

Solution when Global Pandemic resurrects paper-based PROs creating collection headaches for Data Managers

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The world before COVID-19 (who remembers that?!?)

- Site and Subject data captured electronically
 - Real time data collection
 - Accurate
 - In native language
- Paper assessments used as back up solution
 - Time consuming to enter data
 - Higher risk to data integrity
 - Language limitations



The COVID-19 Impact

- Countrywide Lockdowns and Site Closures
- Shift towards Paper Assessments
- Industry backup solutions did not anticipate global lockdowns
- Needed an innovative approach



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Key Requirements for Sponsor/Sites

- Low to no additional burden on sites / subjects
- Maintain High Data Integrity
- No change in how data is stored or transferred
- Data available quickly



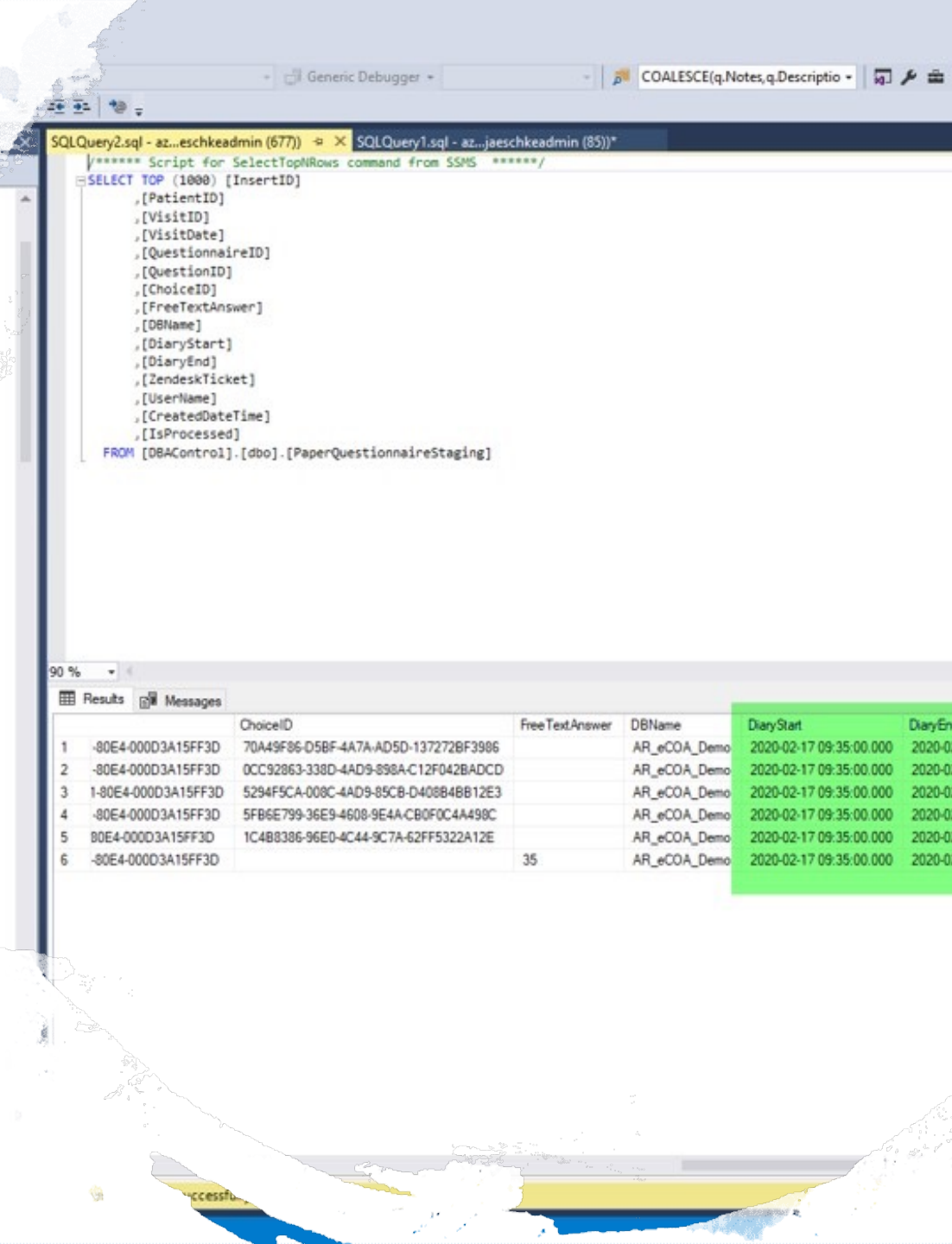
Key Requirements for Data Entry

- Scalable across multiple studies and PROs
- Eliminate language barriers
- Simple and efficient
- Human Readable
- Cost effective



The Solution

- Dynamic spreadsheets mapped to existing parent/child relationship database model
- User Interface quick and easy to use
 - Logical steps aligned with paper assessments
 - Drop down selection boxes with valid choices
 - Text translations, displaying both English and native language
- Verification steps incorporated
 - Data entered held in staging table to allow validation prior to committing



User Interface Example

Drop down selection boxes

[illegible]

Logical order
aligned with paper
assessment

Valid choices in human readable format

User Interface – Data Entry

Step 1	Database Name	Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site 1	QuestionnaireType	Clinician
Step 2	Questionnaire Name		QuestionnaireID	E06FE47D-126F-E811-80E3-000D3A1029A9
Step 3	Subject Number		PatientID	
Step 4	Visit (Keep Empty for HH Questionnaires) Enter Visit Date (Date Only and empty for HH questionnaires)	Day 1 Followup (Day 14)	Projected Date	2020-02-13 00:00:00.0000000 +03:00
Step 5		11-Feb-2020		
Step 6	Enter Diary Start (Date and Time)	11-Feb-2020 00:00	Dup Questionnaire Data Entry	No
Step 7	Enter Diary End (Date and Time)	11-Feb-2020 00:00	Complete?	Yes
Step 8	Enter Zendesk Ticket (Number Only)		Data Entry Override?	
Step 9	Select Culture Name (Optional)			

Insert Data to Staging

Question #	Question Text	Question Choice	Free Text Entry	Question Input Type	Question Required?	Question Min
Question 1	1. Glabellar Lines (at rest)	0 = None 0		RadioButton	Y	
Question 2	2. Glabellar Lines (at maximum frown)	0 = None 0		RadioButton	Y	

User Interface – Verification

Step 1 Step 2 Step 3 Step 4	Select Zendesk Ticket to Review	Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site en-US	InsertID Approved/Rejected By	6a9ac260-24bf-43d9-819f-1c0d4ba87dda
	Enter Email Address To Sent Script (Optional)			
	Select Culture (if not English)			
	Include English with other Culture?			

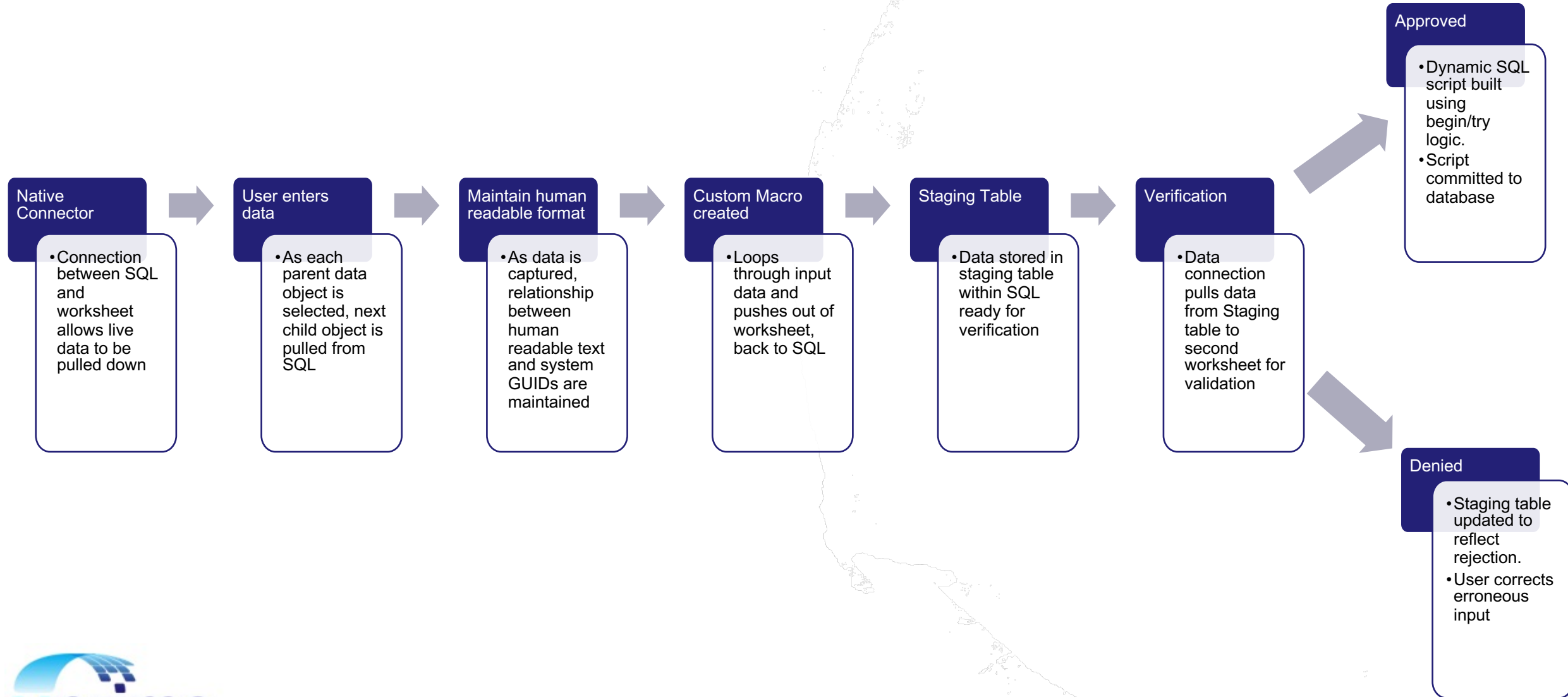
Approve Data

Reject Data

Row Number	Data Point	Value
1	InsertID	6a9ac260-24bf-43d9-819f-1c0d4ba87dda
2	DBName	
3	PatientNumber	
4	VisitID	5
5	VisitName	Day 1 Followup (Day 14)
6	VisitStatusAfterScriptRun	Complete
7	VisitDate	2020-02-11 00:00:00.0000000 +03:00
8	DiaryStart	2020-02-11 00:00:00.0000000 +03:00
9	DiaryEnd	2020-02-11 00:00:00.0000000 +03:00
10	ZenDeskTicket#	
11	UserWhoInserted	
Investigator-rated Facial Wrinkle Scale Answer Sheet Frown Lines Facial_Wrinkle_Scale_with_photonumeric_guide_(FWS)_Site 1		
12	QuestionnaireName	
13	1. Glabellar Lines (at rest)	0 = None 0
14	2. Glabellar Lines (at maximum frown)	0 = None 0



Behind the Scenes



So... was it successful?

- Low to no additional burden on sites / subjects
 - Optimized existing processes
- Maintain High Data Integrity
 - Human Readable format
 - Verification process
- No change in how data is stored or transferred
- Data available quickly
 - 24/7 data entry
 - Time reduction of 120% vs previous paper solution



So... was it successful?

- Scalable across multiple studies and PROs
 - Dynamic mapping against existing relational database
- Eliminate language barriers
 - Text Translations
- Simple and Efficient
 - Logical data entry requiring minimal technical knowledge
- Cost Effective
 - Built in house using existing applications and resources



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Any Questions?

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