



clinovo
Clinical Data Solutions



Advanced Data Visualization for Clinical Trials

Ale Gicqueau, Clinovo, President

Barbara Elashoff, PatientProfiles, CEO

Clinovo

1208 E. Arques Avenue, Suite 114

Sunnyvale, CA 94085

contact@clinovo.com

+1 800 987 6007

www.clinovo.com



Presentation outline

- Business case requirements
- Clinical trial design
- Clinical data standard conversion
- Advanced data visualization
 - Patient Profile
 - Trends
 - Timelines
 - Listings

Introduction

- “It is all about the data” J. Chris Scalet
- Decision-makers makes sense of the data with advanced visualization techniques
- Critical in successful \$41B merger with Schering-Plough
- Identifying redundancies & inefficiencies
 - Ex. Expense reports discrepancies
- 80% is consolidating and cleaning the data



Business case requirements

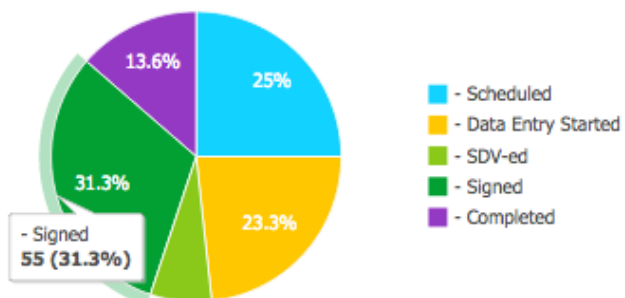
- Early phase oncology clinical trial with 10 patients and six follow-up visits
- Total study length 1 year
- Small budget
- Demographics, Inclusion/Exclusion, Medical History, Vital Signs, ECG, Physical Exam, Labs, Adverse Events, Concomitant Medications
- Clinical data standard (CDISC)
- Advanced data visualization

- Selection of Open Source Cloud-based EDC
- Use CDASH standard to minimize data standardization and later conversion to SDTM
- Use drag-and-drop Forms Studio to build CRFs
- Deploy in 12 seconds to the Cloud

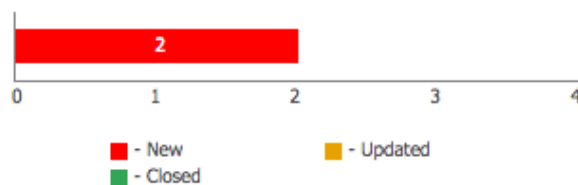
Interactive Dashboard



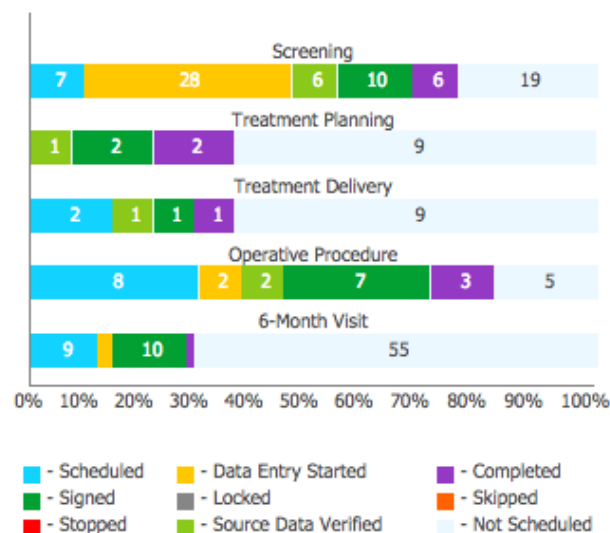
Events Status Summary



My Discrepancies

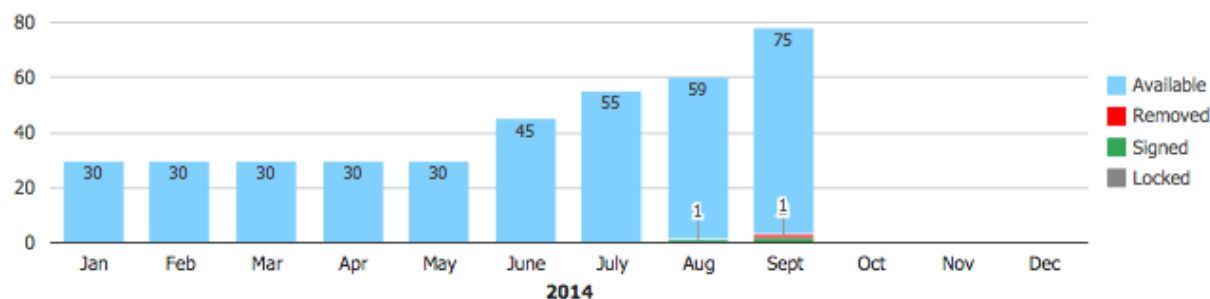


Event Status Details



Next

Enrollment Progress



Previous

EDC build process

- 30 unique CRF
- 287 Edit Checks
- Data entry from sites
- Query resolution
- Create SAS datasets

Conversion to CDISC SDTM

Open source

A SAS-based Excel framework that automatically converts data to CDISC SDTM

Features :

- Create and customize mapping files
- Generate the SDTM domains
- Generate the Define.xml
- Validate the SDTM domains

Challenges:

- Data cleaning
- Incomplete data
- Non standard domains
- Suppqual variables

Mapping to SDTM



	A	B	C	D	E	F
1	Dataset	Merge Key	CDISC variable	Expression	Comments	Explanation
2	demog	sitecode	STUDYID	study		source dataset 'demog'
3			DOMAIN	&domain		Macro variable &domain is available in each tab, and is assigned the name of the tab
4			USUBJID	%CONCATENATE(_variables=study sitecode patid)		is used to concatenate the list of variables
5			SUBJID	patid		
6			RFSTDTC	%D_RFST(_dataset=trtinf_date=trinfdt_key=patid_ivrsds=ivrs_ivrsdt=randdat)		Macro to create the firstdose variable. This variable will then be merged later on with all other datasets so that we have a reference when the first dose was provided for the drug.
7			RFENDTC	%SORTLOOKUP(_dataset=disc_variable=fupdat_key=patid_sort_variable=fupdat_keeplast)		
8			SITEID	sitecode		
9			INVID	invcode		
10			BRTHDTC	%FORMAT(_variable=brthdat_format=yymmdd10)		%FORMAT applies a SAS format or a user defined format to a variable
11			SEX	%GENDER(_gender=sex)		%GENDER Creates gender SDTM variable as defined in spec
12			RACE	%D_RACE()		%D_RACE Creates race SDTM variable as defined in spec
13			ETHNIC	upcase(ethnic)		SAS functions like upcase() can be used to define a CDISC variable
14			DMDTC	%FORMAT(_variable=formdat_format=yymmdd10)		
15			~RACEAMER	%D_RACESUPPQUAL()		~ character means that this variable is not in the SDTM specifications and will be put in SUPPQUAL.
16			~RACEASN	%D_RACESUPPQUAL()		SUPPQUAL worksheet contains the definition of the suppqual variable.
17			~RACEBLK	%D_RACESUPPQUAL()		%D_RACESUPPQUAL Creates race suppqual variables as race term, e.g. WHITE
18			~RACEHWI	%D_RACESUPPQUAL()		
19			~RACEWHT	%D_RACESUPPQUAL()		
20			~RACENA	%D_RACESUPPQUAL()		
21	siteinv(drop=invcode)	sitecode	INVNAM	trim(lname) "." fname		The SAS options can be used along with the source dataset, eg: (drop=invcode)
22			COUNTRY	"USA"		The value for the CDISC variable COUNTRY will be the string "USA".
23	eligassess	patid	USUBJID	%CONCATENATE(_variables=study sitecode patid)		
24	stdygrp	patid	SUBJID	patid		
25	all		AGE	year(infcondt)-year(brthdat)-(month(brthdat)>month(infcondt))- (month(brthdat)=month(infcondt) and day(brthdat)>day(infcondt))		"all" instructs that all previous datasets need to be merged by USUBJID.
26			DMDY	input(@DMDTC,yymmdd10.) - input(@RFSTDTC,yymmdd10.) + (input(@DMDTC,yymmdd10.) >= input(@RFSTDTC,yymmdd10.))		The symbol '@' allows the use of a CDISC variable after it has been created in other assignment statements.
27			AGEU	%CONVERTIF(_if_variable=@AGE,_if_value=.,_then_value=.,_else_value=YEAR)		%CONVERTIF Replaces a value by another using condition.
28			ARMCD	%CONVERTIF(_if_variable=trtrgp,_if_value=Active,_then_value=DrugA,_else_value=PLACEBO)		

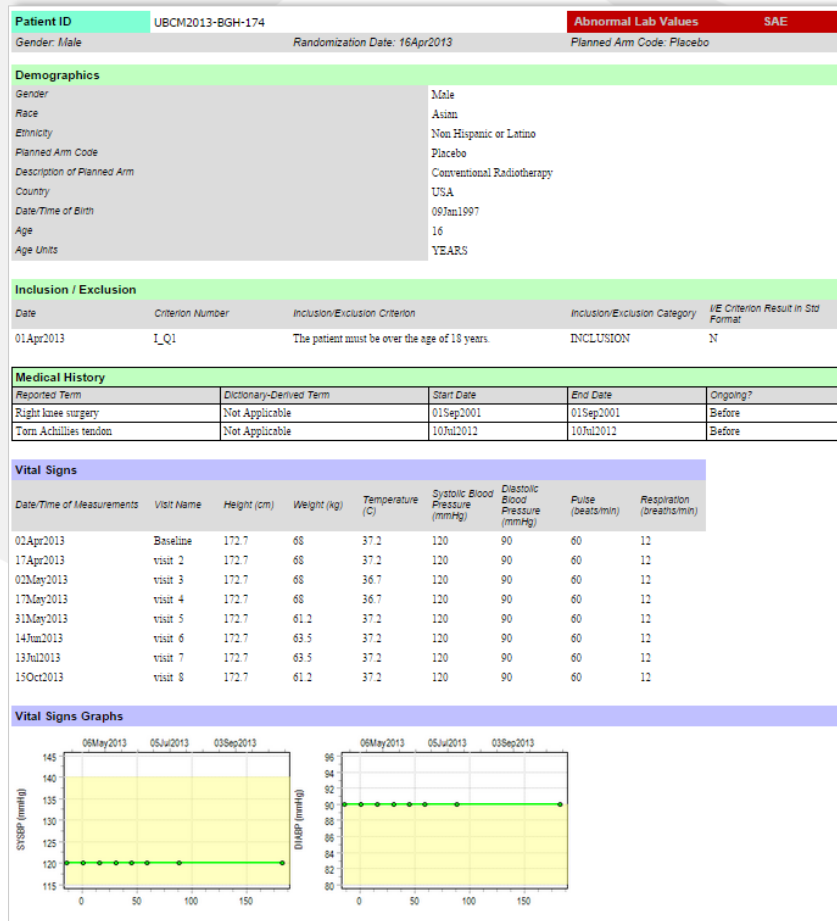
Patient Profiles Integration



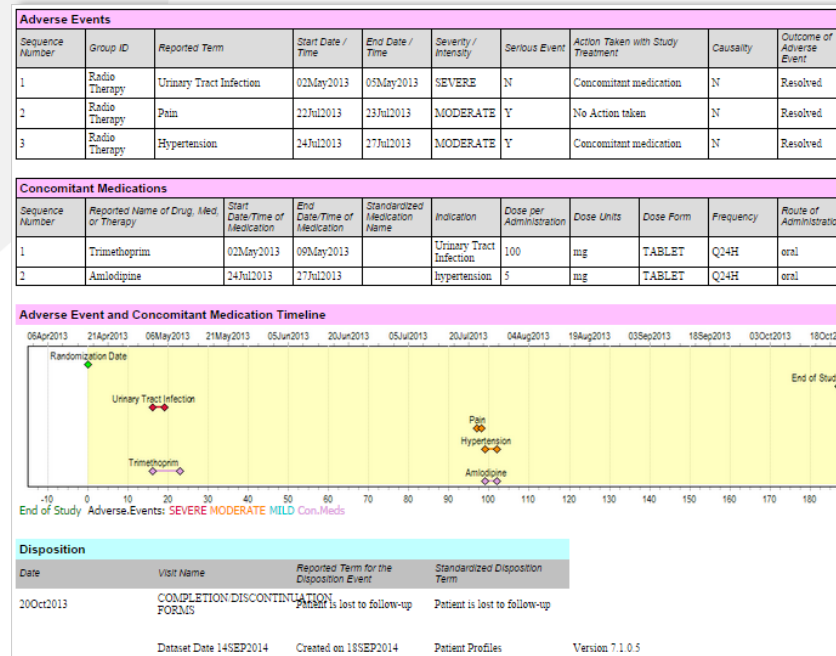
- ClinCapture template based on SDTM
 - DM, IE, MH, PE, VS, EG, LB, AE, CM, DS
- Works for any EDC study with the domains above defined
- Batch or real-time integration

Challenges

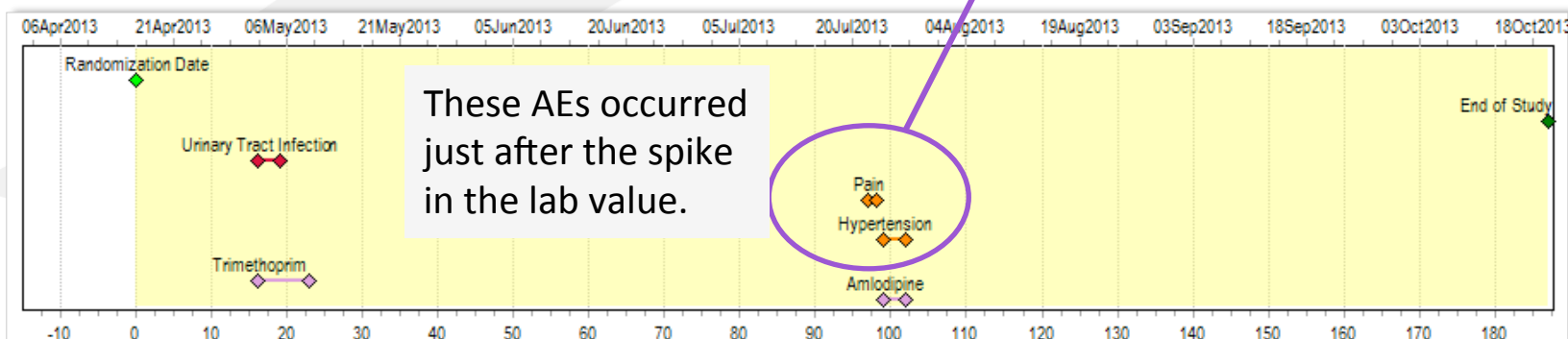
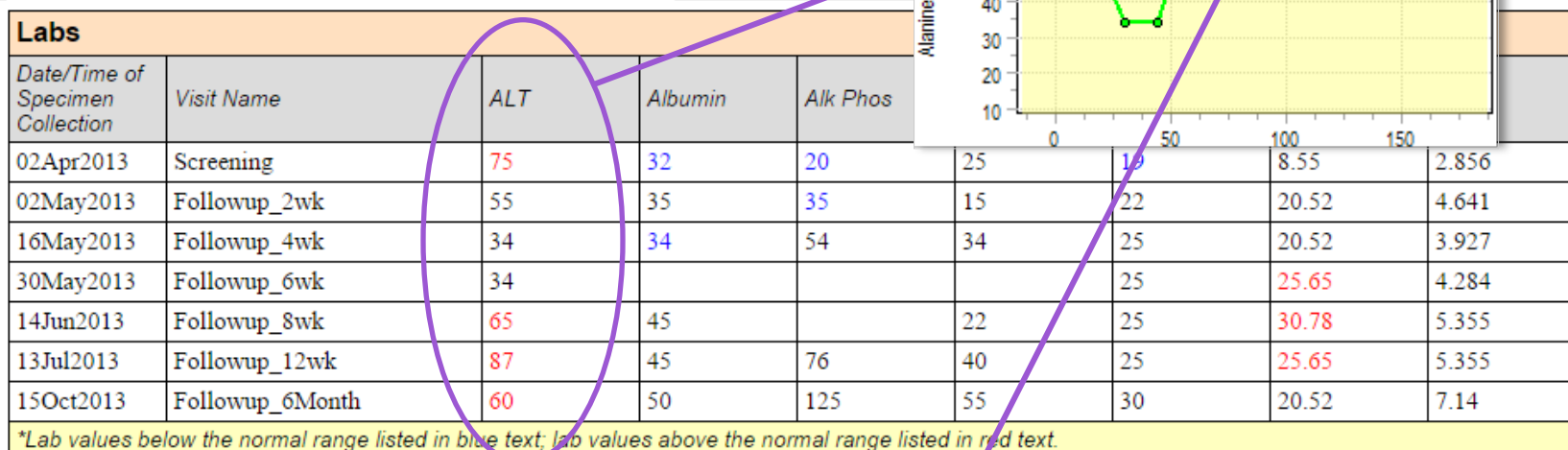
- Iterations to address for incomplete or inaccurate data
- Building a template for all (missing PC, EX)
- Integration issues.
- Automation may break due to data unpredictability



- View patient data in a visual “patient chart”



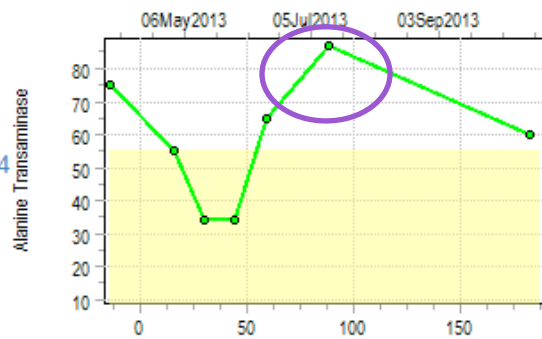
- Color-code tables to indicate high and low values
- View tables alongside graphs and timeline



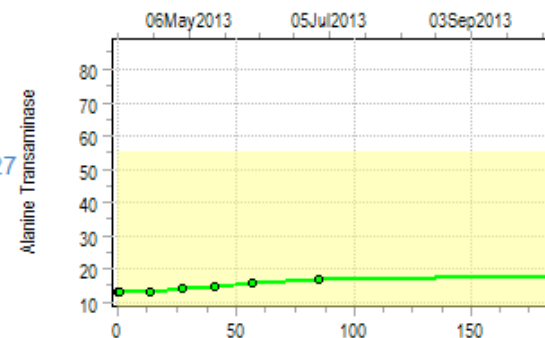
Portal – Trends

View all patients' ALT graphs together on one page to see if this patient's spike is unusual

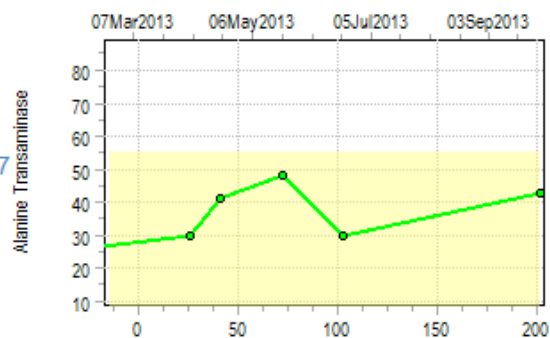
UBCM2013-BGH-174



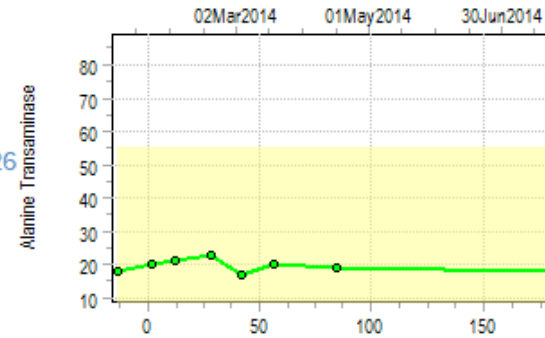
UBCM2013-BMC-127



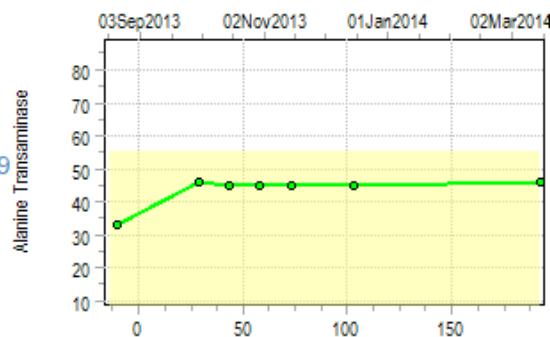
UBCM2013-BGH-147



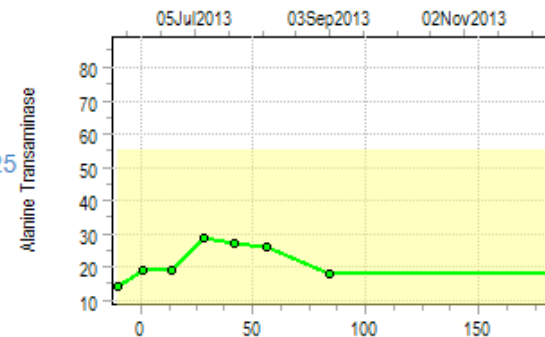
UBCM2013-BMC-126



UBCM2013-BGH-009



UBCM2013-BMC-125





■ Overall Incidence and Incidence By Site of Each Event

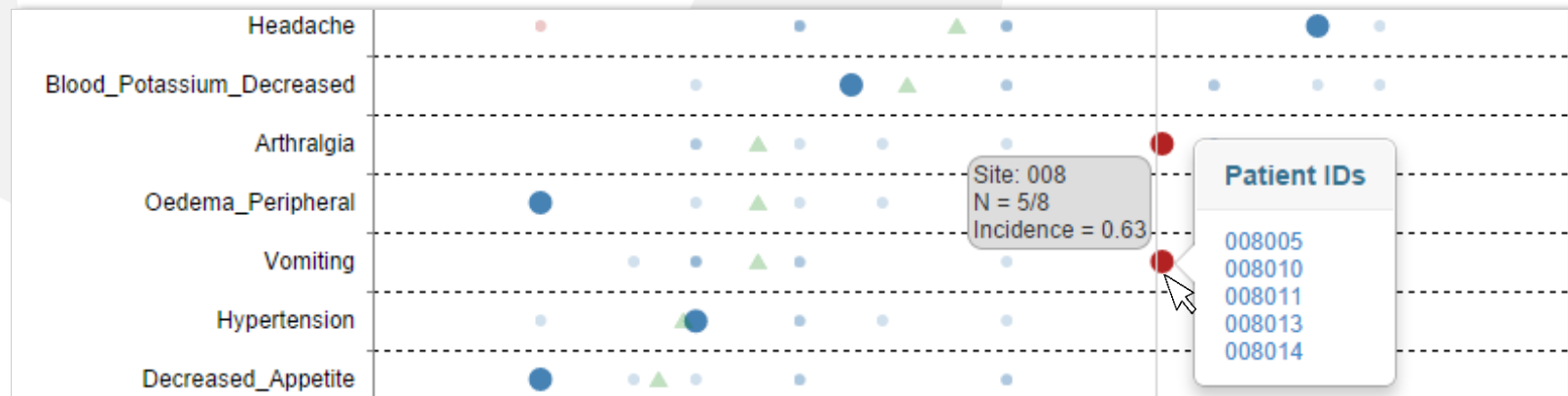


Portal – Interactive Summary AE Plot

- Vomiting at 1 site is statistically significantly greater than at all the other sites.



- Hover over the point and see the incidence for vomiting at that site, plus the patient IDs. Click on a patient ID to be brought to that patient's profile to view the AE in the context of the whole patient.



The shift in data visualization



- Need to do data exploration w/o programming
- Access outliers w/o exploration
- Looking for interactive dashboard and listings
- Sophisticated users: Click-through, web 2.0, exportable, color-rich, drag-and-drop

“Everything should be made as simple as possible, but no simpler.” - Albert Einstein