



## The IR-4 Process (cont'd)

**Organizing/establishing/  
implementing the QA  
schedule and monitoring  
program**



## Implementing the QA Schedule

- The IR-4 QAU
- Spring Planning
- Assigned QA
- Timelines and Submission Schedules

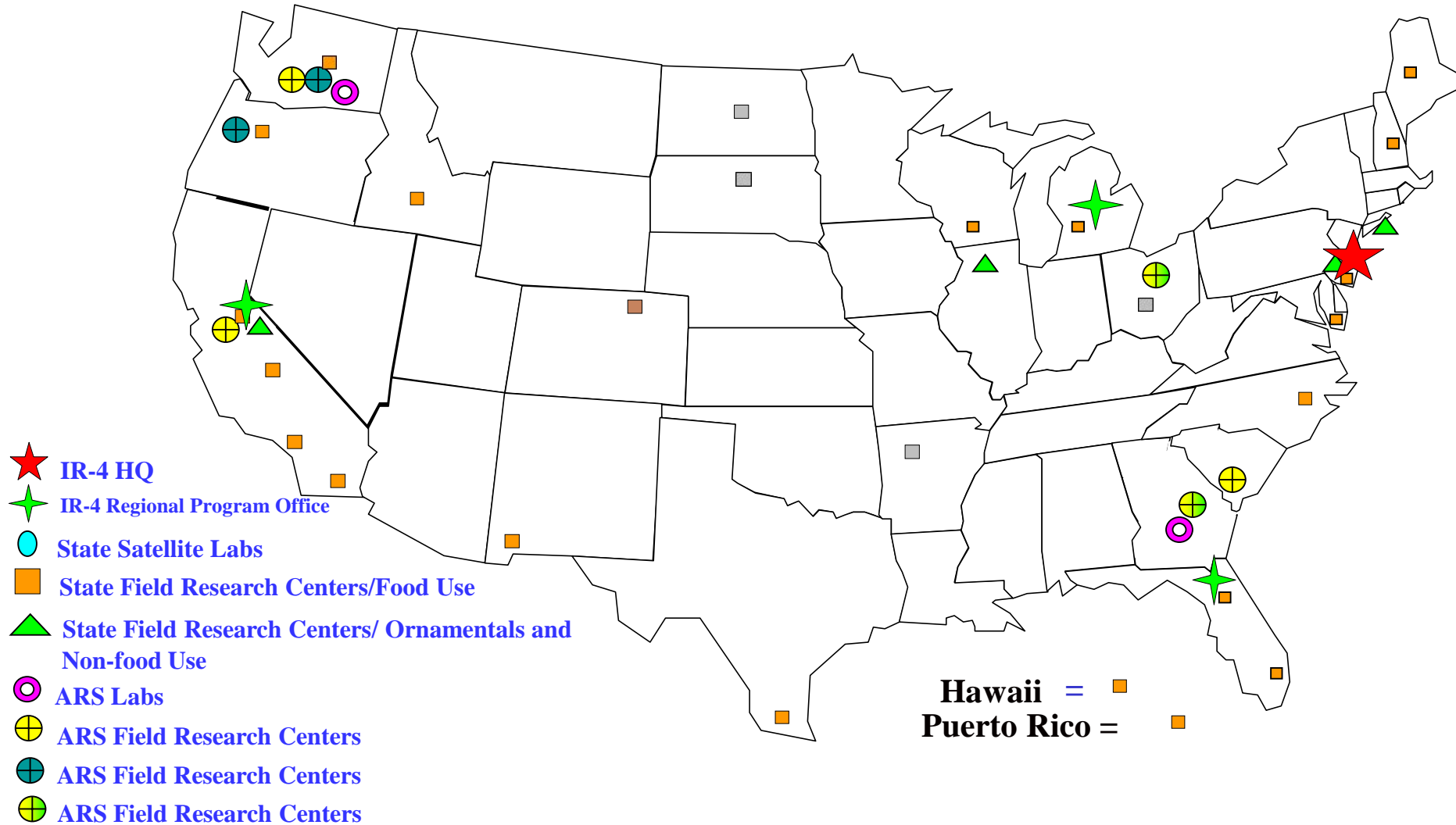
## The IR-4 QAU

- Headquarters – Tammy, Jane and Juliet
- North Eastern - Jane
- North Central – Michael and Lisa (Eileen at Univ of Wisconsin)
- Southern – Kathleen and Yavuz (Lisa at Tifton)
- Western - Martin and Sherita (Mary Lynn at Yakima)

## Implementing the QA Schedule

- Spring Planning Meeting
  - Field QA Inspections
  - Field Data Book Audits
  - Analytical in-life Inspections
  - Analytical Data and Summary Report Audits
  - Final Report Inspections

**IR-4 Project Infrastructure - Pesticide Residue work  
 65 studies/450 field trials**





## Implementing the QA Schedule

Field QA Inspections:

Adequate # for each test site

Adequate # for each Study

Target 25% inspection coverage



# Implementing the QA Schedule

ID	# of trials	Cooperator	PR#	Field Trial	Trial Targeted	Lab	Center	State	Reg	Assigned QA	Region	Priority	Study Director	Chemical	Commodity	Comment
1																
531	1	Jordon, Grant	12666	20-NY01	done	20-	NER ACDS	NY						FLUPYRADIFURONE (BAYER)	Beets, Greens	
436	1	Stinn, Lisa	12477	19-K*188		19-CANADA		K*	K	k	CANADA	A	AHN	PYRIDATE (BELCHIM)	MINT	(Reg 7A)
2	1	Oman, Clark (CAT)	12570	19-CO117	T, done	19-YAR01	WSR Field Compass Agri-Tech	CO	W	h	WSR	A	LENNON	QUINCLORAC (ADAMA,ALBAGH)	APPLE	
437	1	Spotanski, Jess	09907	19-NE485	T, done	19-MIR14	NCR Field Midwest Research	C*	C	c	NCR	B	SAMOIL	FLONICAMID (FMC,ISK)	BEET (SUGAR)	added 4/1/19
3	2	Clodius, Markus	12373	19-CBC259		19-CANADA		BC	K	k	CANADA	A	MALEGUS	BENZOINDIFLUPYR (SYNGEN)	STRAWBERRY	
4	2	Clodius, Markus	12515	19-BC426	T, done	19-FLR03		BC	K	s	CANADA	A	PIKE	CYCLANILIPROLE (ISK)	LETTUCE (GH)	
6	2	Hausbeck, Dr. Mary K.	12291	19-MI415	T, done	19-FLR08	NCR Field MSU Hausbeck	MI	C	s	NCR	A	HOMA	PICARBUTRAZOX (NISSO)	LETTUCE (GH)	
5	2	Hausbeck, Dr. Mary K.	11691	19-MI409	T	19-YAR05	NCR Field MSU Hausbeck	MI	C	h	NCR	A	BARNEY	DIMETHOMORPH + AMETOCTRADIN (BASF)	TOMATO (GH)	(small)
9	2	Palmer, Scott	12220	19-NY277	T, done	19-MIR08	NER Field Reality Research	NY	E	c	NER	A	BONETTI	DIQUAT (SYNGEN)	GRAPE	
12	2	Sylvia, Marty	10361	19-MA192	T, done	19-CAR19	NER Field U of Mass	MA	E	w	NER	A	BONETTI	TEBUCONAZOLE (ADAMA,ALBAGH,BAYER)	CRANBERRY	
11	2	Sylvia, Marty	12639	19-MA194	T, done	19-FLR03	NER Field U of Mass	MA	E	s	NER	A	LENNON	QUINCLORAC (ADAMA,ALBAGH)	CRANBERRY	(Decline)
13	2	Van Woerkom, Anthony	11995	19-MI208	T, done	19-CAR09	NCR Field MSU Fennville (TNRC)	MI	C	w	NCR	A	SAMOIL	BIFENAZATE (MACDERMID,UPL NA)	BLUEBERRY	
14	2	Van Woerkom, Anthony	11995	19-MI209		19-CAR09	NCR Field MSU Fennville (TNRC)	MI	C	w	NCR	A	SAMOIL	BIFENAZATE (MACDERMID,UPL NA)	BLUEBERRY	
15	3	Nield, David	12293	19-BC16	T, done	19-MIRO2		BC	K	c	CANADA	A	SAMOIL	FLONICAMID (FMC,ISK)	BASIL (GH)	
16	3	Nield, David	12511	19-BC424		19-CAR08		BC	K	w	CANADA	A	HOMA	FLUTIANIL (LANDIS,NAI,OATAGRIO)	CUCUMBER (GH)	(decline)(miniature variety)
17	3	Nield, David	12291	19-BC15		19-FLR08		BC	K	s	CANADA	A	HOMA	PICARBUTRAZOX (NISSO)	LETTUCE (GH)	
21	4	Chapman, Scott	11920	19-WI206		19-FLR12	NCR Field UWIS Arlington	WI	C	s	NCR	A	HOMA	FLUAZINAM (ISK,SYNGEN)	STRAWBERRY (NON-BEARING)	
18	4	Chapman, Scott	11752	19-WI410	T	19-FLR11	NCR Field UWIS Arlington	WI	C	s	NCR	A	PIKE	BOSCALID + PYRACLOSTROBIN (BASF)	STRAWBERRY (GH)	
19	4	Chapman, Scott	11790	19-WI411		19-CAR04	NCR Field UWIS Arlington	WI	C	w	NCR	A	PIKE	CYFLUMETOFEN (BASF)	PEPPER (BELL & NONBELL)	(bell)
20	4	Chapman, Scott	12075	19-WI414	T, done	19-YAR02	NCR Field UWIS Arlington	WI	C	h	NCR	A	PIKE	ETHABOXAM (VALENT)	CELERY (GH TRANSPLANT, FIELD)	
23	4	Hanscomb, Darrell O	12515	19-NS427		19-FLR03		NS	K	s	CANADA	A	PIKE	CYCLANILIPROLE (ISK)	LETTUCE (GH)	
24	4	Hanscomb, Darrell O	12291	19-NS274	T, done	19-FLR08		NS	K	s	CANADA	A	HOMA	PICARBUTRAZOX (NISSO)	LETTUCE (GH)	(decline)
25	4	Hanscomb, Darrell O	12481	19-CNS292		19-LSRC317		NS	K	k	CANADA	A	COURCELLES	PICARBUTRAZOX (NISSO)	BASIL (GH)	(GH)
22	4	Hanscomb, Darrell O	12373	19-CNS164		19-CANADA		NS	K	k	CANADA	A	MALEGUS	BENZOINDIFLUPYR (SYNGEN)	STRAWBERRY	
26	4	Henricks, Mary	11786	19-ON299		19-CAR01		ON	K	w	CANADA	A	PIKE	CYFLUMETOFEN (BASF)	CUCUMBER	(pickling)
27	4	Henricks, Mary	11787	19-ON300		19-CAR02		ON	K	w	CANADA	A	PIKE	CYFLUMETOFEN (BASF)	CANTALOUPE	



# Implementing the QA Schedule

ID	Chemical	Commodity	PR#	Trial Targeted	Cooperator	Field Trial	Lab	Center	State	# of trials	Reg	Assigned QA	Region	Priority	Study Director	Comment
1																
306	ABAMECTIN (SYNGEN)	DRAGON FRUIT (PITAYA)	12262	T, done	Tannenbaum, Rebecca	19-FL136	19-MIR07	SOR Field Florida TREC	FL	15 S	c	SOR	A	PIKE		(Decline)
86	ABAMECTIN (SYNGEN)	DRAGON FRUIT (PITAYA)	12262	done	Kam, James	19-HI169	19-MIR07	WSR Field U of Hawaii	HI	8 W	c	WSR	A	PIKE		
307	ABAMECTIN (SYNGEN)	DRAGON FRUIT (PITAYA)	12262		Tannenbaum, Rebecca	19-FL137	19-MIR07	SOR Field Florida TREC	FL	15 S	c	SOR	A	PIKE		
192	ABAMECTIN (SYNGEN)	DRAGON FRUIT (PITAYA)	12262		Robles Vazquez, W.	19-PR332	19-MIR07	SOR Field U of PR, Isabella	PR	12 S	c	SOR	A	PIKE		
304	ABAMECTIN (SYNGEN)	SUGAR APPLE	07830	T, missed	Tannenbaum, Rebecca	19-FL118	18-MIR01	SOR Field Florida TREC	FL	15 S	c	SOR	A	PIKE		
305	ABAMECTIN (SYNGEN)	SUGAR APPLE	07830		Tannenbaum, Rebecca	19-FL119	18-MIR01	SOR Field Florida TREC	FL	15 S	c	SOR	A	PIKE		
108	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Reicks, Graig	19-SD484	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 7)
102	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668	T, done	Reicks, Graig	19-SD463	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(processing)(black oil)(reg 5)
103	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Reicks, Graig	19-SD464	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 5)
107	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Reicks, Graig	19-SD483	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 7)
104	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Reicks, Graig	19-SD465	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 5)
217	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Hamilton, Cary	19-NM442	19-FLR13	WSR Field NMSU	NM	13 W	s	WSR		PIKE		
105	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668	T, done	Reicks, Graig	19-SD481	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 7)
106	ACETAMIPRID (NISSO,UPL NA)	SUNFLOWER	12668		Reicks, Graig	19-SD482	19-FLR13	NCR Field SDSU	SD	8 C	s	NCR		PIKE		(reg 7)
119	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824		Harvey, John	19-WA*384	19-TBD	ARS Field Wapato WA	WA	10 W		ARSW	A	BONETTI		
231	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824	done	Koskela, Ms. Gina	19-OR316	19-TBD	WSR Field OSU NWREC	OR	14 W		WSR	A	BONETTI		
230	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824	T, see 316	Koskela, Ms. Gina	19-OR315	19-TBD	WSR Field OSU NWREC	OR	14 W		WSR	A	BONETTI		
274	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824	T,done	Meeks, Mr. Will	19-ID175	19-TBD	WSR Field U of Idaho	ID	15 W		WSR	A	BONETTI		
351	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824		Peng, Wilson	19-WA385	19-TBD	WSR Field WSU Prosser	WA	16 W		WSR	A	BONETTI		
352	ASULAM (UPL NA)	CLOVER (SEED CROP)	11824		Peng, Wilson	19-WA386	19-TBD	WSR Field WSU Prosser	WA	16 W		WSR	A	BONETTI		
204	AZOXYSTROBIN + BENZOVIDIFLUPYR (SYNGEN)	STEVIA	12532		Benzen, Ms. Sharon D.	19-CA*74	19-MIR12	ARS Field Salinas CA	CA	13 W	c	ARSW	A	LENNON		
368	AZOXYSTROBIN + BENZOVIDIFLUPYR (SYNGEN)	STEVIA	12532		Batts, Roger B.	19-NC231	19-MIR12	SOR Field NC State	NC	20 S	c	SOR	A	LENNON		
408	AZOXYSTROBIN + BENZOVIDIFLUPYR (SYNGEN)	STEVIA	12532	T, done	Ennes, D. (Kearney)	19-CA73	19-MIR12	WSR Field UC ANR KARE	CA	28 W	c	WSR	A	LENNON		
367	AZOXYSTROBIN + BENZOVIDIFLUPYR (SYNGEN)	STEVIA	12532	T, done	Batts, Roger B.	19-NC230	19-MIR12	SOR Field NC State	NC	20 S	c	SOR	A	LENNON		(Decline)
289	AZOXYSTROBIN + BENZOVIDIFLUPYR (SYNGEN)	STEVIA	12532	T, done	Ross, Marylee	19-MD203	19-MIR12	NER Field U of Maryland	MD	15 E	c	NER	A	LENNON		
387	AZOXYSTROBIN + FLUDIOXONIL (SYNGEN)	AVOCADO (POST HARVEST)	12552	T	Skiles, Keri	19-CA88	19-MIR01	WSR Field UC ANR KARE	CA	21 W	c	WSR	A	LENNON		
409	AZOXYSTROBIN + FLUDIOXONIL (SYNGEN)	AVOCADO (POST HARVEST)	12552		Ennes, D. (Kearney)	19-CA87	19-MIR01	WSR Field UC ANR KARE	CA	28 W	c	WSR	A	LENNON		
193	AZOXYSTROBIN + FLUDIOXONIL (SYNGEN)	AVOCADO (POST HARVEST)	12552		Robles Vazquez, W.	19-PR333	19-MIR01	SOR Field U of PR, Isabella	PR	12 S	c	SOR	A	LENNON		
309	AZOXYSTROBIN + FLUDIOXONIL (SYNGEN)	AVOCADO (POST HARVEST)	12552		Tannenbaum, Rebecca	19-FL144	19-MIR01	SOR Field Florida TREC	FL	15 S	c	SOR	A	LENNON		
308	AZOXYSTROBIN + FLUDIOXONIL (SYNGEN)	AVOCADO (POST HARVEST)	12552	T	Tannenbaum, Rebecca	19-FL143	19-MIR01	SOR Field Florida TREC	FL	15 S	c	SOR	A	LENNON		





# Implementing the QA Schedule

21	4 Chapman, Scott	11920	19-WI206		19-FLR12	NCR Field UWIS Arlington	WI	C	s	NCR	A	HOMA	FLUAZINAM (ISK,SYNGEN)	STRAWBERRY (NON-BEARING)	
18	4 Chapman, Scott	11752	19-WI410	T	19-FLR11	NCR Field UWIS Arlington	WI	C	s	NCR	A	PIKE	BOSCALID + PYRACLOSTROBIN (BASF)	STRAWBERRY (GH)	
19	4 Chapman, Scott	11790	19-WI411		19-CAR04	NCR Field UWIS Arlington	WI	C	w	NCR	A	PIKE	CYFLUMETOFEN (BASF)	PEPPER (BELL & NONBELL)	(bell)
20	4 Chapman, Scott	12075	19-WI414	T, done	19-YAR02	NCR Field UWIS Arlington	WI	C	h	NCR	A	PIKE	ETHABOXAM (VALENT)	CELERY (GH TRANSPLANT, FIELD)	

## Implementing the QA Schedule

### Assigned QA

Based on location of analytical work

- Leader Lab studies stay in the Region
- All other labs (and analytical data) are submitted to HQ



# Implementing the QA Schedule

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**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: 2/13/2020

CHEMICAL/COMMODITY	FIELD RESEARCH DIRECTOR/AUDITOR	FIELD RESEARCH DIRECTOR (FRD)	FIELD ID#	FIELD START	COLLECT SAMPLE	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.
12036	PROMETRYN																
	PEPPER (BELL & NONBELL)																
	BARNEY/NCR	Leach, Nathan	17-CA115	01/15/17	06/15/17	07/15/17	09/15/17	12/21/17	03/14/18	05/08/18	17-MIR11	07/17	04/19	11/21/16	11/16	11/18	
		Kyser, Guy	17-CA116	02/14/17	07/14/17	09/01/17	11/30/17	12/04/17	03/20/18	04/26/18	17-MIR11	07/17	04/19				
		Leach, Nathan	17-CA117	01/15/17	06/15/17	07/15/17	09/15/17	12/21/17	03/14/18	05/08/18	17-MIR11	07/17	04/19				
		Ennes, D. (Kearney)	17-CA118	02/08/17	08/17/17	09/15/17	11/15/17	11/13/17	01/11/18	02/08/18	17-MIR11	07/17	04/19				
		Ennes, D. (Kearney)	17-CA119	02/15/17	08/24/17	09/15/17	11/15/17	10/24/17	11/27/17	01/12/18	17-MIR11	07/17	04/19				
		Dittmar, Dr. Peter	17-FL157	01/17/17	07/06/17	08/15/17	10/18/17	08/08/17	10/10/17	01/12/18	17-MIR11	07/17	04/19				
		Fraelich, Ben	17-GA*176	01/20/17	07/17/17	08/11/17	10/13/17		05/08/18	10/30/18	17-MIR11	07/17	04/19				
		Zandstra, Dr. Bernard H.	17-MI228	05/01/17	10/09/17	10/30/17	12/01/17	11/21/17	11/27/17	02/08/18	17-MIR11	07/17	04/19				
		Freiberger, Tom	17-NJ281	02/21/17	07/27/17	08/10/17	12/06/17	10/18/17	02/08/18	03/12/18	17-MIR11	07/17	04/19				
		Hamilton, Cary	17-NM296	01/15/17	09/15/17	10/15/17	01/15/18	05/21/18	09/18/18	11/01/18	17-MIR11	07/17	04/19				
		Horst, Leona	17-OH*321	04/26/17	10/12/17	10/19/17	11/10/17	12/04/17	02/08/18	04/12/18	17-MIR11	07/17	04/19				
		Wade, Paul	17-SC*391	01/25/17	07/05/17	08/10/17	09/14/17	08/21/17	08/21/17	10/16/17	17-MIR11	07/17	04/19				
		Marconi, Cristina	17-TX417	05/24/17	11/30/17	12/11/17	01/13/18	05/08/18	10/31/18	12/06/18	17-MIR11	07/17	04/19				

**Total # of PRs:** 1

**Total # of Trials:** 13

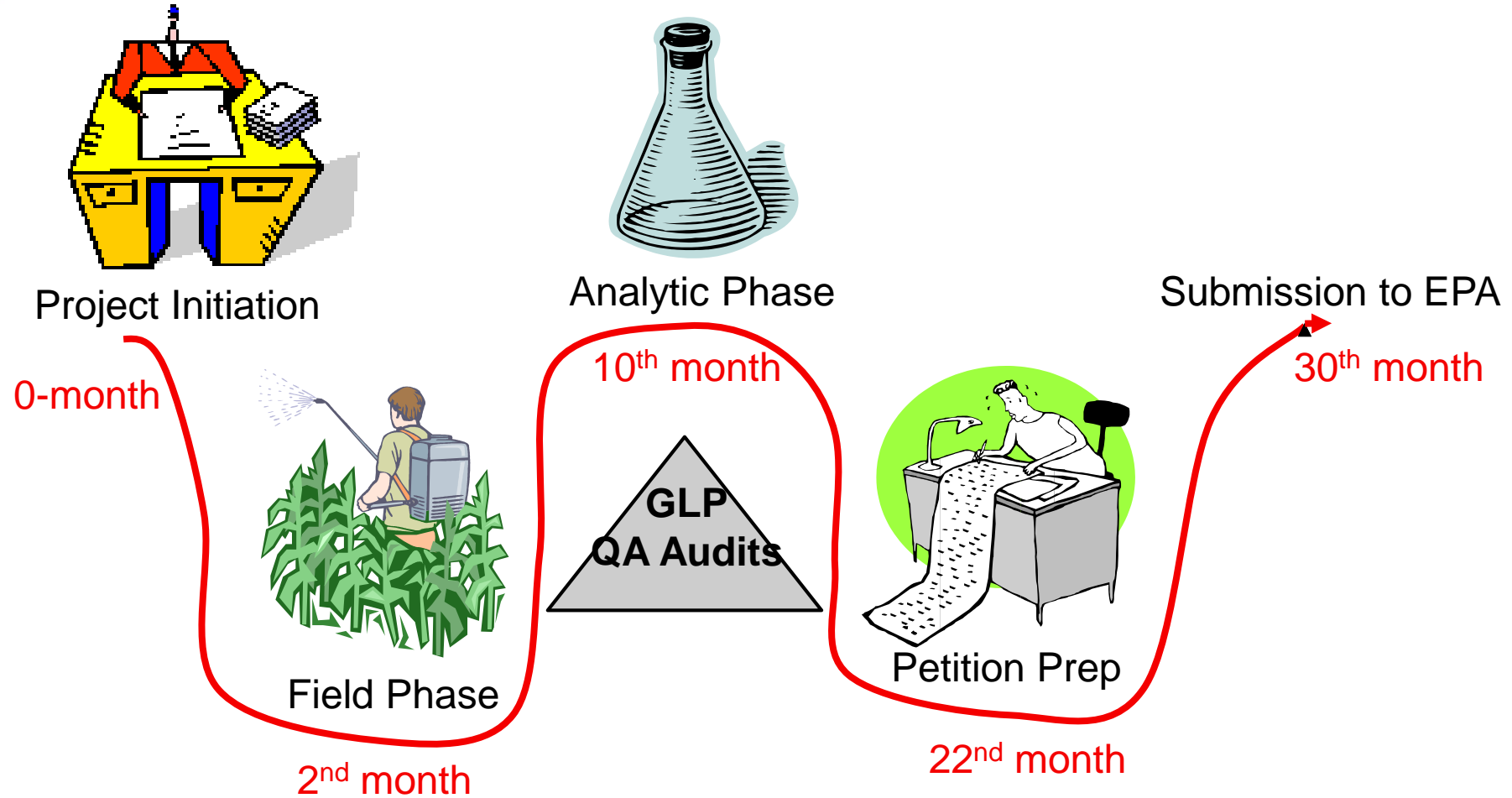
**Total # of Dropped:** 0  
(included in Total # of Trials)

**Total # Chemical:** 1

**Total # Commodity:** 1

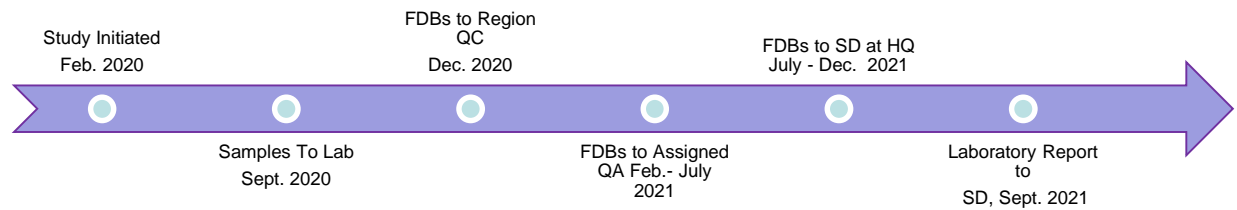
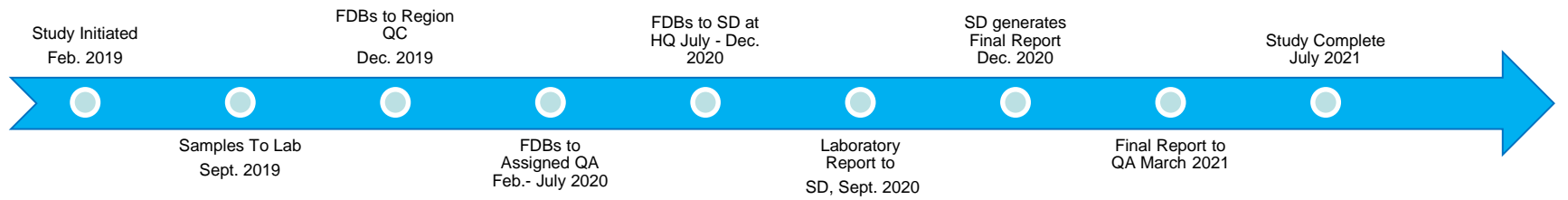
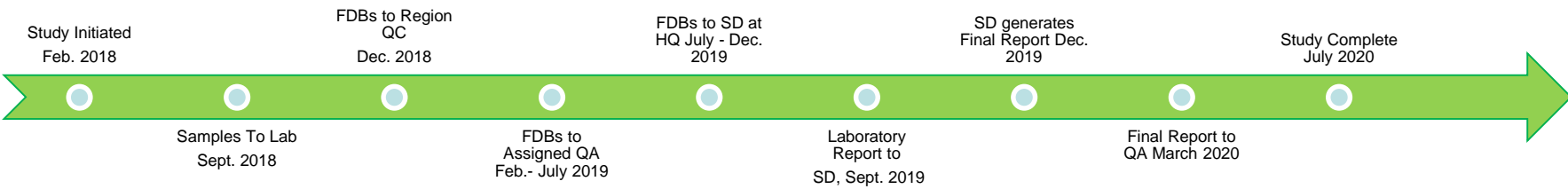
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# Time line and Submissions – 30 month





# Implementing the QA Schedule



## Submission Schedules

- Based on 30-month timeline
- Some studies are expedited to 24 months, with TFM approval
- Are subject to change depending on most recent information
- QA and Reg. Manager meet >4 times per year to update
- Updated schedule shared with regional QA

## Implementing the QA Schedule

### QA Inspections/Audits during the 30-month time line

- Field Critical Phase (FCPI) – early in the study, performed usually by regional QA  
**(but the lines are blurring)**
- Field Raw Data Audits (FRDA) – after QC, done by the assigned QA
- Lab Critical Phase (LCPI) – happening while FRDAs are occurring
- Analytical Raw Data and Analytical Summary Reports (ARDA and ASRA) – should occur after all FRDAs have been done, but more and more FRDAs are straggling
- FRA1 – 3 to 6 months after receiving the ASRs, done by the assigned QA
- FRA2 – done at the end to verify corrective actions of the FRA1, all QA statements of final reports generated at HQ

# Implementing the QA Schedule



Questions?





## The IR-4 Process

- **Dan Kunkel** - overview and global impact
- **Van Starner** — tracking stakeholder needs (PCRs), developing the annual plan for residue and performance research
- **Debbie Carpenter** — planning/conducting the residue program (field and lab)
- **Tammy Barkalow** — organizing and implementing the QA monitoring program
- [Bill Barney](#) — using crop grouping, compiling final reports, submissions to EPA, securing labels