OneSource: Automated EHR to eCRF Data Capture in Regulatory-Grade Clinical Trials

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INTRODUCTION

- Standardized and efficient approaches to data capture are critical in clinical drug development.
- Abstraction of electronic health record data and entry into electronic case report forms (eCRF) represents a major barrier for timely data capture.
- The OneSource platform was designed designed to be integrated with local Electronic Health Record (EHR) systems supporting automated electronic capture of structured source data (eSource) across multiple clinical centers.

METHODS

- The OpenClinica (Waltham, MA) electronic data capture (EDC) system was configured to support randomized subjects for concurrent investigational agents and a control arm.
- A Substitutable Medical Applications, Reusable Technologies (SMART) on Health Level Seven (HL7) Fast Health Interoperability Resources (FHIR) App was developed to launch within EHR systems (EPIC & Cerner) to enable source data capture of **laboratory** and **concomitant medication** data.
- We deployed the solution in the multicenter I-SPY COVID platform trial with over 3,200 patients including a Real World Data (RWD) observational cohort.
- Data quality and data capture efficiencies were assessed by comparing (using an ANOVA statistical test with a co-variate for site) the manually entered laboratory data to data captured by eSource through the EHR integration

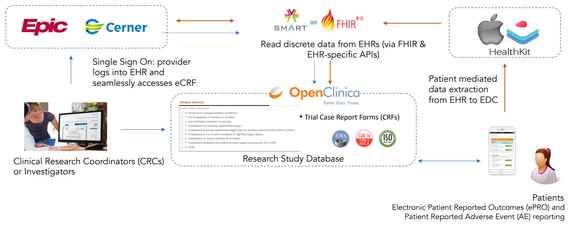

Figure 1: SMART on FHIR integration through 1) on site, institution configuration with Epic and Cerner EHR and 2) EHR access points for patient mediated access. Both approaches result in high quality, efficient transfer of discrete data from the EHR to the study database system.

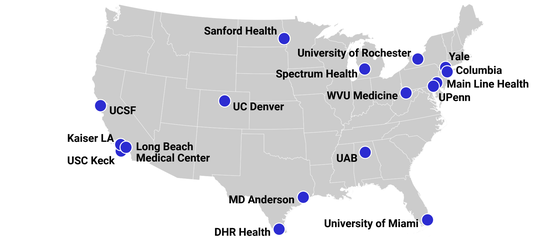

Figure 2: 18 I-SPY COVID sites with OneSource V2 implementations in production.

Item Name (OneSource variable name)	CDISC Item OID	Item Label (text on CRF)	FHIR Observation Resource Element Name
effective_date_of_lab_tests	I_LABS_EFFECTIVE_DATE_OF_LAB_TESTS	Effective Date of Lab (UTC-05)	observation.effectiveDateTime
observation_id	I_LABS_OBSERVATION_ID		observation.identifier
test_name	I_LABS_TEST_NAME	Test Name	Observation.code.display
loinc_code	I_LABS_LOINC_CODE	LOINC Code	observation.code.isolate
cdisc_label	I_LABS_CDISC_LABEL	CDISC Label	Translated in OpenClinica from LOINC code
lab_value	I_LABS_LAB_VALUE	Value	observation.valueQuantity or observation.valueString
units	I_LABS_UNITS	Units	observation.valueQuantity
issued_date	I_LABS_ISSUED_DATE	Issued Date of Lab Tests	observation.issued
ref_range_low	I_LABS_REF_RANGE_LOW	Ref. Range Low	observation.referenceRange.low
ref_range_high	I_LABS_REF_RANGE_HIGH	Ref. Range High	observation.referenceRange.high
ref_range_text	I_LABS_REF_RANGE_TEXT	Ref. Range Text	observation.referenceRange.text
lab_interpretation	I_LABS_LAB_INTERPRETATION	Lab Interpretation	observation.interpretation
status	I_LABS_STATUS	Lab Status	observation.status
study_day	I_LABS_STUDY_DAY	Study Day	Translated in OpenClinica from effective date

Table 1: Lab Result fields for EHR to EDC integration showing CDISC, eCRF item and FHIR Observation Resource mapping

Item Name (OneSource variable name)	CDISC Item OID	Item Label (text on CRF)	FHIR Observation Resource Element Name
effective_period_start	I_MEDS_EFFECTIVE_PERIOD_START	Effective Period Start	MedicationStatement.effectivePeriod
medication_name	I_MEDS_MEDICATION NAME	Medication Name	MedicationStatement.Medication
medication_code	I_MEDS_MEDICATION_CODE	Medication Code	MedicationStatement.Medication.code
dose_quantity	I_MEDS_DOSE_QUANTITY	Dose Quantity	MedicationStatement.doseQuantity
dose_unit	I_MEDS_DOSE_UNIT	Dose Unit	MedicationStatement.doseQuantity
dose_delivery_method	I_MEDS_DOSE_DELIVERY_METHOD	Dose Delivery Method	MedicationStatement.method
med_status	I_MEDS_MED_STATUS	Medication Status	MedicationStatement.status
category	I_MEDS_CATEGORY	Category	MedicationStatement.category

Table 2: Concomitant Medications fields for EHR to EDC integration showing CDISC, eCRF item and FHIR Observation Resource mapping

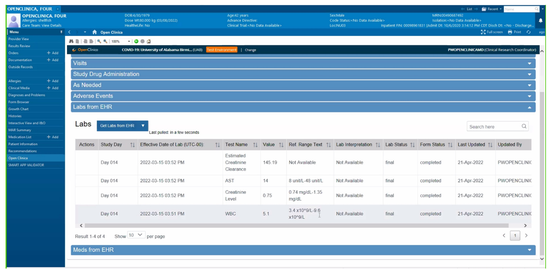

Figure 3 OneSource is embedded within the EHR system display lab data that has been automatically pulled into the I-SPY COVID database

RESULTS

- 8,099 eCRFs from 878 subjects were evaluated for data entry quality
- Using OneSource automated capture, data entry times dropped to a median of 3.28 minutes, a decrease in data entry time by 45.8% ($p<0.0001$), a time savings of 2.8 minutes per form.
- Manual entry vs. EHR entered lab data for the same subject and lab results shows on average a discordance of 10.3%.

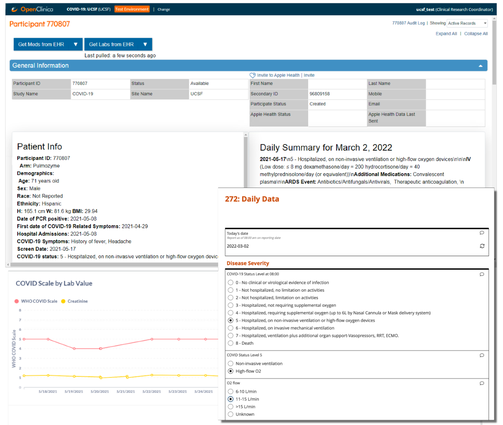

Figure 4: OneSource user interface with decision support displays that are configured to show lab results, Adverse Events, and other research or clinical variables over time. For data entry, the daily data intake launches for data entry for the WHO clinical progression scale

Across all sites - Summary	OneSource	Patients	eCRFs	median
	Before	615	5766	6.05
	After	263	2333	3.28
	Total	878	8099	

Site	Before	After	Time Savings	Percent Change	Discordance Rate(%)
Site A	5.94	2.51	3.43	57.74%	7
Site B	5.28	2.42	2.86	54.17%	
Site C	6.98	7.03	-0.05	-0.72%	10.7
Site D	5.73	2.28	3.45	60.21%	11.8
Site E	11.27	2.63	8.64	76.66%	13.1
Site F	4.71	1.77	2.94	62.42%	2.4
Site G	5.66	3.4	2.26	39.93%	20.6
Site H	17.45	13.91	3.54	20.29%	6.5
Mean				**46.34%**	**10.3**

Table 3: OneSource savings in time in data entry (green) and discordance in lab value entry (yellow)

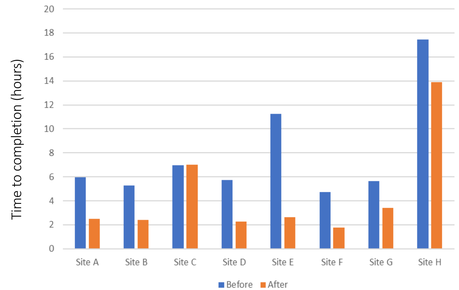

Figure 6: Median data completion time for the patient entry forms requiring daily capture of data associated with the study's primary end point.

CONCLUSION

- Improvements in the efficiency and accuracy of data capture are important advances in controlling the rising costs of clinical trials.
- OneSource automated capture resulted in a significant time savings, much improved data accuracy, sponsor-receipt of 'real time' data much more quickly, and better staff satisfaction
- OneSource has the additional benefits of low implementation costs and reusability across sites compared to other EHR integration approaches.
- **If every site had used OneSource across site from trial startup, 2,300 hours would have been saved for data entry alone.**

	Before OneSource	After OneSource
System log-in	log into two systems: EHR and EDC with different log-ins	one-click secure launch of I-SPY COVID research system within EHR
Tracking EHR to study patient ID mapping	spreadsheet, notebooks	automated
Data Entry for discrete data (labs, med, vitals)	Manual	automated
Data capture scope	Minimal as manual, costly. Focus is on a subset of lab data that is reasonable to manually enter	Comprehensive with ancillary identifiers, reference ranges; Ability to conduct ancillary studies with all labs and con meds
Data quality	Costly due to manual verification with source data verification	High quality data that is traceable to source system, the EHR, with 21 CFR Pt 11-compliant audit trail
Integration of Clinical Care and Research	Not possible as two separate systems	Seamless displays, entry and reporting within the EHR environment
Site reimbursement, incentivizing sites to join trial with limited staffing during pandemic	eCRF data completion milestone payments delayed due to sites invoicing quality issues, manual review	Automated site ayments upon completion of eCRF milestones; no need for site invoicing

Table 4: OneSource platform benefits compared to standard trial management