

Updates to the IR-4 Master Schedule / eDOCs – an electronic document management system

Feb. 28 - March 1, 2017

Tammy W. Barkalow RQAP-GLP Assistant Director, Quality Assurance And Special Guest



Master Schedule

- What is a master schedule?
- What are the fields available to sort a master schedule?
- What has been changed on the master schedule?
- How is the master schedule used?



Master Schedule

What is a master schedule?

a master schedule sheet of <u>all studies</u> conducted at the testing facility indexed by <u>test substance</u>, and <u>containing the test system</u>, <u>nature of study</u>, <u>date study was initiated</u>, <u>current status of each study</u>, <u>identity of the sponsor</u>, and <u>name of the study director</u>.



Master Schedule - What is Required?

- all studies conducted at the testing facility
- indexed by test substance, and
- containing the test system,
- nature of study,
- date study was initiated,
- current status of each study,
- identity of the sponsor, and
- name of the study director
- The IR-4 master schedule is explained in HQ SOP 4.4 r7



IR-4 MASTER SCHEDULE (IR-4=SPONSOR) All Studies MOR Unless Coded Otherwise Estimated Dates except for ACT (=ACTUAL DATES) Good Laboratory Practice Studies (GLP) Studies

Print Date: 2/21/2017

_	CUEMICAL (COMMODITY	FIELD DESCAPOLI	FIELD.	FIEL D	COLLECT	CAMPI FO	EIEL D				LAD	LAD	ACT. STUDY		EVD	ACT. STUDY
PR#	STUDY DIRECTOR/AUDITOR	FIELD RESEARCH DIRECTOR (FRD)	FIELD ID#	FIELD START	SAMPLE	SAMPLES SHIPPED	COMP.	RFC	TO QA Rec		LAB START	LAB COMP		EXP. START	EXP. TERM.	COMP
11111	IPCONAZOLE ONION (SEED TRT) LENNON/HQ	Seed Treatment	NA NA	_		_	_		NA	ST-SGS01		_		3 02/13	_	
1111	IPCONAZOLE ONION (SEED TRT)															- —
-	LENNON/HQ	Stewart, D.	13-CA103	NA	10/01/13	10/31/13	11/30/13	12/06/13	12/17/13 03/21/	14 13-TIR03	06//13	3	02/05/13	02/13	11/14	
	•	Boutwell, Brent	13-CA104				DROPPED		09/30/	16 13-TIR03	06//13	DISCARD				
		Skiles, Keri	13-CA105	NA	08/05/13	08/15/13	10/15/13	08/22/13	12/10/13 03/19/	14 13-TIR03	06//13	3				
		Benzen, Ms. Sharon D.	13-CA*106	NA	10/01/13	10/15/13	12/31/13	02/20/14	02/27/14 04/09/	14 13-TIR03	06//13	3				
		Meeks, Mr. Will	13-ID11	NA	08/20/13	10/20/13	12/20/13	02/04/14	05/25/14 07/10/	14 13-TIR03	06//13	3				
		Ross, Marylee	13-MD20				DROPPED		04/20/	16 13-TIR03	06//13	DISCARD				
		Craig, Maury (NMSU)	13-NM16				DROPPED		04/23/	14 13-TIR03	06//13	DISCARD				
		Bellinder, Dr. Robin	13-NY17				DROPPED		11/18/	13 13-TIR03	06//13	DISCARD				
		Riddle, Geoff	13-ON09	NA	08/28/13	10/30/13	12//13		05/27/14 07/07/	14 13-TIR03	06//13	3				
		Riddle, Geoff	13-ON10	NA	07/15/13	10/30/13	12//13		05/27/14 07/08/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC10	NA	08/23/13	10/15/13	11/15/13	12/29/13	05/27/14 07/08/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC15	NA	08/22/13	10/15/13	11/15/13	12/29/13	05/27/14 07/11/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC16	NA	08/16/13	09/01/13	10/01/13	12/29/13	05/27/14 09/16/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC17	NA	08/16/13	09/01/13	10/01/13	12/29/13	05/27/14 09/17/	14 13-TIR03	06//13	3				
		Hadd, Renaud	13-QC21				DROPPED		07/16/	14 13-TIR03	06//13	DISCARD				
		Hadd, Renaud	13-QC22				DROPPED		07/16/	14 13-TIR03	06//13	DISCARD				
		Wade, Paul	13-SC*12	NA	06/05/13	07/10/13	08/21/13	11/13/13	12/02/13 02/20/	14 13-TIR03	06//13	3				
		Rodriguez, Alfredo	13-TX20				DROPPED		07/07/	14 13-TIR03	06//13	DISCARD				
		Craig, Maury (NMSU)	14-NM499				DROPPED		NA	13-TIR03	06//13	DISCARD				
		Bellinder, Dr. Robin	14-NY333	NA	08/27/14	08/29/14	09/30/14	10/28/14	11/21/14 12/05/	14 13-TIR03	06//13	3				
		Jobin, Tristan	14-QC411	NA	08/22/14	09/15/14	11/15/14	11/10/14	11/25/14 12/09/	14 13-TIR03	06//13	3				
		Jobin, Tristan	14-QC412	NA	08/22/14	09/15/14	11/15/14	11/10/14	11/25/14 12/08/	14 13-TIR03	06//13	3				
		Rodriguez, Alfredo	14-TX495	10/01/14	03/18/15	04/08/15	05/30/15	06/23/15	10/01/15 10/21/	15 13-TIR03	06//13	3				



Master Schedule

FIELD ID# - year + state + (* if ARS) + trial number assigned

<u>FIELD START</u> – estimated date from FRD (From letter sent with FDB**** VERY IMPORTANT LETTER****)

COLLECT SAMPLE – estimated date from FRD

SAMPLES SHIPPED - estimated date from FRD

FIELD COMP. - estimated date from FRD

RFC - date HQ receives from FRD on the blue postcard that the FDB has gone to the RFC



RFC TO QA – date HQ receives QC info from RFC indicating the FDB has been sent to QA HQ Recd. - Date FDB is received at HQ LAB ID# - year + Lab code + assigned sequential # of studies at that lab LAB START – estimated date from the lab LAB COMP – date ASR / contributing Scientist report is received at HQ



- The dates (estimated) are not replaced with an actual date once the activity occurs.
- They are only replaced with new dates if circumstances (such as unfavorable weather) require that the trial initiation be delayed to later in the year.



IR-4 MASTER SCHEDULE (IR-4=SPONSOR) All Studies MOR Unless Coded Otherwise Estimated Dates except for ACT (=ACTUAL DATES) Good Laboratory Practice Studies (GLP) Studies

Print Date: 2/21/2017

_	CUEMICAL (COMMODITY	FIELD DESCAPOLI	FIELD.	FIEL D	COLLECT	CAMPI FO	EIEL D				LAD	LAD	ACT. STUDY		EVD	ACT. STUDY
PR#	STUDY DIRECTOR/AUDITOR	FIELD RESEARCH DIRECTOR (FRD)	FIELD ID#	FIELD START	SAMPLE	SAMPLES SHIPPED	COMP.	RFC	TO QA Rec		LAB START	LAB COMP		EXP. START	EXP. TERM.	COMP
11111	IPCONAZOLE ONION (SEED TRT) LENNON/HQ	Seed Treatment	NA NA	_		_	_		NA	ST-SGS01		_		3 02/13	_	
1111	IPCONAZOLE ONION (SEED TRT)															- —
-	LENNON/HQ	Stewart, D.	13-CA103	NA	10/01/13	10/31/13	11/30/13	12/06/13	12/17/13 03/21/	14 13-TIR03	06//13	3	02/05/13	02/13	11/14	
	•	Boutwell, Brent	13-CA104				DROPPED		09/30/	16 13-TIR03	06//13	DISCARD				
		Skiles, Keri	13-CA105	NA	08/05/13	08/15/13	10/15/13	08/22/13	12/10/13 03/19/	14 13-TIR03	06//13	3				
		Benzen, Ms. Sharon D.	13-CA*106	NA	10/01/13	10/15/13	12/31/13	02/20/14	02/27/14 04/09/	14 13-TIR03	06//13	3				
		Meeks, Mr. Will	13-ID11	NA	08/20/13	10/20/13	12/20/13	02/04/14	05/25/14 07/10/	14 13-TIR03	06//13	3				
		Ross, Marylee	13-MD20				DROPPED		04/20/	16 13-TIR03	06//13	DISCARD				
		Craig, Maury (NMSU)	13-NM16				DROPPED		04/23/	14 13-TIR03	06//13	DISCARD				
		Bellinder, Dr. Robin	13-NY17				DROPPED		11/18/	13 13-TIR03	06//13	DISCARD				
		Riddle, Geoff	13-ON09	NA	08/28/13	10/30/13	12//13		05/27/14 07/07/	14 13-TIR03	06//13	3				
		Riddle, Geoff	13-ON10	NA	07/15/13	10/30/13	12//13		05/27/14 07/08/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC10	NA	08/23/13	10/15/13	11/15/13	12/29/13	05/27/14 07/08/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC15	NA	08/22/13	10/15/13	11/15/13	12/29/13	05/27/14 07/11/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC16	NA	08/16/13	09/01/13	10/01/13	12/29/13	05/27/14 09/16/	14 13-TIR03	06//13	3				
		Jobin, Tristan	13-QC17	NA	08/16/13	09/01/13	10/01/13	12/29/13	05/27/14 09/17/	14 13-TIR03	06//13	3				
		Hadd, Renaud	13-QC21				DROPPED		07/16/	14 13-TIR03	06//13	DISCARD				
		Hadd, Renaud	13-QC22				DROPPED		07/16/	14 13-TIR03	06//13	DISCARD				
		Wade, Paul	13-SC*12	NA	06/05/13	07/10/13	08/21/13	11/13/13	12/02/13 02/20/	14 13-TIR03	06//13	3				
		Rodriguez, Alfredo	13-TX20				DROPPED		07/07/	14 13-TIR03	06//13	DISCARD				
		Craig, Maury (NMSU)	14-NM499				DROPPED		NA	13-TIR03	06//13	DISCARD				
		Bellinder, Dr. Robin	14-NY333	NA	08/27/14	08/29/14	09/30/14	10/28/14	11/21/14 12/05/	14 13-TIR03	06//13	3				
		Jobin, Tristan	14-QC411	NA	08/22/14	09/15/14	11/15/14	11/10/14	11/25/14 12/09/	14 13-TIR03	06//13	3				
		Jobin, Tristan	14-QC412	NA	08/22/14	09/15/14	11/15/14	11/10/14	11/25/14 12/08/	14 13-TIR03	06//13	3				
		Rodriguez, Alfredo	14-TX495	10/01/14	03/18/15	04/08/15	05/30/15	06/23/15	10/01/15 10/21/	15 13-TIR03	06//13	3				





IR-4 MASTER SCHEDULE (IR-4=SPONSOR) All Studies MOR Unless Coded Otherwise Estimated Dates except for ACT (=ACTUAL DATES) Good Laboratory Practice Studies (GLP) Studies

Print Date: 2/21/2017

CHEMICAL/COMMODITY PR# STUDY DIRECTOR/AUDITOR	FIELD RESEARCH DIRECTOR (FRD)	FIELD ID#	FIELD START		SAMPLES SHIPPED	FIELD COMP.	REC	TO QA	HQ Recd.	LAB ID#	LAB START	LAB COMP	ACT. STUDY INIT.	EXP. START	EXP. TERM.	ACT. STUDY COMP.
A11286 METALDEHYDE ALL CROPS XX-WALKER/HQ	Reference Characteriztion N	IA	NA	NA	NA	NA			NA	RC-RCR01	05/05	02/06	05/01/0	5 05/05	08/07	02/06
B11266 METALDEHYDE ALL CROPS XX-WALKER/HQ	Reference Characteriztion N		NA NA	NA NA	NA NA	NA NA			NA NA	RC-RCR01	08/19/0	8 09/08	06/01/0	8 06/08	07/08	09/08
C11288 METALDEHYDE ALL CROPS XX-WALKER/HQ	Reference Characteriztion N	IA	NA	NA .	NA .	NA			NA .	RC-RCR01	05/14/1	2 01/13	05/14/1	2 05/12	08/12	01/15/13

Total # of PRs:

1



- What are the fields available to sort a master schedule?
- PR#
- Chemical
- Commodity (crop/test system)
- Field study year
- Field Trial Location State
- Study completed: yes or no
- Status: XX- archived, XC cancelled



- What are the fields available to sort a master schedule? Cont.
- FRD name of GLP FRD from protocol
- Lab study year date assigned to the lab
- Processing Lab
- Analytical/Seed Treatment Lab
- Study QA Auditor
- Study Director
- Test Site Facility *****recently updated
- Boxes on the bottom



- What has been changed on the master schedule?
- Test Site Facility (Center):
 - Audited the list of FRDs associated with the centers and made major corrections
 - Updated the names of the Test Site Facilities to harmonize with the nomenclature used in eQA
 - Added several new elements for looking up studies or trials
 - Listed Canadian studies so FRDs have their Canadian Sponsored trials on their master schedules (updated quarterly)



- How is the master schedule used?
 - <u>FRD</u>
 - shows your test sites historical list of trials
 - If sorted by "study completed –yes" can see which containers maybe be discarded
 - QA sorted by multiple ways to retrieve information about test sites, studies, status of FDB reviews, completion of studies, etc.
 - <u>EPA</u> uses to select a current/recent trial for auditing during an inspection
 - <u>Lab</u> can use to check estimated dates for sample shipment and see when last shipment is expected



Demos:

- How to find out if all studies are done for a specific chemical and site?
- What about for a specific FRD?
- How can I check where my FDBs are?
- How do I know if a study is close to being done?
- When was the last time we performed a trial on a specific chem/crop?
- Where else are trials going on?



Electronic QA Reporting System - eQA

Update:

- 3435 audit packets have been created in the eQA system since Oct. 2013
- Locations (102) and permissions groups (206)
 differentially assigned to the 142+ users identified and
 entered into the system
- eQA Vender, QSI has updated the software to version
 7.2
- eQA was also updated to permit document management. We now call our system eQA/eDOCs.



eDOCs

eDOCs

- Allows us to post documents (pdfs) to the system (using for analytical methods and certificates of analysis)
- Allows us to notify individuals that a new document is available (using for QA protocols) and have them acknowledge receipt
- Permits us to post confidential documents and provide them to a controlled list of users
- Will permit us to form review groups on active documents (doc share), collect comments (doc review), electronically approve documents (HQ SOPs) and assign training events that are captured and documented by the system.



eQA / eDOCs

Go To eQA/eDOCs -

- Demo how to bring up C of As?
- How do I look for protocol and changes for:
 - a study?
 - for a chemical?
 - For all protocols of a given crop?

How do I set up a "favorites search"?