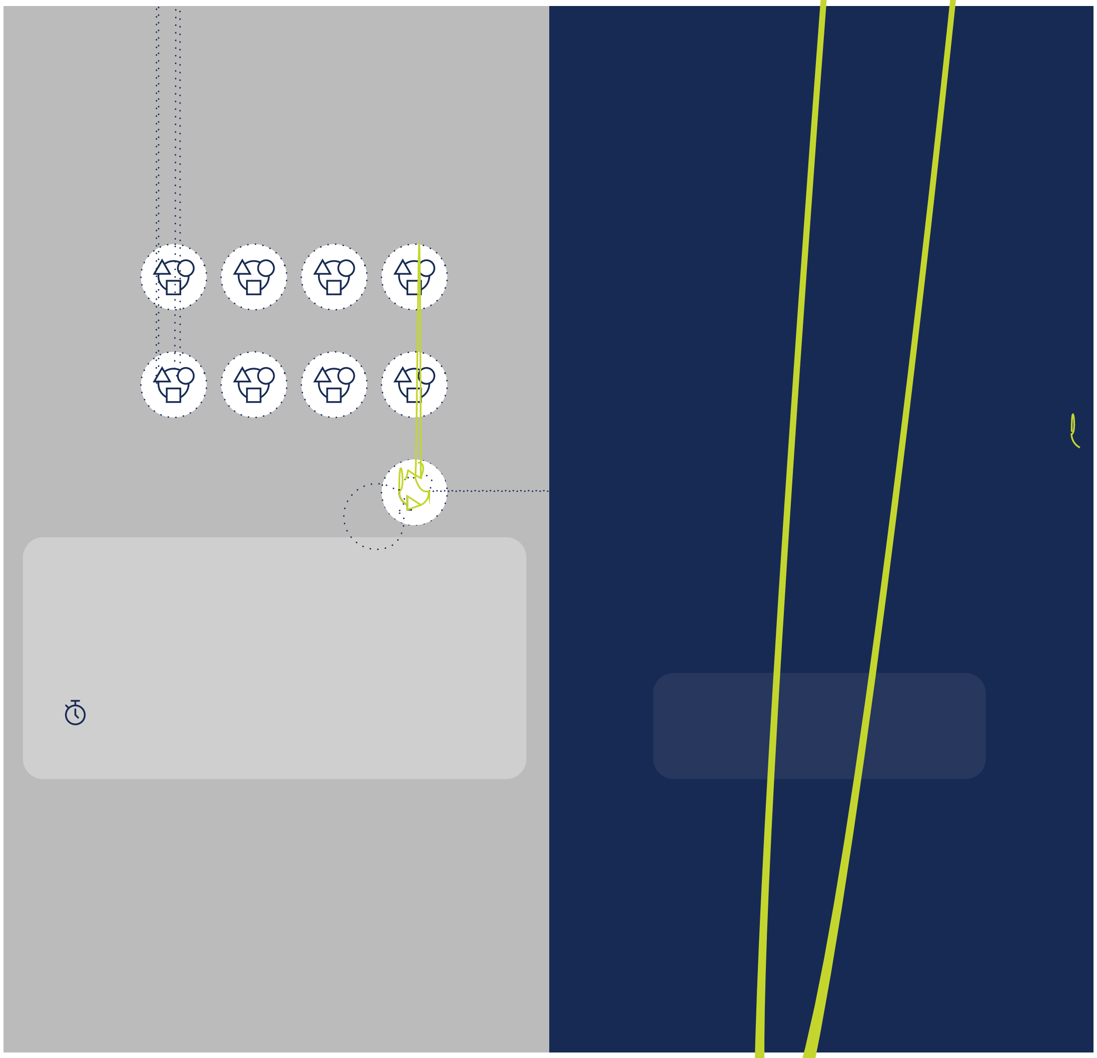
D e he hee i e f he ia , c bi ed i h he e a d e ci f da a c ec i , adi i a CDM ce e d ha e bee abe he ea -i e e ie a d a a i ha a e i ed b hi i a ia .

AUTOMATED DATA TRANSFORMATION

The e a e i e da a f a a da d ed a diffe e age f c i ica ia , a d af e databa e ck, da a i diffe e e a be agg ega ed a d a f ed. Tha ca ake a ig i ca a f eff a d i e, ica eek . H e e , i h i c ea i g eS ced da a, da aba e ck ca cc ch icke , ce he da a ca be ce ed i i e ige a d a a ed a , e i i a i g he eed f a a i i g a d ce e i ca i .

Thi i ib e i g de CDM a f ha ea e agg ega e da a i ea - i e a d ce a d i ec he da a ia e e digi a i h a a ed a d i e ige a g i h de ec a a ie , i c i e cie , a d a e , ha h d be e i ed ac a da a ce (eCRF, ePRO, Se , eS ce, e c.). Fig e 4 ide a i a ed c a i f he adi i a a d de i ed CDM ce e .

F e 4: A C a f T ad a Ve M de ed Da a Ma a e e P ce e

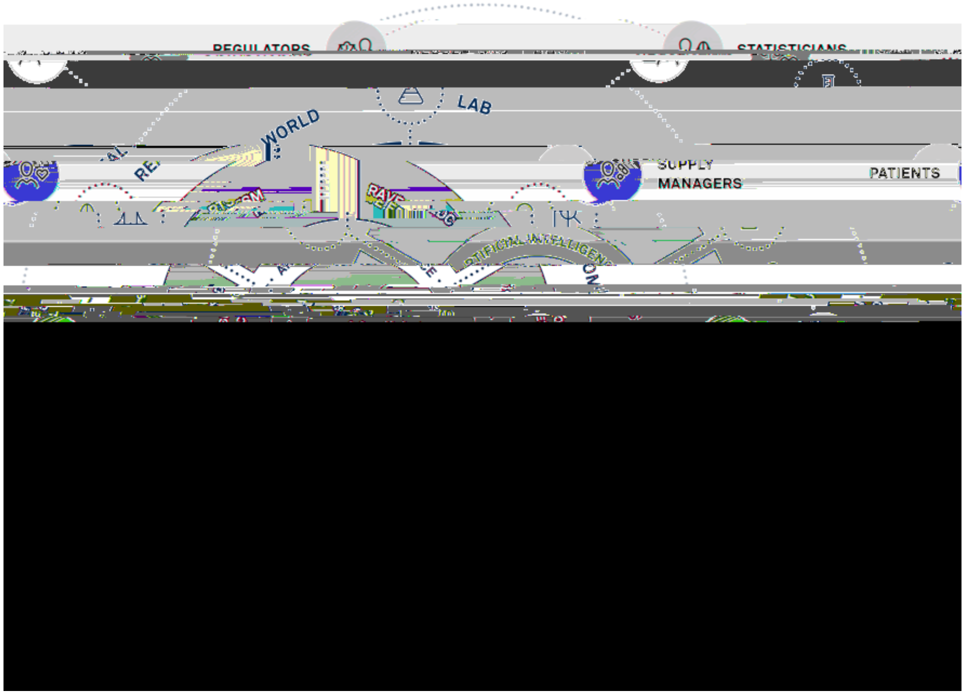


Copyright 2021 Medidata Solutions, Inc., a Dassault Systèmes company

S a

The f e f CDM i he e a d i i ca ab e e ib e i e e ab e i ed a d i e ige da a d c i ica ia hich a e i c ea i g e ia he abi i he i e high e ci high e a ie ce ic da a i ac i ie ed ea i e i igh a d i a e d i e be e d e ec i de M de i ed CDM a f a e e abi g d c c be de ed ac a da a ce ; a da a ea a e c ida ed i a i g e i ed CDM a f i h da a ce ag ic ha a e i e ige d i e ea i ed a d a a ed K a d faci i a e i e ac i be ee a akeh de i a ia a hi e d i i g i igh ha a e ib e i g a a ache CDM (Fig e 5).

F e 5: U d C ca Da a Ca e a d Ma a e e


REGULATORS
STATISTICIANS
LAB
WORLD
RE
SUPPLY
MANAGERS
PATIENTS
ARTIFICIAL INTELLIGEN

Thi ca ab e e ib e a d i e ige a ach i e abi g fa e d a i e fa e da aba e ck highe da a a i a d ed ced eff f da a e ie c ea ck a d a f a i U i a e he e i a e a i g f e ef cie

References

Industry Standard Research. EDC Market Dynamics and Service Provider Performance Report. December 2020.

Myshko, D. Wearables in Clinical Trials. PharmaVoice.com. March 2019. Available at: https://www.pharmavoice.com/article/2019-03-wearables/

SCDM. August 2020. The Evolution of Clinical Data Management to Clinical Data Science (Part 3: The evolution of the CDM role) - A Reflection Paper on the evolution of CDM skillsets and competencies.

Sheetz N, Wilson B, Benedict J, et al. Evaluating Source Data Verification as a Quality Control Measure in Clinical Trials. Therapeutic Innovation & Regulatory Science. 2014;48(6):671-680.

Stokman P, Ensign L, Langeneckhardt D, et al. Risk-based Quality Management in CDM: An Inquiry into the Value of generalized query-based data cleaning. Journal of the Society for Clinical Data Management. 2021;1(1).

Tufts Center for the Study of Drug Development. 2021. January/February. Tufts CSDD Impact Report: Rising Protocol Design Complexity is Driving Rapid Growth in Clinical Trial Data Volume. January/February. Vol. 23 No. 1.

Copyright 2021 Medidata Solutions, Inc., a Dassault Systèmes company