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## Visual Verification... four years on

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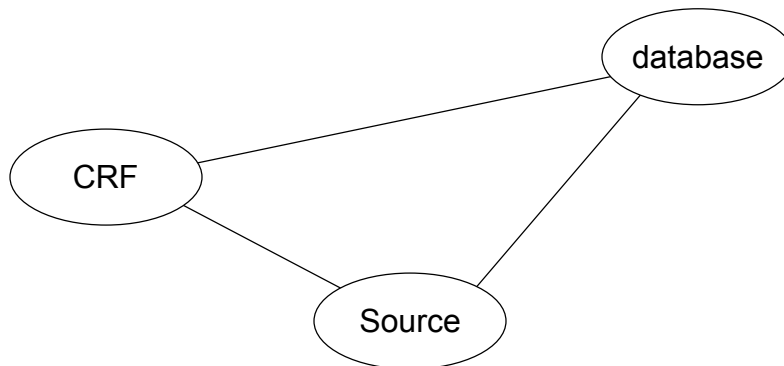
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### Goal: Database = CRF = Source



### Reconciling database with source

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Corrections initiated during monitoring:

- independent of QC → refax → audit trail.
- may result in disagreement between database and source.

### DataFax CRF Image Processing

WHO	Validation Level		Status of image/record	QC report
	From	To		
CDA	0 (NRB)	1	<b>Image logged in</b> (header keys only)	No
		2	<b>New data entered</b>	
		3	<b>Refaxed data entered</b>	
CDC	2+3	4	Data reviewed; <b>Data Management cycle complete</b>	Yes
CRA	4	5	Visual Verification (V.V.) of changes made to CRF prompted by monitoring and recorded on <b>SDV Form</b> . <b>Data have been monitored</b> (but are not necessarily clean)	Yes
DSA	5	6	<b>Data clean and locked</b>	No

## Visual Verification

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- **WHY:** Reconcile database with source
- **WHEN:** After data have been monitored and image processed to validation level (VL) 4.
- **HOW:** Build set by patient for visit(s) monitored.
- **WHAT:**
  - Visually Verify SDV form with images.
  - Validate (by record or set) VL4 → VL5.

V.V. is now deployed in all studies using one or more of the following methods...



## Flavours of Visual Verification

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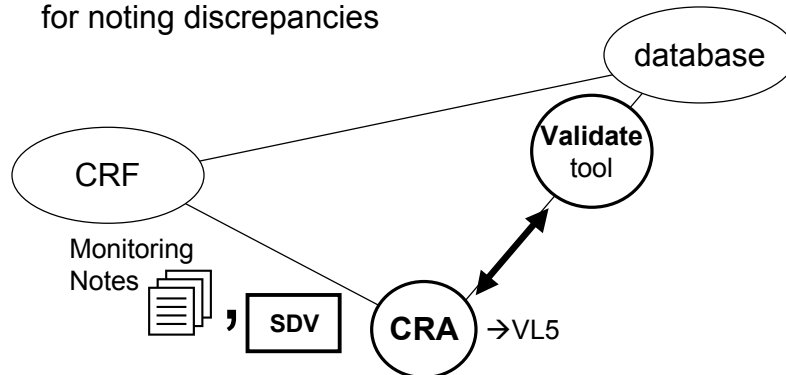
- Direct V.V.
- Hybrid V.V.
- Indirect or Third Party “V.V.-3”



## Primary method: Direct V.V.

### CRA monitoring DataFax studies

- Employees directed to use DataFax-tuned SDV forms
- CRO monitors may have other standards for noting discrepancies



## Direct V.V. doesn't always work

- Connectivity issues
  - What's my password?
  - My token's broken.
  - I got kicked out and can't get back in again.
  - The farmers in the village sawed through the telephone cable. They don't like the internet.



## Direct V.V. doesn't always work

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- Training challenges:  
Why do we have to do this?
  - This is double-work; I've looked at the CRFs during monitoring.
  - We've just replaced the CRA and we only have a few visits to monitor.



## Direct V.V. doesn't always work

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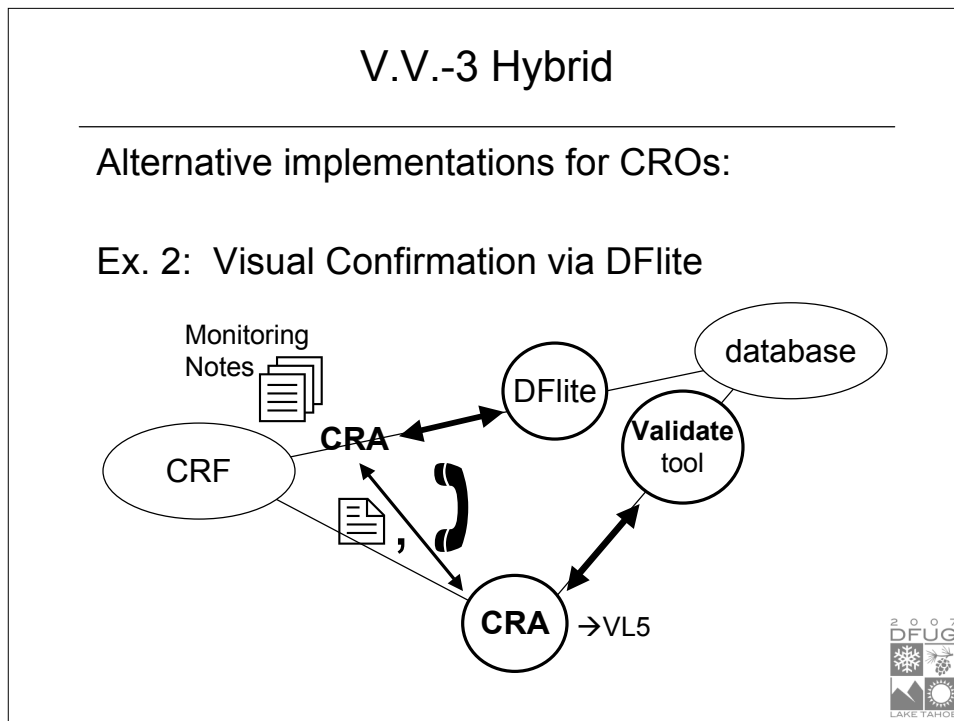
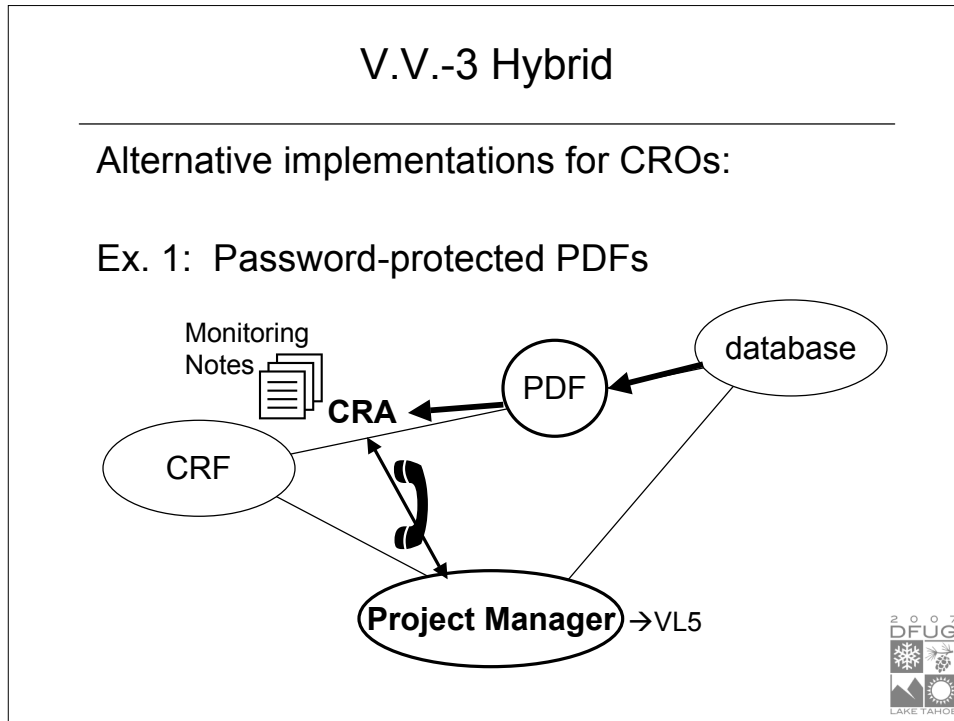
- Training challenges:  
Working in DataFax
  - Now that I'm in, what do I do again?

Quote from CRO CRA Field Monitor:

*Yes, I finally got in. It is frustrating if you only use DataFax for two subjects and one site. If I were doing it more, I would find it very useful. But now that we go to monitor every 12 weeks, it is out of site (ha ha) out of mind, so to speak.*

- Oh, I didn't notice that I changed the data.
  - I just moved all the log forms by mistake...
- Process further challenged by global trials






## One step backward; two forward?

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- Backward: remove need for ClinOps to use the validation tool
  - All images moved by a third-party
- Dependent on mandatory use of a DataFax-tuned SDV form for ALL monitors



## V.V.-3: Monitoring Tool

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**Source Document Verification Form**

PDL BioPharma  
Protocol CDN-1406

Subject ID: 9988

TO BE COMPLETED BY MONITOR:


Corrections: For each data field that is discrepant-with-source, identify the Visit, CRF, and data field number.  
Follow-up: If issue is not resolved at monitoring visit, enter "X" in Follow-Up needed; leave Date blank.  
Completed: When correction verified with source, enter "X" for Complete and the Date of correction on CRF. If correction is verified at a subsequent monitoring visit, circle the new information.

Source Data Verification (SDV) Form

Monitor's Signature: *Sign off these changes here*

Monitoring Date(s): 01May07

LINE	Visit No.	CRF <small>(if log, include Page)</small>	Field No.	DATA FIELD TO BE CORRECTED <small>(if field number is not sufficient, add enough detail to identify the location of the correction)</small>	Follow-up needed	Complete	Date of change on CRF
1	1	MHX-1 p1	2	<i>asthma began 1960</i>		X	<i>01May07</i>
2	1	#110 p01		<i>knee surgery 01Apr03</i>	X		
3	1	54		<i>Source unavailable</i>	X		
4	1	15	4	<i>15:13</i>		X	<i>01May07</i>
5	2	SD11	3d	<i>Panic attack</i>		X	<i>01May07</i>
6	p02	MED-3	1	<i>2nd AE No. 006</i>		X	<i>01May07</i>
7							



## V.V.-3: Monitoring Tool

### Source Document Verification Form

PDL BioPharma  
Protocol CDN-1406

Source Data Verification (SDV) Form

Monitor's Signature: *Sign off these changes here*

Subject ID: 9988

Monitoring Date(s): 01May07 +15Jun07

TO BE COMPLETED BY MONITOR:

**Corrections:** For each data field that is discrepant-with-source, identify the Visit, CRF, and data field number.  
**Follow-up:** If issue is not resolved at monitoring visit, enter "X" in Follow-Up needed; leave Date blank.  
**Completed:** When correction verified with source, enter "X" for Complete and the Date of correction on CRF. If correction is verified at a subsequent monitoring visit, circle the new information.

Line Item	Visit No.	CRF (if log, include Page)	Field No.	DATA FIELD TO BE CORRECTED (if field number is not sufficient, add enough detail to identify the location of the correction)	Follow-up needed	Complete	Date of change on CRF
1	1	MHX-1 p1	2	asthma began 1960		X	01May07
2	1	#110 p01	7	knee surgery 01Apr03	X	X	15/06/07
3	1	54		Source unavailable located	X	X	n/a
4	1	15	4	15:13		X	01May07
5	2	SD11	3d	Panic attack		X	01May07
6	p02	MED-3	1	2nd AE No. 006		X	01May07
7							



## V.V.-3: Processing in DataFax

- CRA submits SDV form
- Using SDV form, V.V. Processor:
  - builds a set to match
  - visually checks that the “Date of change on CRF” is reflected on CRF image.

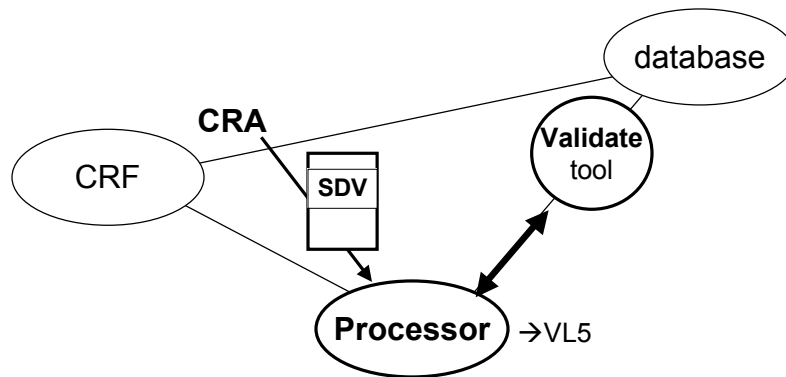
Field No.	DATA FIELD TO BE CORRECTED (if field number is not sufficient, add enough detail to identify the location of the correction)	Follow-up needed	Complete	Date of change on CRF
2	asthma began 1960		X	01May07
7	knee surgery 01Apr03	X	X	15/06/07

- Validates record VL4 → VL5



## One step backward; two forward?

- Mandatory use of DataFax-tuned SDV forms
- In-house Processor “V.V.-3” → VL5



## Maintaining “monitored” status

- Q: What happens to refaxed data?
- A: Track status using a screen variable and edit-checks.



