Planning DataFax Studies for CDISC Compliance

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Why Do We Need Data Standards? 1 of 3

- It takes approximately 15 years for a typical drug to go through the clinical development process!
- Such slowness is expensive, consuming both financial and human resources, which reduces the total research that can be done.
- An inefficient clinical development process is not just expensive but harmful to patients worldwide.

Why Do We Need Data Standards? 2 of 3

- Clinical trial designs have become larger and more complex over the past generation.

- The ability to electronically collect, archive, and manipulate large amounts of data with relative ease has led to more data being collected, which tends to make analyses increasingly complex and more time intensive to duplicate.

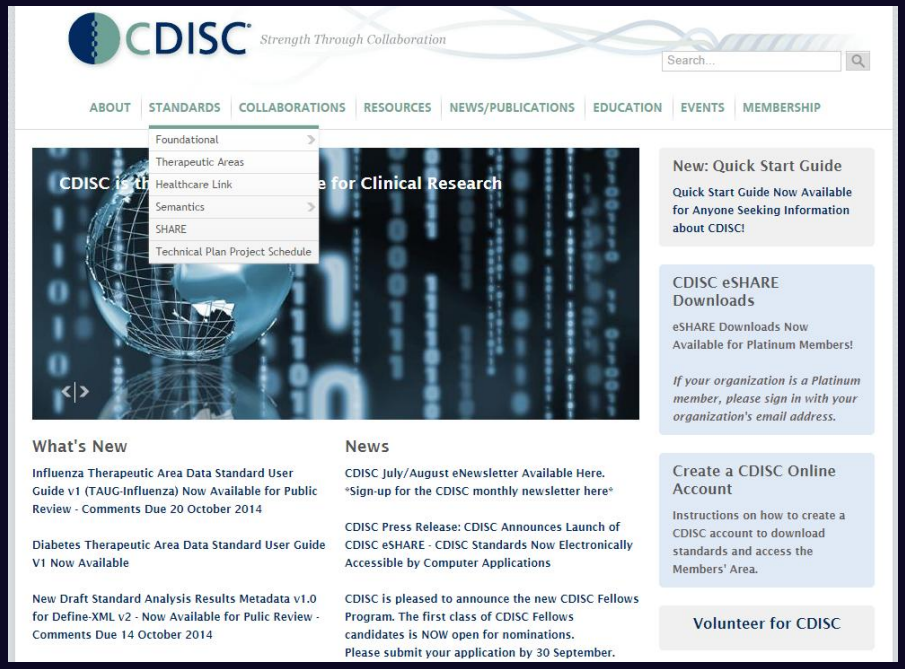
- Clinical trial documentation (e.g. Protocols, CSRs, SAPs, etc.) have correspondingly grown in length and complexity.

Why Do We Need Data Standards? 3 of 3

- Largest benefits are still primarily hypothetical.
- Perhaps the greatest potential benefit is easier meta-analyses. The FDA wants to be able to do sophisticated data mining on the ocean of clinical data it processes.
- It is hoped that better data standards will permit easier combination of clinical trial data with patient data. This is in its infancy.
- Personalized/genetic medicine will drive data to be used in a more sophisticated way.

What is CDISC? 1 of 3

- "CDISC is an open, multidisciplinary, non-profit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development."



What is CDISC? 2 of 3

- CDISC has high-level cross-pollination with some of the largest pharmaceutical companies and CROs.
- CDISC's board of directors includes current executives from Sanofi, Quintiles, GlaxoSmithKline, and AstraZeneca.
- CDISC is part of growing ecosystem of interconnected groups working to streamline the clinical development process, e.g. C-Path, TransCelerate, IHE, etc.

What is CDISC? 3 of 3

- The Clinical Data Interchange Standards Consortium (CDISC) was founded in 1997.
- Development of standards has been driven primarily using collaborative, consensus-based working groups.
- Most important data standards – ODM, CDASH*, SDTM, ADaM – have been available for a decade.

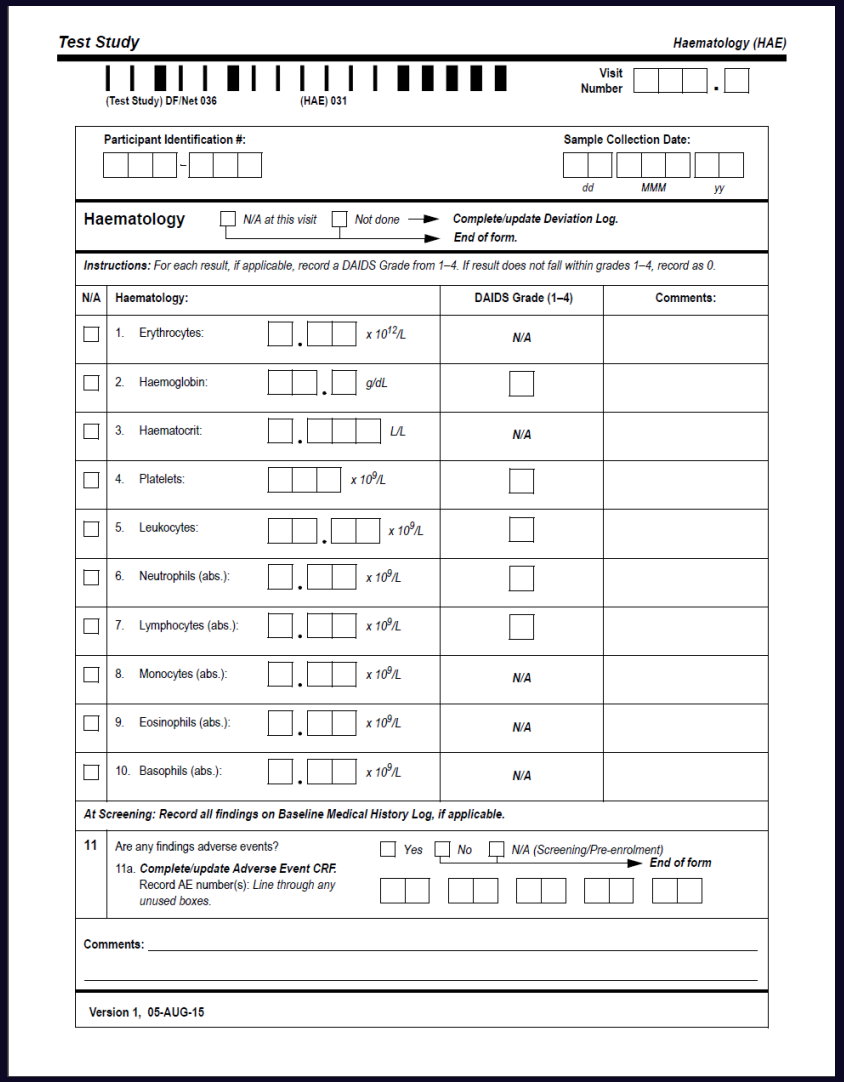
SDTM

- Standard Data Tabulation Module
- Standard structure for data tabulations
- Observations described by a series of variables
- Collected in domains: collection of logically related observations with a common topic

Domains

- Currently 44+ domains
  - DM: Demographics
  - VS: Vital Signs
  - LB: Laboratory Test Results
  - CM: Concomitant Medications
  - AE: Adverse Events
  - Etc.

Laboratory CRF



Test Study ***Haematology (HAE)***

(Test Study) DF/Net 036 (HAE) 031

Visit Number ☐☐☐.☐

Participant Identification #: ☐☐☐-☐☐☐

Sample Collection Date: ☐☐ dd ☐☐☐ MMM ☐☐ yy

Haematology ☐ *N/A at this visit* ☐ *Not done* → ***Complete/update Deviation Log.*** ***End of form.***

Instructions: *For each result, if applicable, record a DAIDS Grade from 1–4. If result does not fall within grades 1–4, record as 0.*

N/A	Haematology:	DAIDS Grade (1–4)	Comments:
☐	1. Erythrocytes: ☐.☐☐ x 10^{12}/L	*N/A*	
☐	2. Haemoglobin: ☐☐.☐ g/dL	☐	
☐	3. Haematocrit: ☐.☐☐☐ L/L	*N/A*	
☐	4. Platelets: ☐☐☐ x 10^{9}/L	☐	
☐	5. Leukocytes: ☐☐.☐☐ x 10^{9}/L	☐	
☐	6. Neutrophils (abs.): ☐.☐☐ x 10^{9}/L	☐	
☐	7. Lymphocytes (abs.): ☐.☐☐ x 10^{9}/L	☐	
☐	8. Monocytes (abs.): ☐.☐☐ x 10^{9}/L	*N/A*	
☐	9. Eosinophils (abs.): ☐.☐☐ x 10^{9}/L	*N/A*	
☐	10. Basophils (abs.): ☐.☐☐ x 10^{9}/L	*N/A*	

At Screening: Record all findings on Baseline Medical History Log, if applicable.

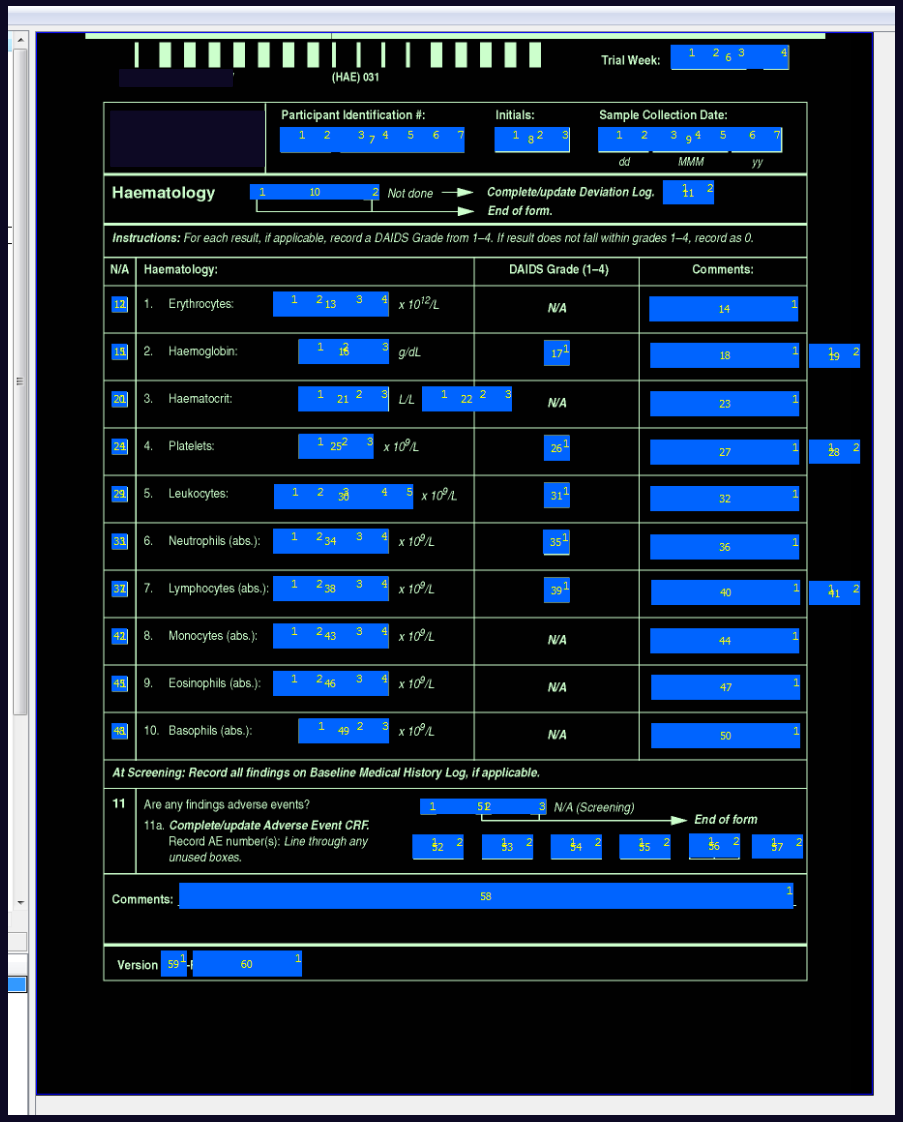
11 Are any findings adverse events? ☐ *Yes* ☐ *No* ☐ *N/A (Screening/Pre-enrolment)* → ***End of form***

11a. ***Complete/update Adverse Event CRF.*** Record AE number(s): *Line through any unused boxes.* ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Comments: _____

Version 1, 05-AUG-15

Setup: Previous DataFax Versions



(HAE) 031

Trial Week:

Participant Identification #: | Initials: | Sample Collection Date: (dd MMM yy)

Haematology — Not done → Complete/update Deviation Log. / End of form.

Instructions: *For each result, if applicable, record a DAIDS Grade from 1–4. If result does not fall within grades 1–4, record as 0.*

N/A	Haematology:	DAIDS Grade (1–4)	Comments:
12	1. Erythrocytes: x 10^{12}/L	N/A	14
19	2. Haemoglobin: g/dL	17	18
20	3. Haematocrit: L/L	N/A	23
24	4. Platelets: x 10^{9}/L	26	27
29	5. Leukocytes: x 10^{9}/L	31	32
33	6. Neutrophils (abs.): x 10^{9}/L	35	36
37	7. Lymphocytes (abs.): x 10^{9}/L	39	40
42	8. Monocytes (abs.): x 10^{9}/L	N/A	44
45	9. Eosinophils (abs.): x 10^{9}/L	N/A	47
48	10. Basophils (abs.): x 10^{9}/L	N/A	50

At Screening: Record all findings on Baseline Medical History Log, if applicable.

11 — Are any findings adverse events? N/A (Screening) → End of form

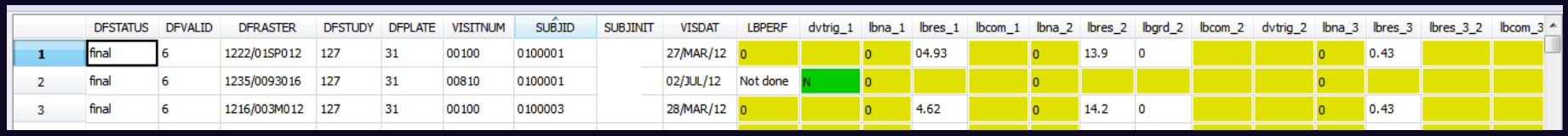
11a. ***Complete/update Adverse Event CRF.*** Record AE number(s): *Line through any unused boxes.* 52 53 54 55 56 57

Comments: 58

Version 59 – 60

Output: List View

- One row per record



	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	VISITNUM	SUBJID	SUBJINIT	VISDAT	LBPERF	dvtrig_1	lbna_1	lbres_1	lbcom_1	lbna_2	lbres_2	lbgrd_2	lbcom_2	dvtrig_2	lbna_3	lbres_3	lbres_3_2	lbcom_3
1	final	6	1222/01SP012	127	31	00100	0100001		27/MAR/12	0		0	04.93		0	13.9	0			0	0.43		
2	final	6	1235/0093016	127	31	00810	0100001		02/JUL/12	Not done	N	0			0					0			
3	final	6	1216/003M012	127	31	00100	0100003		28/MAR/12	0		0	4.62		0	14.2	0			0	0.43		

What CDISC Wants: SDTM Format

- One row per result

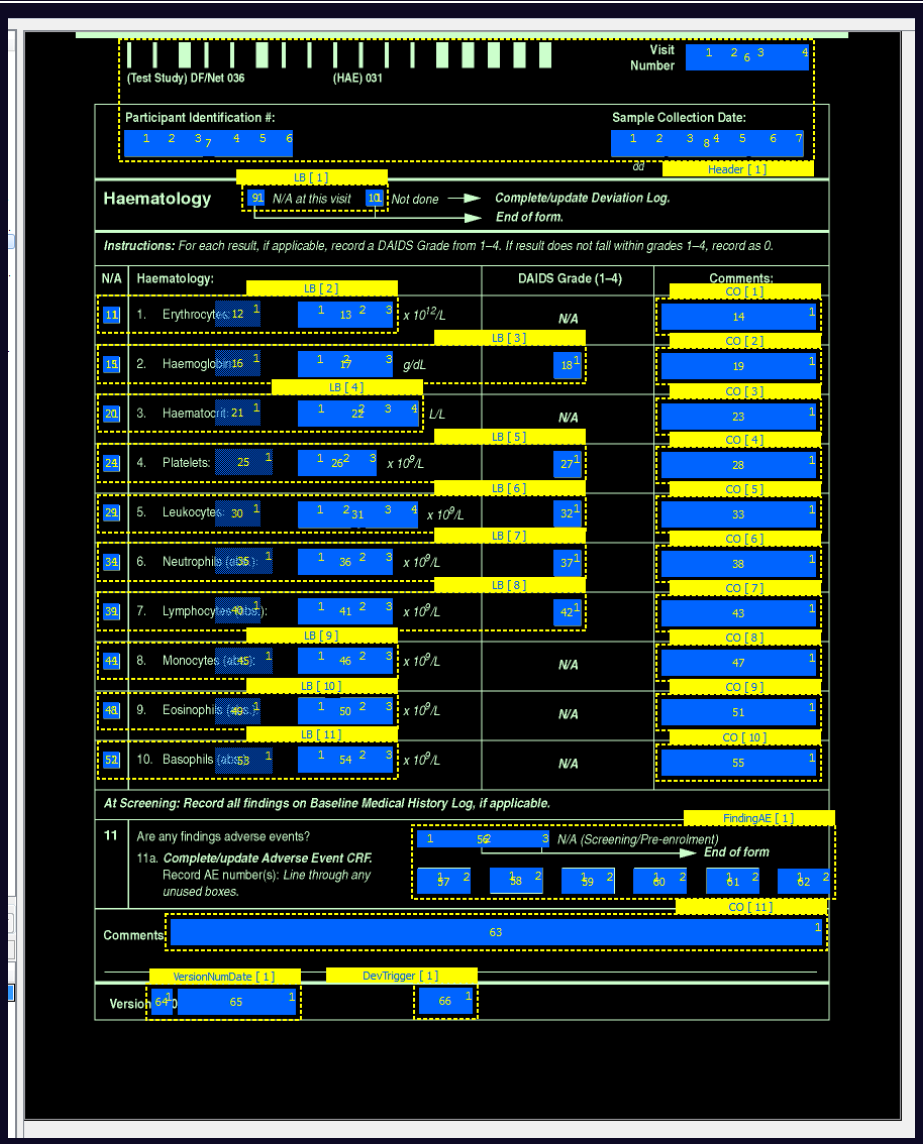
lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBORNRLO	LBORNRHI	LBSTRESC
1	ABC	LB	ABC-001-001	1	ALB	Albumin	CHEMISTRY		30	g/L	35	50	3.0
2	ABC	LB	ABC-001-001	2	ALP	Alkaline Phosphatase	CHEMISTRY		398	IU/L	40	160	398
3	ABC	LB	ABC-001-001	3	ALP	Alkaline Phosphatase	CHEMISTRY		350	IU/L	40	160	350
4	ABC	LB	ABC-001-001	4	ALP	Alkaline Phosphatase	CHEMISTRY						374
5	ABC	LB	ABC-001-001	5	WBC	Leukocytes	HEMATOLOGY		5.9	10^9/L	4	11	5.9
6	ABC	LB	ABC-001-001	6	LYMLE	Lymphocytes	HEMATOLOGY	DIFFERENTIAL	6.7	%	25	40	6.7
7	ABC	LB	ABC-001-001	7	NEUT	Neutrophils	HEMATOLOGY	DIFFERENTIAL	5.1	10^9/L	2	8	5.1
8	ABC	LB	ABC-001-001	8	PH	pH	URINALYSIS		7.5		5.0	9.0	7.5

How to Achieve This in DataFax?

- Previous versions: mapping behind the scenes (e.g., in SAS)
- 2014.1: modules!
- Think of a module as a domain

Setup: 2014.1 Using Modules



Output: List View: Modules

	DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	DFPID	DFMNAME	DFMID	DFMREF	LBORRES	LBSTAT	LBTESTCD	LBDTC	lbstna	DFCREATE	DFMODIFY
1	incomplete	1	1518R0015001	35	18	1010	000001	LB2	5195	1	Reactive	Unchecked	HIVELISA		Unchecked	15/05/05 14:11:43	15/05/05 14:13:40
2	incomplete	1	1518R0016002	35	21	1010	000001	LB2	5195	1	Negative	Unchecked	TRICH		Unchecked	15/05/05 14:23:28	15/05/05 14:23:28
3	incomplete	1	1518R0016002	35	21	1010	000001	LB2	5195	2	Negative	Unchecked	NGON		Unchecked	15/05/05 14:23:28	15/05/05 14:23:28
4	incomplete	1	1518R0016002	35	21	1010	000001	LB2	5195	3	Not detected	Unchecked	CHLAMYDI		Unchecked	15/05/05 14:23:28	15/05/05 14:23:28
5	incomplete	1	1518R0016002	35	21	1010	000001	LB2	5195	4	Negative	Unchecked	HBSAB		Unchecked	15/05/05 14:23:28	15/05/05 14:23:28
6	incomplete	1	1518R0016002	35	21	1010	000001	LB2	5195	5	Negative	Unchecked	HCSAB		Unchecked	15/05/05 14:23:28	15/05/05 14:23:28

- Much closer to what we need
- One row per result
- Pulls lab data from different plates
- Less mapping behind the scenes

DFexport: Modules, 1 of 2

- Data records are exported in ASCII plain text format

DFexport

DFexport — Client-side, command-line interface for exporting data by plate, field or module

Synopsis

`DFexport` [-S *server*] [-U *username*] [-C *password*] [-Mname *moduleName* | -Mnum *moduleID* | -Pnum [# | qc | reason | new | lost]] [-status *#, #-#*] [-level *#, #-#*] [-visit *#, #-#*] [-site *#, #-#* | -patient *#, #-#*] [-plate *#, #-#*] [-create *list*] [-modify *list*] [-resolve *list*] [-Pattern *string* | -pattern*string*] [-expr *string*] [-ALL *criteria* | -ANY *criteria*] [-Fnum *#, #-#* | -Fname *field-name_list* | -Falias *fieldalias_list*] [-joinALL plt#[*moduleFields*]... | -joinANY plt#[*module-Fields*]...] [-c | -j] [-d] [-p] [-z] [-h] [-H *header_list*] [-L *lostcode*] [-w | -a] [-o [*outfile* | -]] [-e *errlog*] {*study#*}

DFexport: Modules, 2 of 2

- Records can be exported by plate

DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	DFPID	DFMNAME	DFMID	DFMREF	ptid	Date	visit	POunk	RCXrptdt	DFCREATE	DFMODIFY
1	3	1506/001D016	10	124	0200	138640018	Header	5332	1	138640018	09/FEB/2015	0200			15/02/10 11:22:34	15/02/23 15:34:55
1	3	1506/001Z003	10	124	0200	138640033	Header	5332	1	138640033	11/FEB/2015	0200			15/02/11 10:46:30	15/02/23 15:52:54
4	2	1507/000Y002	10	124	0200	138640065	Header	5332	1	138640065	12/FEB/2015	0200			15/02/17 11:59:16	15/02/17 11:59:16
1	3	1507/002C002	10	124	0200	138640065	Header	5332	1	138640065	12/FEB/2015	0200			15/02/17 11:59:16	15/02/23 16:24:20
1	3	1507/0025001	10	124	0200	138640090	Header	5332	1	138640090	16/FEB/2015	0200			15/02/17 12:07:55	15/02/23 16:37:53
1	3	1507/0035001	10	124	0200	138640139	Header	5332	1	138640139	18/FEB/2015	0200			15/02/19 10:52:05	15/02/23 16:47:57
1	3	1508/0005001	10	124	0200	138640170	Header	5332	1	138640170	19/FEB/2015	0200			15/02/19 10:58:46	15/02/23 16:56:34
4	2	1508/002V002	10	124	0200	138640214	Header	5332	1	138640214	24/FEB/2015	0200			15/02/24 11:10:31	15/02/24 11:10:31
1	3	1508/002W001	10	124	0200	138640214	Header	5332	1	138640214	24/FEB/2015	0200			15/02/24 11:10:31	15/02/24 17:46:43
1	3	1509/000J001	10	124	0200	138640286	Header	5332	1	138640286	26/FEB/2015	0200			15/02/27 12:59:31	15/03/03 14:26:25
1	3	1509/001H002	10	124	0200	138640299	Header	5332	1	138640299	26/FEB/2015	0200			15/03/02 10:49:56	15/03/03 14:37:59
1	3	1510/0007001	10	124	0200	138640317	Header	5332	1	138640317	05/MAR/2015	0200			15/03/05 13:23:19	15/03/05 13:45:18
4	3	1509/001M001	10	124	0200	138640334	Header	5332	1	138640334	02/MAR/2015	0200			15/03/02 10:53:50	15/03/03 14:46:25
4	2	1510/0032001	10	124	0200	138640334	Header	5332	1	138640334	02/MAR/2015	0200			15/03/02 10:53:50	15/03/09 10:59:23
1	2	1510/003T001	10	124	0200	138640334	Header	5332	1	138640334	02/MAR/2015	0200			15/03/02 10:53:50	15/03/10 09:26:07
1	3	1509/002K015	10	124	0200	138640369	Header	5332	1	138640369	03/MAR/2015	0200			15/03/03 10:13:29	15/03/03 14:51:42
1	3	1510/0001001	10	124	0200	138640452	Header	5332	1	138640452	05/MAR/2015	0200			15/03/05 13:08:58	15/03/05 14:14:30
1	2	1510/0027001	10	124	0200	138640471	Header	5332	1	138640471	05/MAR/2015	0200			15/03/09 10:08:29	15/03/09 10:08:29

- Or across plates by module

DFSTATUS	DFVALID	DFRASTER	DFSTUDY	DFPLATE	DFSEQ	DFPID	DFMNAME	DFMID	DFMREF	LBTESTCD	LBORRES	LBSTAT	LBTOX	pcrdone	LBDTC	pcrqual	pcrntdt	rbcabs	wbcabs	rbcless	wbcless	rbcgr	wbcgr	lbstna	glucbel	DFCREATE	DFMODIFY
2	1	1518R0015001	35	18	1010	000001	LB	5164	1	HIVPCR	00200000	0		1	01/MAY/15	2	0							0		15/05/05 14:11:43	15/05/05 14:13:40
2	1	1518R0016001	35	19	1010	000001	LB	5164	1	PH	3.0															15/05/05 14:23:03	15/05/05 14:23:03
2	1	1518R0014001	35	31	1010	000001	LB	5164	1			0														15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	2	RBC	3.50													0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	3	HGB	10.5		1											0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	4	HCT	0.301													0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	5	PLAT	137		0											0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	6	WBC	02.90		0											0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	7	NEUT	1.56		0											0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	8	LYM	0.98		0											0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	9	MONO	0.20													0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	10	EOS	0.06													0		15/05/05 13:50:16	15/05/05 13:52:28
2	1	1518R0014001	35	31	1010	000001	LB	5164	11	BASO	0.10													0		15/05/05 13:50:16	15/05/05 13:52:28

DFsas: Modules

- In the process of implementing this – coming soon!

Questions?