MTN-020

Data Communiqué #1

Overview

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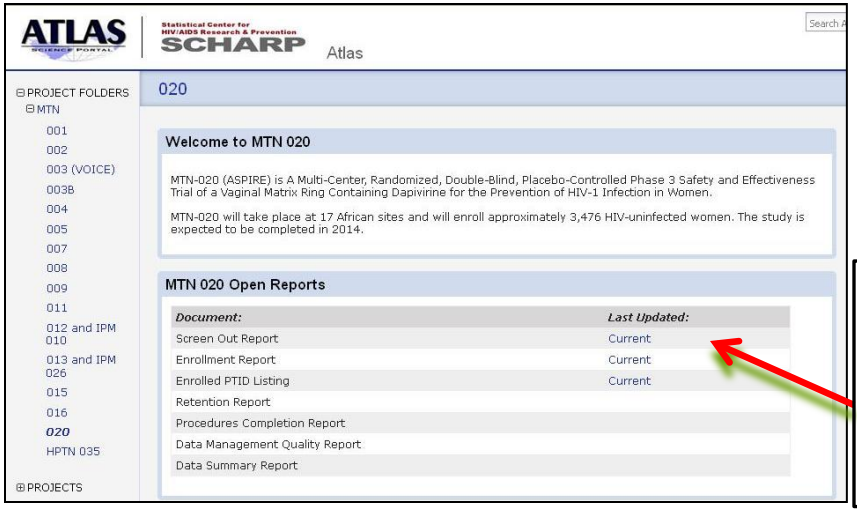
A Study to Prevent Infection with a Ring for Extended Use

Updates

1. Screen Out Report and Enrollment (Accrual) Report now on Atlas (web address = atlas.scharp.org)

- The MTN-020 Screen Out Report and Enrollment (Accrual) report are available in the Open Reports section of the MTN-020 Atlas web page. No sign-in or password is required – you will just need to agree to the terms of use when prompted.
- These reports are updated each day based on data received and entered at SCHARP.



Click on "Current" under the *Last updated* column to view each report.

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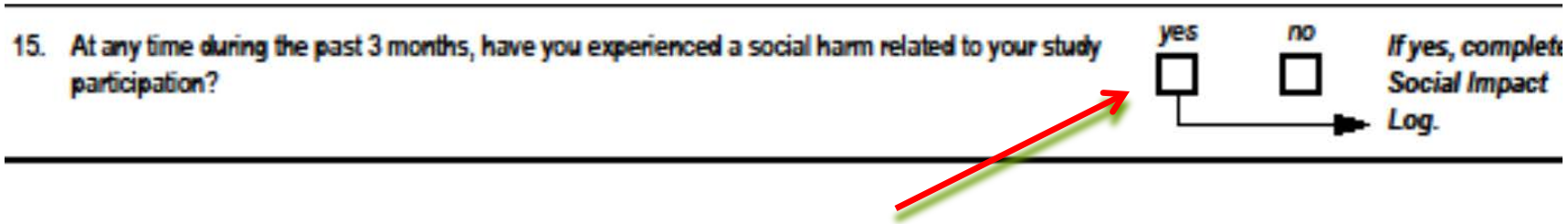
CRF Completion Clarifications

1. Behavior Assessment item 15

- Mark “yes” if a new Social Impact Log CRF has been completed within the past 3 months



For example: If a social harm was reported at Month 4 (and a Social Impact Log completed), mark “yes” at Month 6 and ignore the instruction to complete a Social Impact Log (since one has already been completed at Month 4 as appropriate).

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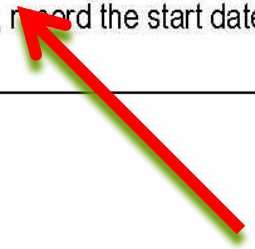
CRF Completion Clarifications

2. Concomitant Medications Log, Start Date for injectable medications

- The Start Date instruction below applies to contraceptive injectable medications only. Non-contraceptive injectables (like medications given in the hospital) may be recorded as a single entry.

Start Date:	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. For oral contraceptives, record the start date (and stop date) for each pill pack.



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CRF Completion Clarifications

3. Contraceptive Medications injected prior to the Screening Visit

- Injections of contraceptive medications used before the Screening Visit <u>are not recorded</u> on CM-1 CRF.

- This CRF only captures medications used on or after the Screening Visit date. If an injection used prior to the Screening Visit is recorded, this will results in a QC since the “date stopped” will be prior to the Screening Visit date and you will asked to mark the entry for delete.

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CRF Completion Clarifications

4. Enrollment CRF, items 9-12 form instruction

- The last sentence of this instruction, which currently reads, “If any procedures are not completed, bring the participant back to the clinic for procedure completion as soon as possible” only applies to item 10, the collection of plasma for archive.

- If plasma archive was not collected on the day of randomization (Enrollment), make every attempt to bring the participant back as soon as possible to collect and archive specimen at an interim visit prior to Month 1.

9.	Was the Baseline ACASI questionnaire completed?	*yes* ☐	*no* ☐
10.	Was plasma for archive collected?	*yes* ☐	*no* ☐
11.	Was self-collected vaginal fluid swab collected?	*yes* ☐	*no* ☐
12.	Was vaginal ring inserted?	*yes* ☐	*no* ☐

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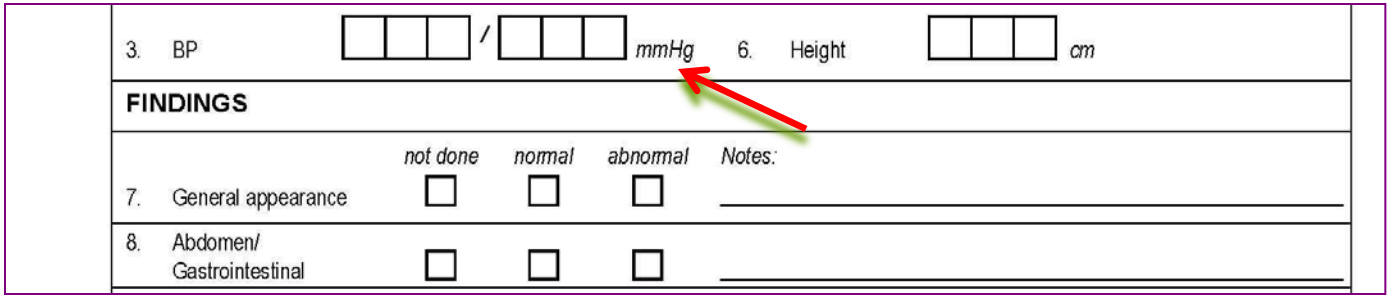
CRF Completion Clarifications

5. Physical Exam CRFs (Screening, Enrollment, Abbreviated)

- These CRFs can only capture 1 BP reading per visit. If more than 1 BP reading is performed at a visit, record the blood pressure reading used for clinical assessment/management on the CRF. Line through a previous reading and record the relevant reading in the white space as needed.

- All other readings, along with reason why multiple readings were taken, should be documented in participant's file.



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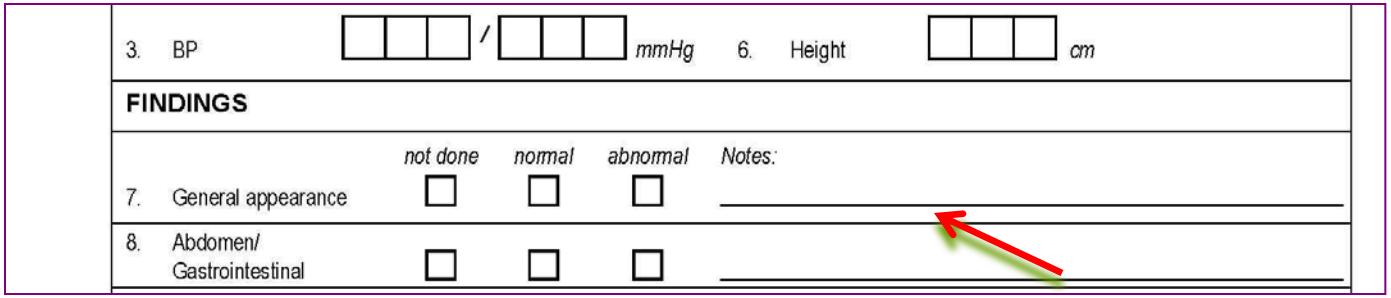
CRF Completion Clarifications

5. Physical Exam CRFs (Screening, Enrollment, Abbreviated)

- Within the symptom-directed findings section of these CRFs, the “Notes” field is required for any item with ‘abnormal’ marked.

- Sites may also record Notes for items marked ‘normal’ if they wish (for documenting a normally-healed scar, for example)



3.	BP ☐☐☐/☐☐☐ mmHg	6.	Height ☐☐☐ cm		
FINDINGS					
		not done	*normal*	*abnormal*	*Notes:*
7.	General appearance	☐	☐	☐	_____
8.	Abdomen/ Gastrointestinal	☐	☐	☐	_____

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CRF Completion Clarifications

6. Pre-Existing Conditions, Severity grade

- If a Pre-existing condition is resolved as of the Enrollment Visit, do not make any changes to the severity grade (similar to what is done when resolving AEs). Mark that condition as not ongoing at Enrollment.

1. Condition	Onset Date (MMM / yy)	Staff Initials/Date
Neck pain	SEP / 12	JMB 02SEP12

Comments	Ongoing at Enrollment? (yes / no)	Severity Grade (grade / not gradable)
	☐ / ☒ JMB 15SEP12	1 / ☐

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CRF Completion Clarifications

6. Pre-Existing Conditions, Severity grade

- If a Pre-existing condition first identified at the Screening Visit is ongoing at Enrollment, assess the severity grade at the Enrollment Visit and update the severity grade (up or down) as applicable to reflect the severity at the time of Enrollment/randomization.

1. Condition	Onset Date	Staff Initials/Date
Neck pain	MMM: SEP; yy: 12	JMB 02SEP12
Comments	**Ongoing at Enrollment?**	**Severity Grade**
	yes: X; no: ☐	grade: 2; not gradable: ☐

JMB 15SEP12

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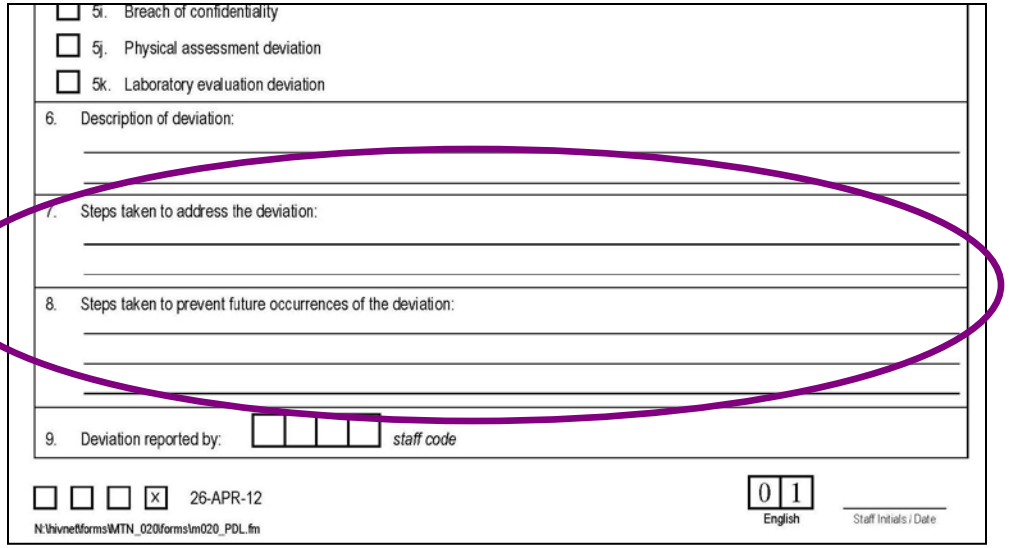
CRF Completion Clarifications

7. Protocol Deviations Log

- Actions documented in Items 7 & 8 are not required to be completed in order to fax the CRF to SCHARP. The PDL Log should be transmitted once the CRF is completed, even if all of the actions/plans described in items 7 & 8 are still in-progress.



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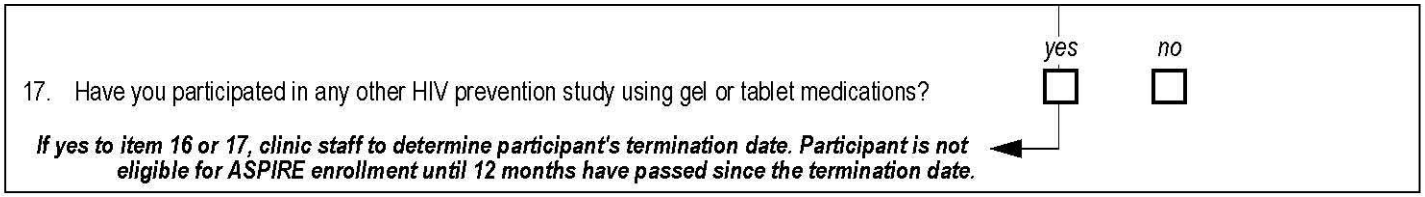
CRF Completion Clarifications

8. Screening Behavioral Eligibility, Item 17

- Item 17 asks the potential participant if she has participated in any other HIV prevention studies that uses gel or tablet medications – this item also include any vaginal ring studies (IPM 027) or HPTN 052 as well.
- MTN-001 participants are fine to enroll, as that study completed more than two years ago.
- If a potential participant has enrolled in IPM 027 or HPTN 052, she must wait 12 months since study termination to be eligible for ASPIRE



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CRF Completion Clarifications

9. Screening Menstrual History, Items 3-6

- Complete these items based on the participant's usual menstrual periods as experienced prior to the Screening Visit. If the participant is amenorrheic, complete items based on her description of her most her most recently experienced menstrual period and provide additional details in Item 8 as needed.
- If the participant reports more than 99 days between her usual menses, record "99" for item 3 (maximum boxes) and provide details in Item 8

3.	Usual number of days between menses (1st day to 1st day)	*minimum* ☐☐ *# of days* TO *maximum* ☐☐ *# of days*
4.	Usual number of bleeding days (record range)	*minimum* ☐☐ *# of days* TO *maximum* ☐☐ *# of days*
5.	First day of last menstrual period	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
6.	Last day of last menstrual period	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* OR *ongoing* ☐

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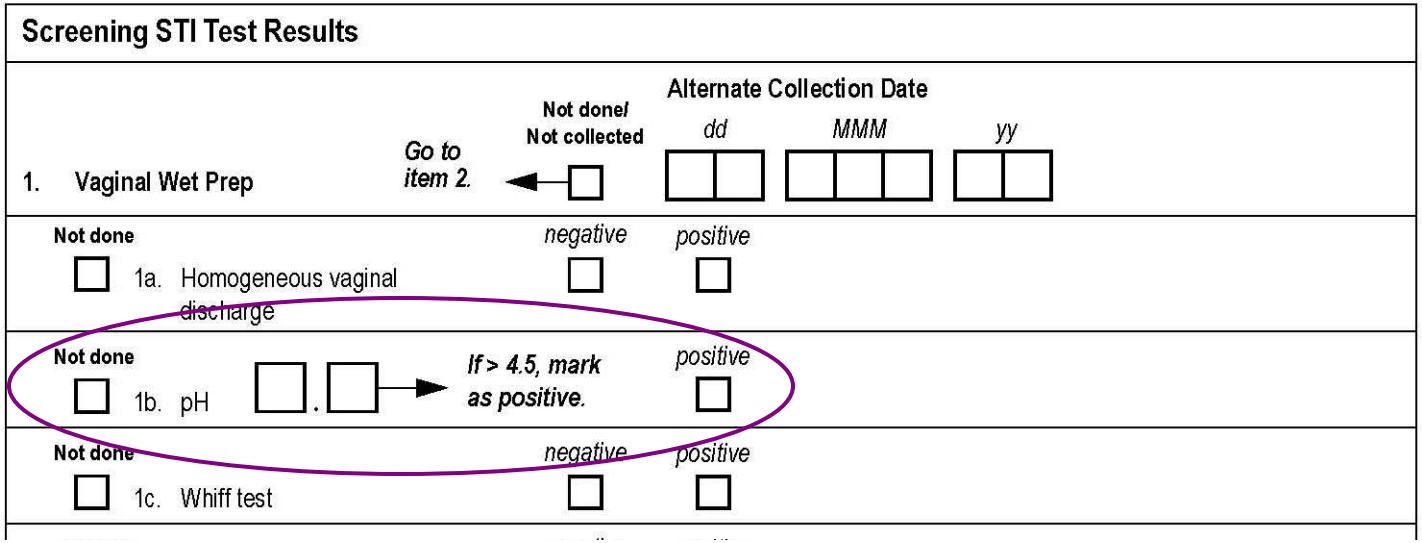
CRF Completion Clarifications

10. Screening STI Test Results, item 1b form instruction

- This form instruction, which states vaginal fluid pH is required at all Semi-Annual Visits and PUEV should be ignored.
- Vaginal fluid pH is required at the Screening Visit per Letter of Amendment #1.



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CRF Completion Clarifications

11. Social Impact Log CRF, item 7 (current status)

- Item 7, which documents the current status of the social harm, is based on participant self-report.
  - For example, mark “unresolved” if the participant reports that she feels the social harm is ongoing (not resolved).

- SCHARP will provide sites with monthly listing of all unresolved social harms that are ongoing for more than 30 days

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CRF Completion Clarifications

12. Vaginal Practices, item 5d

- Item 5d asks participants whether they have inserted fingers inside the vagina in order to clean or insert something. Note that this question does not include instances where the participant has used her fingers to insert a study vaginal ring.

5. In the past 3 months, have you put any of the following inside your vagina?	*yes*	*no*
5a. water only	☐	☐
5b. water plus soap	☐	☐
5c. materials such as paper, cloth, or cotton wool	☐	☐
5d. fingers, to clean or insert something	☐	☐
5e. anything else? Specify: _____	☐	☐

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General Clarifications

1. CRF completion when required visit procedures are repeated at 2nd part of split visit

- When a participant has required study procedures repeated at 2nd part of split visit, document these repeated procedures as an interim visit (using a new VS-1 CRF).

  - Ex: A participant has a split visit at Month 6. At the 1st part of the visit on 13NOV12, all required procedures are completed except for the pelvic exam. At her 2nd part of the Month 6 visit on 18NOV12, the pelvic exam is completed and safety labs are repeated to follow- up on an AE
  - In this scenario, the PE-1 CRFs are assigned Visit Month 6.0. VS-1 for Month 6 is dated 13NOV12. For the safety labs done on 18NOV12, assign Visit Month 06.1 to QLR-1 and complete new VS-1 with a Visit Month of 6.1, dated 18NOV12 to document the interim visit and the interim procedure of safety lab testing.

General Clarifications

2. Ring Adherence CRF completion at Interim Visits

- The Ring Adherence CRF is only completed at the required Monthly, Quarterly, Semi-Annual, and PUEV. It is <u>not</u> completed at Interim Visits.

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General Clarifications

3. Ring Collection/Insertion CRF completion for participants permanently discontinued from product use

- The Ring Collection/Insertion CRF is not required to be completed for those participants who have been permanently discontinued from ring use (for example, due to confirmed HIV infection).

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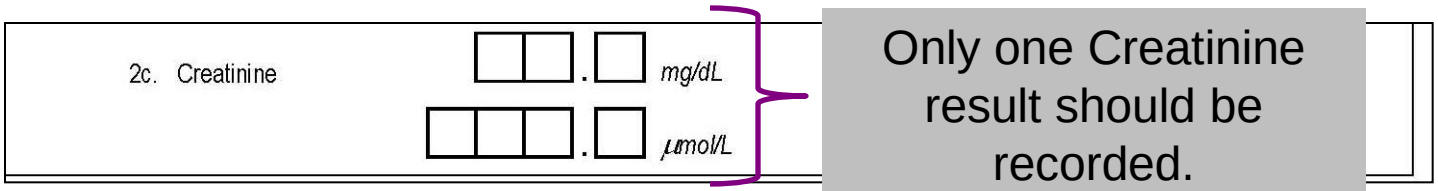
Reminders

1. Creatinine result (item 2c) on Screening and Quarterly Laboratory results CRFs

- Note that per the forms instructions, only one creatinine results is recorded on the CRF (item 2c). SCHARP can only accept one creatinine results to probably perform our safety monitoring checks. If two creatinine results are recorded on a CRF, a QC will be created requiring you to mark for delete (line-through) one of the results.



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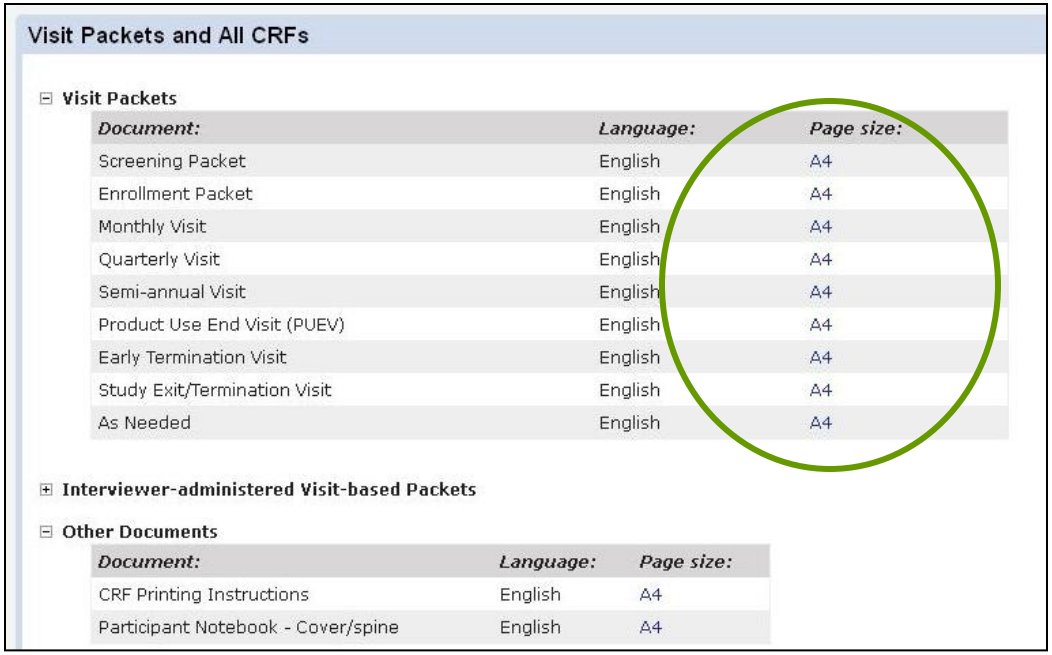
Reminders

1. Case Report Form (CRF) pdf files for printing & participant notebook covers on Atlas

- As a reminder, sites are encouraged to print their own CRF supplies using the pdf files available on the 020 Atlas page.



Visit Packets and All CRFs

⊟ Visit Packets

Document:	Language:	Page size:
Screening Packet	English	A4
Enrollment Packet	English	A4
Monthly Visit	English	A4
Quarterly Visit	English	A4
Semi-annual Visit	English	A4
Product Use End Visit (PUEV)	English	A4
Early Termination Visit	English	A4
Study Exit/Termination Visit	English	A4
As Needed	English	A4

⊞ Interviewer-administered Visit-based Packets

⊟ Other Documents

Document:	Language:	Page size:
CRF Printing Instructions	English	A4
Participant Notebook - Cover/spine	English	A4

Click on "A4" under the Page Size column to bring up the CRF pdf file for printing

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Questions???

- Please contact Jen Berthiaume and Missy Cianciola with any questions you have about this slide presentation or Data Communiqué #1

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We are more than happy to hear from you!