Accelerating EHR Clinical Trial Builds in the Age of EHR

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Current state of EHR Builds for Clinical Trial

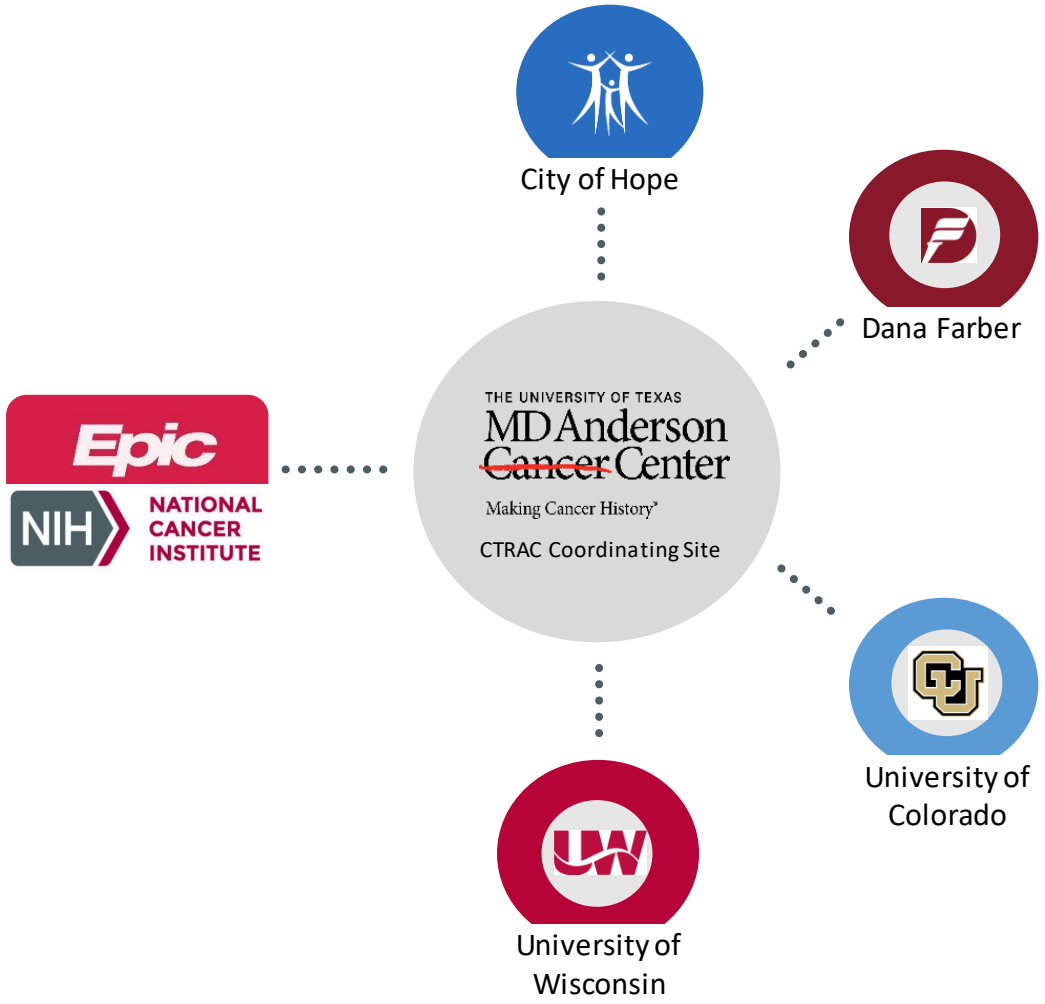
- Research EHR builds are **complex**, **time-consuming**, **costly** and **inefficient** serving only few patients
  - Multiple treatment plans are often needed based on arms, cohorts etc
  - Health systems may have many separate instances of same EHR
- Age of precision medicine has compounded the complexity
  - Example: NCI match has 37 arms and 1,100 sites. Could necessitate > 40,000 builds if all sites opened all arms

20 – 30% of clinical trials and 40 – 50% of treatment plans built in EHR are never used a single time!

*Current state is **REPETITIVE** builds necessitated by **DIFFERENCES** in drug formulary, procedures, SOP and style*

*Our goal is to build **ONCE** and disseminate*

Clinical Trial Rapid Activation Consortium (CTRAC)



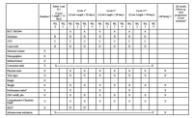
- Collaboration between Academic sites, EHR vendors, and NCI
  - Analyzed existing workflow and builds
  - Form teams to tackle complex problems
- Supported via CCSG supplements

Current Repetitive Process at Each Site

Source Documents

Protocol document

Study calendar



Appendices and ancillary documents

Investigational brochure
Pharmacy manual
Lab manual
…

Content Extraction

Investigational drug information

Protocol information

Resolve missing information and apply site preference and standards

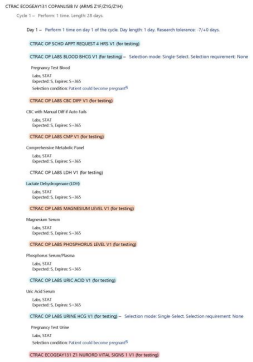
Build Documents

Investigational drug data sheet

Template for Oncology Protocol Content

Massive pivot between task orientation and timepoint orientation

EHR Build



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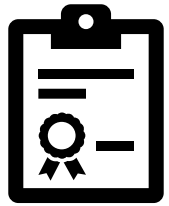
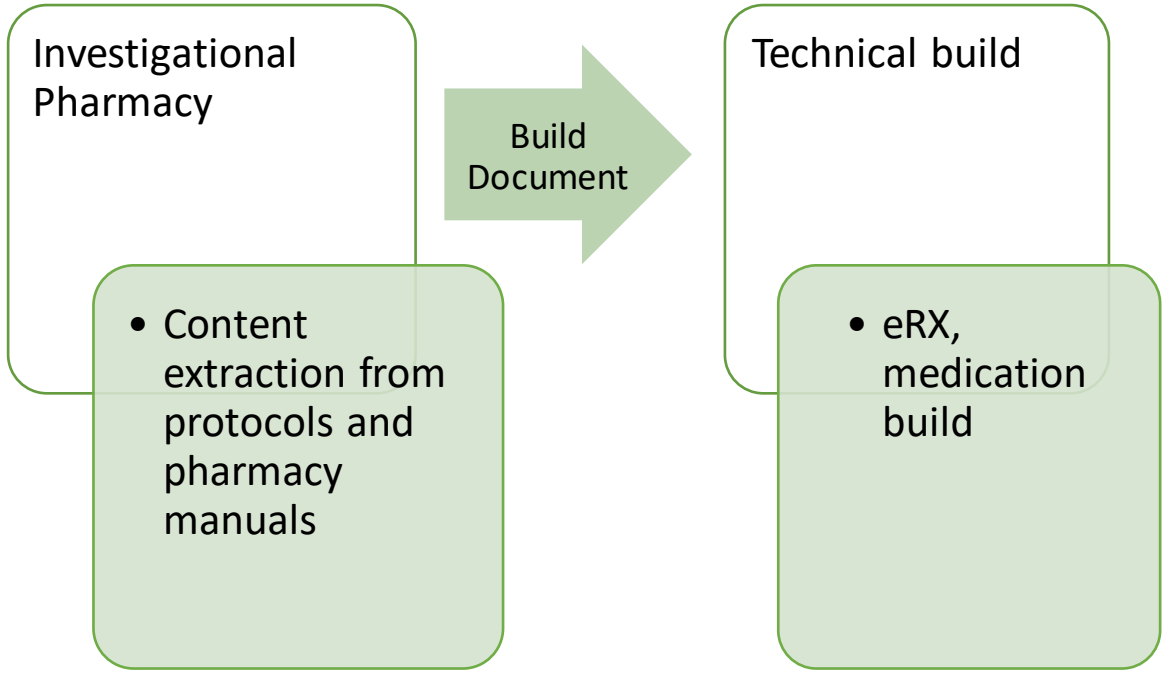


Investigational Drug Build

Medication

- Content in protocols documents and pharmacy manuals
- Many items that PIs do not think about
  - CSTD, protect from light, dose rounding
- Frequent back and forth with sponsors for clarification causing delays



Investigational Drug Data Sheet

Medication

- Structured content extraction maximizing discreet content
- Site decisions needed
- PI/sponsored signed needed for trust

CTRAC Investigational Drug Data Sheet - Non Parenteral Drug

Site Name: MDACC

One drug per sheet. Insert additional sheet as needed. Version 05/27/2021

	Ref #	Field Name	CTRAC Response	Site-Specific Response (Blank if same as CTRAC)
Medication Name	1	Drug Name *Company code name + Generic name + Brand name (if applicable)*	Olaparib	
Medication Supply Source	2	Is this drug FREE of charge to the patient?	Free to Patient	
	3	Is this drug FDA Approved for any indication?	Yes	
	24	Vial/Bottle/Kit assignment needed	No	
	27	Controlled Substance	No	
	34	Sponsor will provide study specific supplies/accessories *example: cooler, ice pack*	No	
Package Info	3	Drug Strength(s)	100mg and 150mg	
	6	Drug Formulation *example: capsule, tablet, powder, suspension*	tablet	
	7	Drug Concentration	NA	
	New	Package Type (*example: bottle, blister pack, carton*)	Bottle	
	33	Package Size(s) supplied by sponsor *example: 30 tablets per bottle, 5 capsules per blister pack, 4 blister packs per carton*	32 tablets per bottle	
	New	Can different strength be combined for single dose	Yes	
	New	Can different form be combined for single dose (examplet: tablets and capsules)	No	Did not specify
Dosing Details	10a	Drug Routes Allowed (multi-select)	PO Ear drops Enteral tube Eye drops Inhaled/nebulized	
	5	Dose Ordering Options (multi-select)	Flat dose – mcg Flat dose – mg mcg/kg mcg/m2 mg/kg	
	New	Final Dose Unit	mg	
	9	Maximum Dose		300mg PO BID (initial dose level) 250mg PO BID (1st dose reduction) 200mg PO BID (2nd dose reduction) discontinue (3rd dose reduction)
	8a	Can medication DOSE be rounded per institutional standard?	Not Protocol Specified*	
	8b	Can medication VOLUME be rounded per institutional standard?	Not Applicable	
	12	Frequency Options	Q12h for 28 day cycle	
Package Storage, Handling, Dispensing Requirements	17	Follow Chemotherapy Precautions	Yes - Protocol Specified	
	20	Use CSTD for preparation	Not Applicable	
	23	Protect from light (final product)	Not Protocol Specified*	
	25	Dispense exact quantity?	Not Protocol Specified*	
	26	Dispense full bottles/containers	Not Protocol Specified*	

Example of Site Decision for Medication Build

Medication

Protocol Text	Field Name	CTRAC	Site
Drug ABC123 is supplied as lyophilized powder in 100 mg vial. ABC123 can be diluted in D5W or NS to final concentration between 1mg/mL to 6.7mg/mL. Final volume of 100 mL or 250 mL is recommended.	Drug Name	ABC123	ABC123
	Drug Formulation	Lyophilized powder	Lyophilized powder
	Diluent	D5W or NS	D5W
	Final Volume	100 or 250 mL	100
	Use CSTD	Not protocol specified	Use CSTD
	Protect from light	Not protocol specified	No

eRX build tool

Medication

CTRAC Investigational Drug Data Sheet

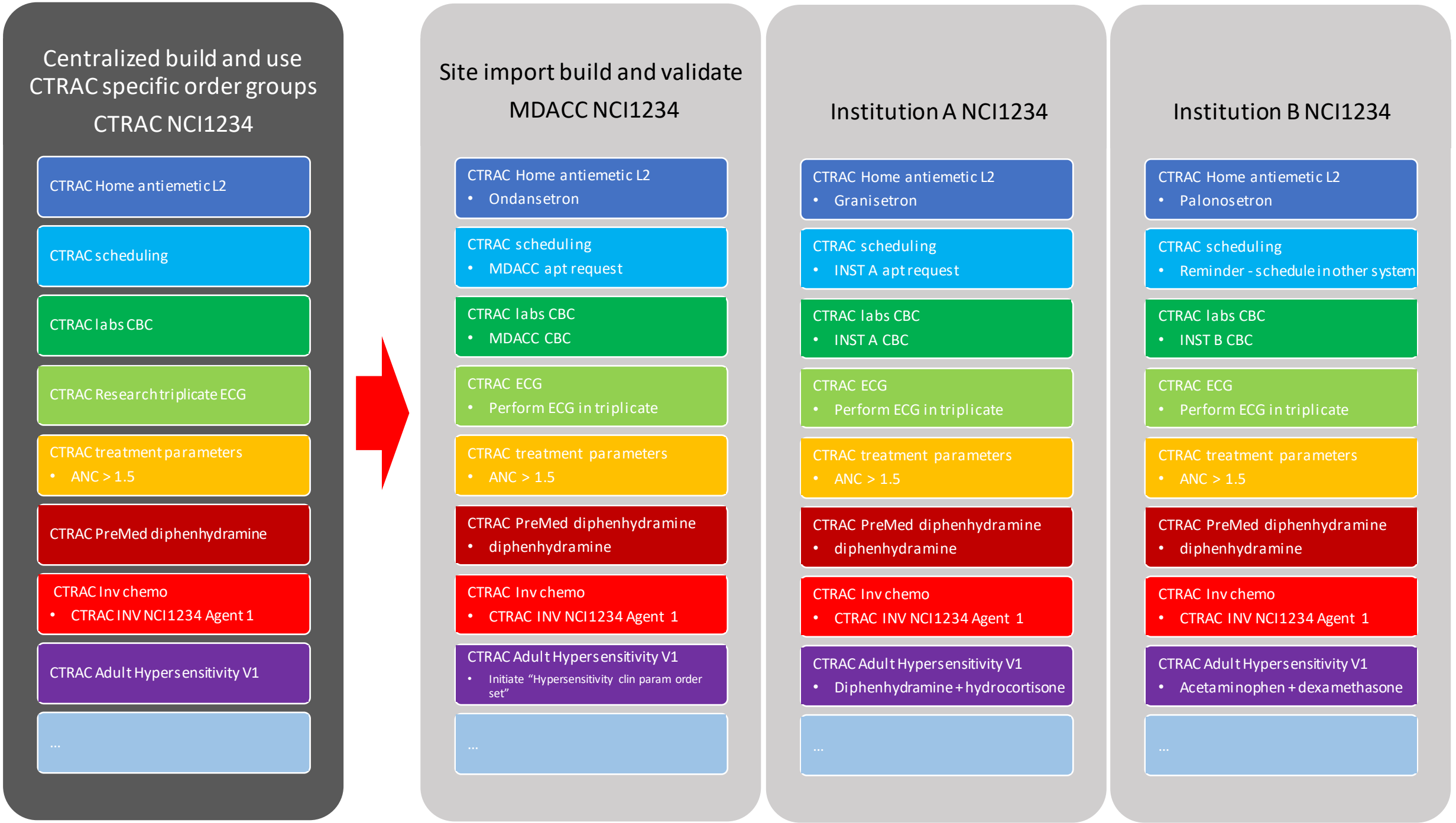
eRX Build Tool

Site specific eRX

- eRX build tool as rules/mapping engine that transforms data from CTRAC Investigational Drug Data Sheet to site specific eRX
- Each site will configure and maintain the site-specific rules
- Phase approach to content coverage and complexity of the build

Analyzed existing workflow and builds

- Treatment plans includes two types of orders
  - Protocol specific (less variable)
    - Investigational meds
    - Special procedures
  - General orders (more variable)
    - Supportive medication
    - IV fluids
    - Parameters
- Used Order Groups to construct a standard representation of the treatment plans, which can then be mapped to local EHR installations


Centralized build and use CTRAC specific order groups
CTRAC NCI1234
CTRAC Home antiemetic L2
CTRAC scheduling
CTRAC labs CBC
CTRAC Research triplicate ECG
CTRAC treatment parameters
• ANC > 1.5
CTRAC PreMed diphenhydramine
CTRAC Inv chemo
• CTRAC INV NCI1234 Agent 1
CTRAC Adult Hypersensitivity V1
...
Site import build and validate
MDACC NCI1234
CTRAC Home antiemetic L2
• Ondansetron
CTRAC scheduling
• MDACC apt request
CTRAC labs CBC
• MDACC CBC
CTRAC ECG
• Perform ECG in triplicate
CTRAC treatment parameters
• ANC > 1.5
CTRAC PreMed diphenhydramine
• diphenhydramine
CTRAC Inv chemo
• CTRAC INV NCI1234 Agent 1
CTRAC Adult Hypersensitivity V1
• Initiate "Hypersensitivity clin param order set"
...
Institution A NCI1234
CTRAC Home antiemetic L2
• Granisetron
CTRAC scheduling
• INST A apt request
CTRAC labs CBC
• INST A CBC
CTRAC ECG
• Perform ECG in triplicate
CTRAC treatment parameters
• ANC > 1.5
CTRAC PreMed diphenhydramine
• diphenhydramine
CTRAC Inv chemo
• CTRAC INV NCI1234 Agent 1
CTRAC Adult Hypersensitivity V1
• Diphenhydramine + hydrocortisone
...
Institution B NCI1234
CTRAC Home antiemetic L2
• Palonosetron
CTRAC scheduling
• Reminder - schedule in other system
CTRAC labs CBC
• INST B CBC
CTRAC ECG
• Perform ECG in triplicate
CTRAC treatment parameters
• ANC > 1.5
CTRAC PreMed diphenhydramine
• diphenhydramine
CTRAC Inv chemo
• CTRAC INV NCI1234 Agent 1
CTRAC Adult Hypersensitivity V1
• Acetaminophen + dexamethasone
...

Defined reusable and protocol specific order groups

Order group folder	Order group name	Order group type	Purpose	Orders(s) included	Comment	No clinical decision
DIAGNOSTIC TESTS	CTRAC OP DIAGTEST ECG V1	Reusable	Evaluate for electrocardiogram abnormalities	ECG	If site does not include diagnostic tests in its protocol build, the order group should be left blank or replaced by a communication order that remind the research team to place order by alternative method.	Yes
Discharge	CTRAC OP DISCH INSTRUCTION V1	Reusable	Communicate discharge instruction and education	Discharge instruction and education	If site does not include Discharge Instructions in its protocol build, the order group should be left blank.	Yes
Flushes	CTRAC IP FLUSHES NS V1	Reusable	Cause line for infusion of medications to be flushed with sodium chloride 0.9% (NS).	Flush line with NS.	If site does not include flushes in its protocol build, the order group should be replaced by a communication order that remind the team to flush line with NS.	Yes
Hypersensitivity	CTRAC IP HSR ADULT HYPERSENS INTERVENTION V1	Reusable	Activate hypersensitivity interventions.	Per local adult hypersensitivity protocol. Order can be the activation of parameter orders/standing order. Alternatively, the protocol can contain multiple individual orders needed for hypersensitivity intervention.	If site does not include hypersensitivity in its protocol build, the order group should be left blank or replaced by a communication order.	No
Labs	CTRAC OP LABS CBC diff v1	Reusable	Cause for blood to be drawn to assess CBC with platelet and differential	CBC with platelet and differential	If site does not include labs in its protocol build, the order group should be left blank or replaced by a communication order that remind the research team to place order by alternative method.	Yes
Pre-Medications	CTRAC IP PREMED ANTIEMETIC - MODERATE EMETOGENICITY V1	Reusable	Antiemetic given prior to therapeutic agents. Two agents from different class are generally given IV. For example, - 5-HT3 antagonist - dexamethasone	Dose, route, and product specific administration instructions.	Frequency, offset times, and additional administration instructions should be added at the PRL level. Examples include ondansetron, granisetron, palonosetron.	No

Clinical Content ⇛ Build Document ⇛ EHR Build

Faithful capture of protocol content is insufficient for build

- Lack of standard in content provided in protocol
  - Complete specification with no flexibility (study drug)
  - Missing from protocol with assumption sites will fill
  - Some specification with flexibility and need for clinical decisions from sites
- Lack of standard in location of key content needed for protocol build
- Existing build process includes micro decisions that are largely undocumented

Centralized build and use CTRAC specific order groups

CTRAC NCI1234

- CTRAC Home antiemetic L2
- CTRAC scheduling
- CTRAC labs CBC
- CTRAC Research triplicate ECG
- CTRAC treatment parameters
  - ANC > 1.5
- CTRAC PreMed diphenhydramine
- CTRAC Inv chemo
  - CTRAC INV NCI1234 Agent 1
- CTRAC Adult Hypersensitivity V1
- …

Export Package

Import Package

Map order group to CTRAC order groups in site system as part of import process

Site import and validate

MDACC NCI1234

- CTRAC Home antiemetic L2
  - Ondansetron
- CTRAC scheduling
  - MDACC apt request
- CTRAC labs CBC
  - MDACC CBC
- CTRAC ECG
  - Perform ECG in triplicate
- CTRAC treatment parameters
  - ANC > 1.5
- CTRAC PreMed diphenhydramine
  - diphenhydramine
- CTRAC Inv chemo
  - CTRAC INV NCI1234 Agent 1
- CTRAC Adult Hypersensitivity V1
  - Initiate “Hypersensitivity clin param order set”
- …

Peer sharing of NCI MATCH Arm Z1F

Followed by iterative refinement and sharing of other studies

CTRAC ECOGEAY131 COPANLISIB IV (ARMS Z1F/Z1G/Z1H)

Cycle 1 – Perform: 1 time. Length: 28 days.

Day 1 – Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -7/+0 days.

CTRAC OP SCHD APPT REQUEST 4 HRS V1 (for testing)

CTRAC OP LABS BLOOD BHCG V1 (for testing) – Selection mode: Single-Select. Selection requirement: None

Pregnancy Test Blood

Labs, STAT
Expected: S, Expires: S+365
Selection condition: Patient could become pregnant¶

CTRAC OP LABS CBC DIFF V1 (for testing)

CBC with Manual Diff if Auto Fails

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS CMP V1 (for testing)

Comprehensive Metabolic Panel

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS LDH V1 (for testing)

Lactate Dehydrogenase (LDH)

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS MAGNESIUM LEVEL V1 (for testing)

Magnesium Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS PHOSPHORUS LEVEL V1 (for testing)

Phosphorus Serum/Plasma

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS URIC ACID V1 (for testing)

Uric Acid Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS URINE HCG V1 (for testing) – Selection mode: Single-Select. Selection requirement: None

Pregnancy Test Urine

Labs, STAT
Selection condition: Patient could become pregnant¶

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 1 V1 (for testing)

Vital signs

Nursing Instructions, STAT, Expected: S, Expires: S+365, Routine Vital Signs, Pre-dose. Please measure 5-10 min prior to each Copanlisib dose (no more than 4 measurements) until there are two consecutive Blood Pressure results that are less than150/90 mmHg. Hold if Blood Pressure is more than150/90 mmHg

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 2 V1 (for testing)

ONC Nursing Communication

Nursing Instructions, Expected: S, Expires: S+365
Routine Vital Signs, Please measure Blood Pressure post dose: 30 mins +/- 10 mins post start of infusion, 60 mins +/- 10 mins post start of infusion (at end of infusion), 60 minutes +/- 10 mins post end of infusion and 120 minutes +/- 10 mins (post end of infusion)
Pre-dose at Start of Infusion, Please measure Blood Pressure Pre-dose: at Start of Infusion

CTRAC ECOGEAY131 Z1 NURCOMM 1 V1 (for testing)

ONC Nursing Communication 1

Nursing Instructions, Expected: S, Expires: S+365
Please perform glucose monitoring (finger sticks): at start of infusion, at end of infusion, 1 hour post-completion of infusion and 2 hours post-completion of infusion.

CTRAC IP TXPARAM 1 HOLD ANC 3, PLT 100, HGB 9 V1 (for testing)

Treatment conditions 1

Conditional Orders, Expected: S, Expires: S+365
Hold treatment and notify physician if: ANC is less than 3 k/mm3, Platelets less than 100 k/mm3, or Hemoglobin less than 9 gm/dl.

CTRAC IP PCOMM NO STEROID V1 (for testing)

ONC Physician Communication

Provider Communication, Expected: S, Expires: S+365
Corticosteroid pre-medication is NOT allowed.

CTRAC IP IVFLUID NS 0.9% INFUSION V1 (for testing)

NS infusion

IV Maintenance, Intravenous, at 5-100 mL/hr, CONTINUOUS, Starting at treatment start time
Use to keep vein open and flush line.

CTRAC IP PREMED IV ANTIEMETIC L1 MG V1 (for testing)

palonosetron (ALOXI) injection 0.25 mg

Pre-Medications, 0.25 mg, Intravenous, ONCE, Administer over 0.5 Minutes, Starting when released, For 1 dose
Flush line with NS before and after administration. Administer over 30 seconds.

CTRAC ECOGEAY131 Z1 CHEMO INV COPANLISIB V1 (for testing)

15-1111 STUDY copanlisib 60 mg in NS 100 mL IVPB

Investigational, 60 mg, Intravenous, at 104 mL/hr, ONCE, Administer over 60 Minutes, Starting when released, For 1 dose
Flush with NS after administration to clear line of drug. No IV dextrose solutions should be given on the day of infusion.

CTRAC IP FLUSHES NS V1 (for testing)

NS infusion

IV Maintenance, Intravenous, at 5-100 mL/hr, ONCE, Starting at treatment start time, For 1 dose

CTRAC IP PRNMED CLONIDINE HCL V1 (for testing)

CTRAC IP PRNMED IV ANTIEMETIC L1 V1 (for testing)

CTRAC IP HSR ADULT HYPERSENS INTERVENTION V1 (for testing)

CTRAC OP DISCH INSTRUCTION V1 (for testing)

Day 8 – Perform 1 time on day 8 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.

CTRAC OP SCHD APPT REQUEST 4 HRS V1 (for testing)

CTRAC OP LABS CBC DIFF V1 (for testing)

CBC with Manual Diff if Auto Fails

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS CMP V1 (for testing)

Comprehensive Metabolic Panel

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS MAGNESIUM LEVEL V1 (for testing)

Magnesium Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS URIC ACID V1 (for testing)

Uric Acid Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 1 V1 (for testing)

Vital signs

Nursing Instructions, STAT, Expected: S, Expires: S+365, Routine Vital Signs, Pre-dose. Please measure 5-10 min prior to each Copanlisib dose (no more than 4 measurements) until there are two consecutive Blood Pressure results that are less than150 mmHg. Hold if Blood Pressure is more than150/90 mmHg

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 2 V1 (for testing)

ONC Nursing Communication

Nursing Instructions, Expected: S, Expires: S+365
Routine Vital Signs, Please measure Blood Pressure post dose: 30 mins +/- 10 mins post start of infusion, 60 mins +/- 10 min start of infusion (at end of infusion), 60 minutes +/- 10 mins post end of infusion and 120 minutes +/- 10 mins (post end of i
Pre-dose at Start of Infusion, Please measure Blood Pressure Pre-dose: at Start of Infusion

CTRAC ECOGEAY131 Z1 NURCOMM 1 V1 (for testing)

ONC Nursing Communication 1

Nursing Instructions, Expected: S, Expires: S+365
Please perform glucose monitoring (finger sticks): at start of infusion, at end of infusion, 1 hour post-completion of infusion hours post-completion of infusion.

CTRAC IP PCOMM NO STEROID V1 (for testing)

ONC Physician Communication

Provider Communication, Expected: S, Expires: S+365
Corticosteroid pre-medication is NOT allowed.

CTRAC IP PREMED IV ANTIEMETIC L1 MG V1 (for testing)

palonosetron (ALOXI) injection 0.25 mg

Pre-Medications, 0.25 mg, Intravenous, ONCE, Administer over 0.5 Minutes, Starting when released, For 1 dose
Flush line with NS before and after administration. Administer over 30 seconds.

CTRAC ECOGEAY131 Z1 CHEMO INV COPANLISIB V1 (for testing)

15-1111 STUDY copanlisib 60 mg in NS 100 mL IVPB

Investigational, 60 mg, Intravenous, at 104 mL/hr, ONCE, Administer over 60 Minutes, Starting when released, For 1 dose
Flush with NS after administration to clear line of drug. No IV dextrose solutions should be given on the day of infusion.

CTRAC IP FLUSHES NS V1 (for testing)

NS infusion

IV Maintenance, Intravenous, at 5-100 mL/hr, ONCE, Starting at treatment start time, For 1 dose

CTRAC IP PRNMED CLONIDINE HCL V1 (for testing)

CTRAC IP PRNMED IV ANTIEMETIC L1 V1 (for testing)

CTRAC IP HSR ADULT HYPERSENS INTERVENTION V1 (for testing)

CTRAC OP DISCH INSTRUCTION V1 (for testing)

Day 15 – Perform 1 time on day 15 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.

CTRAC OP SCHD APPT REQUEST 4 HRS V1 (for testing)

CTRAC OP LABS CBC DIFF V1 (for testing)

CBC with Manual Diff if Auto Fails

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS CMP V1 (for testing)

Comprehensive Metabolic Panel

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS MAGNESIUM LEVEL V1 (for testing)

Magnesium Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC OP LABS URIC ACID V1 (for testing)

Uric Acid Serum

Labs, STAT
Expected: S, Expires: S+365

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 1 V1 (for testing)

Vital signs

Nursing Instructions, STAT, Expected: S, Expires: S+365, Routine Vital Signs, Pre-dose. Please measure 5-10 min prior to each Copanlisib dose (no more than 4 measurements) until there are two consecutive Blood Pressure results that are less than150/90 mmHg. Hold if Blood Pressure is more than150/90 mmHg

CTRAC ECOGEAY131 Z1 NURORD VITAL SIGNS 2 V1 (for testing)

ONC Nursing Communication

Nursing Instructions, Expected: S, Expires: S+365
Routine Vital Signs, Please measure Blood Pressure post dose: 30 mins +/- 10 mins post start of infusion, 60 mins +/- 10 mins post start of infusion (at end of infusion), 60 minutes +/- 10 mins post end of infusion and 120 minutes +/- 10 mins (post end of infusion)
Pre-dose at Start of Infusion, Please measure Blood Pressure Pre-dose: at Start of Infusion

CTRAC ECOGEAY131 Z1 NURCOMM 1 V1 (for testing)

ONC Nursing Communication 1

Nursing Instructions, Expected: S, Expires: S+365
Please perform glucose monitoring (finger sticks): at start of infusion, at end of infusion, 1 hour post-completion of infusion and 2 hours post-completion of infusion.

CTRAC IP PCOMM NO STEROID V1 (for testing)

ONC Physician Communication

Provider Communication, Expected: S, Expires: S+365
Corticosteroid pre-medication is NOT allowed.

CTRAC IP PREMED IV ANTIEMETIC L1 MG V1 (for testing)

palonosetron (ALOXI) injection 0.25 mg

Pre-Medications, 0.25 mg, Intravenous, ONCE, Administer over 0.5 Minutes, Starting when released, For 1 dose
Flush line with NS before and after administration. Administer over 30 seconds.

CTRAC ECOGEAY131 Z1 CHEMO INV COPANLISIB V1 (for testing)

15-1111 STUDY copanlisib 60 mg in NS 100 mL IVPB

Investigational, 60 mg, Intravenous, at 104 mL/hr, ONCE, Administer over 60 Minutes, Starting when released, For 1 dose
Flush with NS after administration to clear line of drug. No IV dextrose solutions should be given on the day of infusion.

CTRAC IP FLUSHES NS V1 (for testing)

NS infusion

IV Maintenance, Intravenous, at 5-100 mL/hr, ONCE, Starting at treatment start time, For 1 dose

CTRAC IP PRNMED CLONIDINE HCL V1 (for testing)

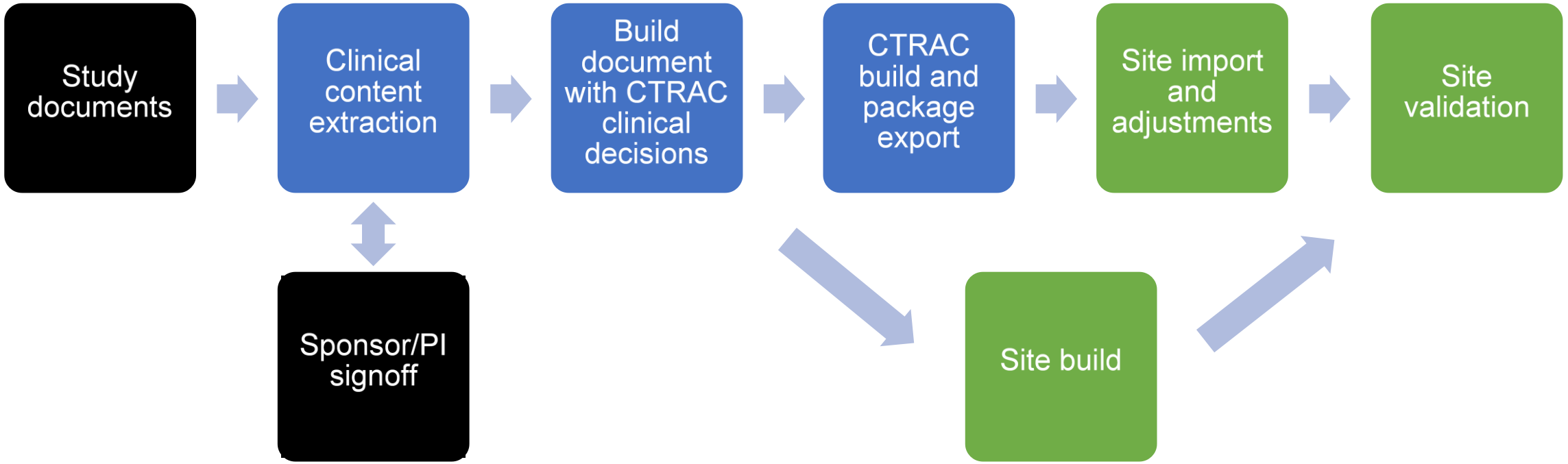
CTRAC IP PRNMED IV ANTIEMETIC L1 V1 (for testing)

CTRAC IP HSR ADULT HYPERSENS INTERVENTION V1 (for testing)

CTRAC OP DISCH INSTRUCTION V1 (for testing)

Cycle 1, days 1, 8 and 15 of protocol exported by MDACC and subsequently imported by U. Colorado

Workflow for EHR-TPC generation and transmission



*We can **DELIVER A PROTOCOL** but sites needs to do substantial post import adjustment to fit local standards*

*Can we deliver more **TAILORED** content*

BEACON Workgroup

Comparison of Order Category Sequences

Epic working on a build wizard to solve preference issue

MDACC	Partners	UW	Unv Colorado	COH
Pre-treatment / Pre-cycle Day	Pre-treatment / Pre-cycle Day	Pre-treatment / Pre-cycle Day	Pre-treatment / Pre-cycle Day	
		Treatment plant information		
		Consent		
		Pre-labs		
		Nursing procedures/monitoring, and assessment		
Take-home chemotherapy			Take-home chemotherapy	
Take-home medications		Take-home medications	Take-home medications	Take-Home Medications
Treatment Day	Treatment Day	Treatment Day	Treatment Day	
		Treatment Plan information		
		Consent		
		IV Access		
Appointment requests				
Take-home chemotherapy				
Take-home medications	Take-home supportive Rx			Take-Home Medications
	Take-home chemotherapy			Oral Chemotherapy
				Appointment Requests
			Pharmacy Communications	
			Provider communications	
Labs	Labs	Pre-labs	Labs	Labs
			Conditional orders	
Pharmacologic studies		Additional labs		Research Labs
Diagnostic tests				
		Treatment conditions		
Nursing orders (vitals; pharmacologic studies)		Nursing procedures/monitoring, and assessment	Nursing instructions	
			ECGs (other)	
			IV maintenance	
Nursing orders (treatment parameters)	Criteria to treat			Treatment Parameters
Provider communication	Communication orders			
Nursing orders - nursing communication				Clinical Trial RN Orders
				Clinic/Infusion RN Orders
Hydration/IV fluids		Hydration	Hydration/ Pre-hydration	Hydration
Pre-medications	Anti-emetics & Pre-medications	Pre-medications	Pre-medications	Pre-Medications
			Medications	
	Hydrations			
	Hypersensitivity	Emergency medications		
			Chemotherapy (investigational	
Chemotherapy/biotherapy/investigational	Chemotherapy	Treatment medications	IV/oral/hormonal/targeted therapy)	Disease Therapies and Investigational
				Islet Product (DM only)
Cell infusion				T Cells
Post-hydration/fluids			Post-hydration	
			Post-infusion labs	
Flushes				
			Break-through antiemetics (inpatient only)	
Supportive care		Supportive care orders	Supportive Care	Supportive Care
Growth factors				
PRN medications				
Hypersensitivity protocol			Infusion/hypersensivitiy Reaction	Emergency Medications
Discharge	Post-treatment orders			
		Conditional orders		
		Take home medications		
		Follow-up		

Rigid site standards and style

Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day

Take-Home Medications

ondansetron (ZOFRAN) 8 MG tablet
Oral, Every 8 hours PRN Starting S Until Discontinued, Normal

Take-Home Chemotherapy

ID-AZD6738 <ceralasertib> (NCI 10358) 20 mg tablet
Take on days 1 through 7 of you chemotherapy treatment. Avoid eating grapefruit, grapefruit juice, or Seville oranges during treatment. Refer to drug diary for instructions.
Oral, 2 times daily Starting S Until Discontinued, Print

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Take on days 1 through 7 of you chemotherapy treatment. Avoid eating grapefruit, grapefruit juice, or Seville oranges during treatment. Refer to drug diary for instructions.
Oral, 2 times daily Starting S Until Discontinued, Print

Criteria to Treat

~~Criteria to Treat~~
Routine, Once Starting when released
For AZAD6738: Hold treatment and notify study team if platelet count < 50,000, ANC < 1,000, Hemoglobin < 8,

Criteria to Treat
Routine, Once Starting when released
For DS-8201A V1: Hold treatment and notify study team if platelet count < 25,000, ANC < 500, Hemoglobin < 8, ALC < 200, Troponin > ULN, AST > 5 x ULN, ALT > 5 x ULN, Total bilirubin > 2 x ULN, serum creatinine >3 x baseline or >6 x ULN, LVEF <45% or > 10% decline from baseline, QTC > 500 ms or > 60% change from baseline

Communication Orders

~~Provider and Nurse Communication~~
Routine, Once Starting when released
On days where both DS-8201a and AZD6738 are administered, AZD6738 should be taken first

Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day

Take-Home Medications

ondansetron (ZOFRAN) 8 MG tablet
Oral, Every 8 hours PRN Starting S Until Discontinued, Normal

Take-Home Chemotherapy

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Treatment Parameters

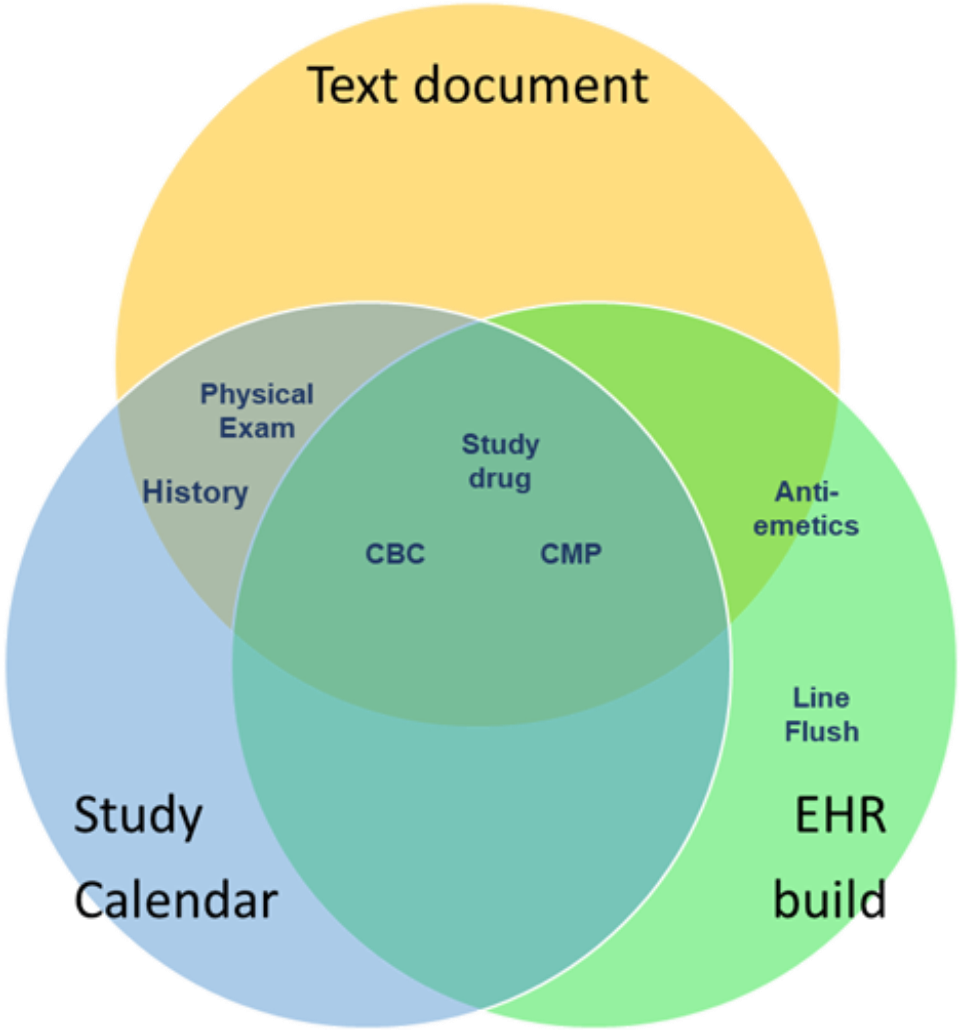
~~Criteria to Treat~~
Routine, Once Starting when released
For AZAD6738: Hold treatment and notify study team if platelet count < 50,000, ANC < 1,000, Hemoglobin < 8,

Criteria to Treat
Routine, Once Starting when released
For DS-8201A V1: Hold treatment and notify study team if platelet count < 25,000, ANC < 500, Hemoglobin < 8, ALC < 200, Troponin > ULN, AST > 5 x ULN, ALT > 5 x ULN, Total bilirubin > 2 x ULN, serum creatinine >3 x baseline or >6 x ULN, LVEF <45% or > 10% decline from baseline, QTC > 500 ms or > 60% change from baseline

Nursing Communication

~~Provider and Nurse Communication~~
Routine, Once Starting when released
On days where both DS-8201a and AZD6738 are administered, AZD6738 should be taken first

Clinical Content



- No one person has full knowledge needed for build and execution
- Differing views based on role
- Need to categorize items in protocol
  - Fully specified
  - CTRAC clinical decision
  - site clinical decision

*Protocol treatment plan at its core is about **TASKS** and **WHEN** (timepoints) to do them*

*Tasks and timepoints can be represented in a **DATABASE***

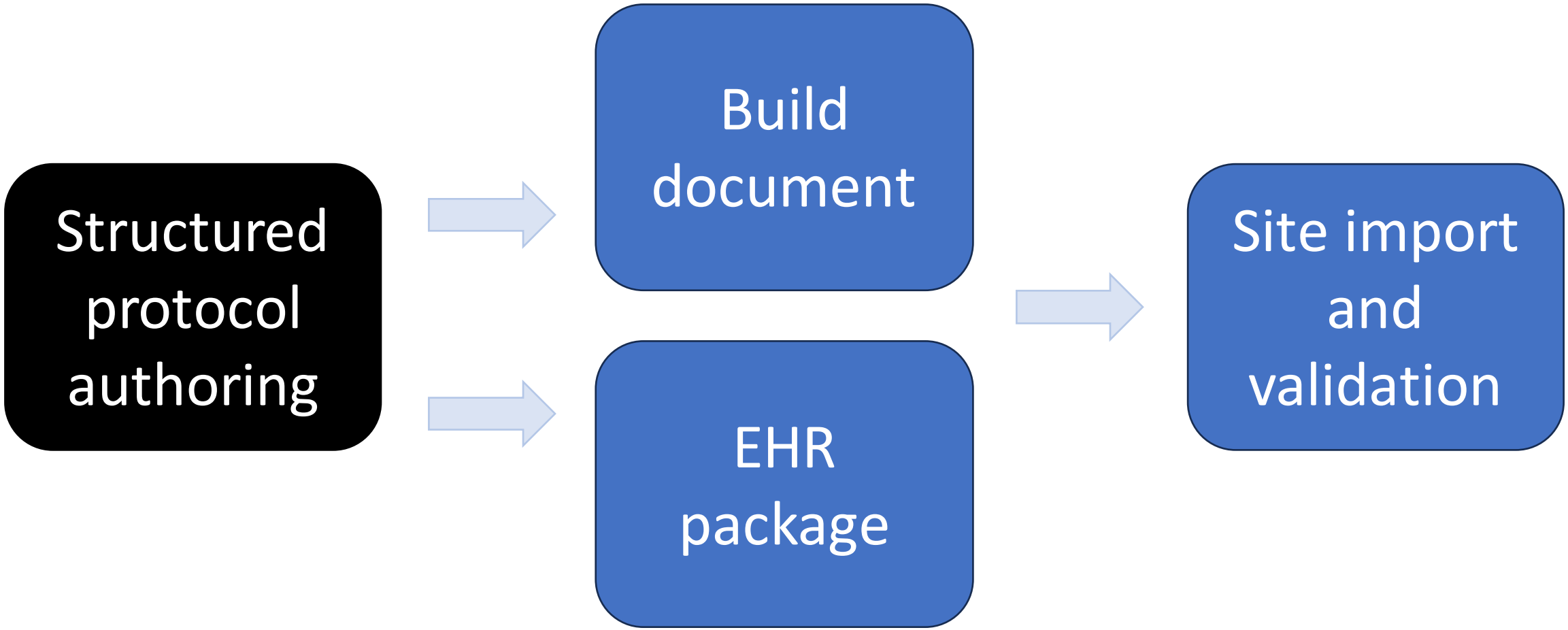
Future direction

- Work continues under newly expended EHR Pilot Consortium
- Standardized clinic content extraction to database represented as tasks and timepoints
- Task library for general tasks
- Application to deliver build content tailored to site standards
- Working with Epic to minimize post import work
- Expand to other EHR

Cycle	Day	Order group
Pretreatment		CTRAC OP HOMEMED ANTIEMETIC - MODERATE EMETOGENICITY V
1	1	CTRAC OP NCI10358 INV AZD6738 HOMECHEMO V1
1	1	CTRAC OP LABS CBC diff v1
1	1	CTRAC OP LABS CMP V1
1	1	CTRAC OP LABS URINE HCG V1
1	1	CTRAC OP NURORD VITAL SIGNS V1
1	1	CTRAC NCI10358 NURCOMM MEDSEQ V1
1	1	CTRAC IP NCI10358 TXPARAM AZD V1
1	1	CTRAC IP NCI10358 TXPARAM DS-8201a v1
1	1	CTRAC OP PROVCOMM STRONG CY3A4 INHIB + INDUC V1
1	1	CTRAC OP PROVCOMM GRAPEFRUIT + SEVILLE ORANGES V1
1	1	CTRAC OP PROVCOMM OPHTHALMOLOGIC EXAM V1
1	1	CTRAC OP PROVCOMM WEIGHT CHANGE >10% V1
1	1	CTRAC IP PREMED ANTIEMETIC - MODERATE EMETOGENICITY V1
1	1	CTRAC IP NCI10358 INV AZD6738 v1
1	1	CTRAC IP NCI10358 INV DS-8201a v1
1	1	CTRAC OP LABS RESEARCH SAMPLE COLLECTION V1
1	1	CTRAC IP PRNMED ANTIEMETIC - FIRSTCHOICE V1
1	1	CTRAC OP DISCH INSTRUCTION V1

Long term goal

- Structured authoring of protocol leveraging task library and content templates
- Structured representation of treatment plan tasks and timepoints
- Deliver tailored build content to sites based on site SOP and workflow
- Develop and mature data standard for treatment plan content
- Reimagine how protocols should be represented in the electronic era


Structured protocol authoring
Build document
EHR package
Site import and validation

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