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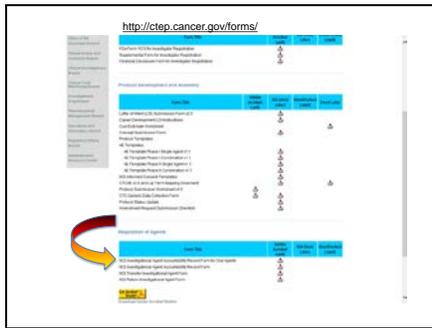


Welcome to this video tutorial on DARP Basics in the PMB Investigational Drug Accountability series.

The video will review the basics of using the NCI Investigational Agent Accountability Record Form, commonly referred to as the Drug Accountability Record Form (DARF).

Any references to the Investigational Agent Accountability Record in this presentation apply exclusively to the NCI DARF.

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You can find the DARF and other forms on the CTEP website at <http://ctep.cancer.gov/forms>.

You will notice there are two forms, the original DARF and the Oral DARF.

DARFs must be maintained to track the disposition of all study-supplied agents for NCI clinical trials.

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The Oral DARF must be used for NCI studies using an oral agent.

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The image shows a scan of a paper form titled 'Investigational Agent Accountability Record'. A red rectangular box highlights the header section, which includes fields for 'Investigational Agent Name', 'Protocol ID', 'Phase', 'Control Record', and 'Batch/Life Record'. Below the header is a large table with multiple columns and rows, intended for recording individual entries.

The original DARF must be used for all NCI studies using formulations not intended for oral administration. Examples include injectable, topical and imaging agents.

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The image shows a screenshot of the electronic version of the 'Investigational Agent Accountability Record' form. The header section is highlighted with a light blue background and labeled 'Writable fields'. Below this, the main data table is highlighted with a light red background and labeled 'Handwrite individual entries'. The form includes fields for 'Investigational Agent Name', 'Protocol ID', 'Phase', 'Control Record', and 'Batch/Life Record'.

Now let's look at the DARF. Notice that within the electronic form available from the CTEP website, the header contains writable fields. The remaining fields are not writable, but are locked for change control and require handwritten entry.

Once the header fields are completed for a specific protocol, the form may be saved to generate additional accountability pages. The edited form may be saved to the user's computer if proper Adobe® software is available.

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If the specific protocol DARF is saved or printed for future use, check the expiration date in the upper right-hand corner to be sure the document is still in date prior to use.

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eDARF=

If your institution uses drug accountability software or eDARFs, the database must be able to produce a paper printout that is identical to the NCI DARF. PMB does not endorse any particular eDARF pharmacy package.

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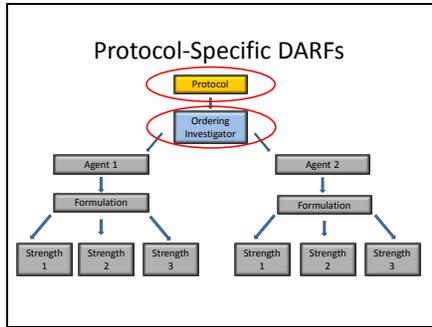
Corrections Made on the DARF

| Line | Protocol No. | Drug Name | Strength | Quantity | Unit | Control No. | Batch No. | Control No. | Batch No. | Control No. | Batch No. |
|------|--------------|--------------------------|----------|----------|------|-------------|-----------|-------------|-----------|-------------|-----------|
| 11 | 7152014 | Received from the NCI | | +20 | 22 | SLX 8786421 | AB | | | | |
| 12 | 7202014 | 87 1204-802 800 mg daily | | -2 | 30 | SLX 8786421 | AB | | | | |
| 13 | 7202014 | 87 1204-802 800 mg daily | | -2 | 18 | SLX 8786421 | AB | | | | |
| 14 | 7202014 | Return to the NCI | | +4 | 22 | SLX 8786421 | JT | | | | |
| 15 | 7152014 | Return to the NCI | | -4 | 18 | SLX 8786421 | AB | | | | |

Corrections made to any paper DARF must be neatly lined out, initialed and dated as in the example on line 14. Erasures or “whiteouts” are not acceptable as shown in the example on line 11.

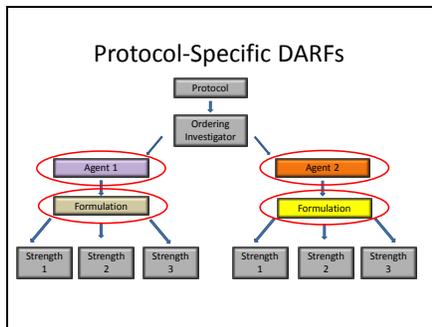
Corrections made in any electronic accountability system also need to be appropriately documented.

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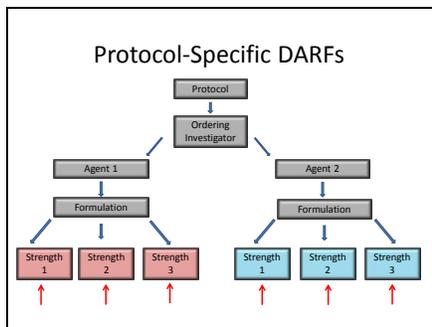
Separate DARFs are required for each protocol and for each ordering investigator.

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Each agent formulation for that protocol must have a separate DARF. Additionally, each strength for that particular agent requires a separate DARF.

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In the example, six DARFs are required, one for each strength.

PMB encourages sites to order agents for only one investigator per protocol to minimize the total number of DARFs being maintained.

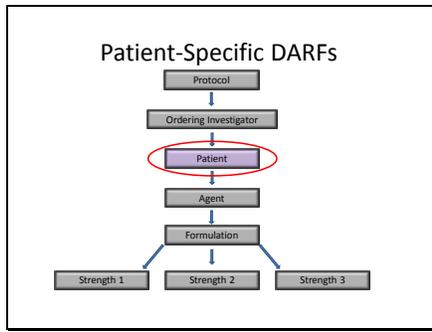
Control dispensing areas and satellite dispensing areas maintain separate DARFs.

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Please note that protocol-specific DARFs are not agent lot specific. Multiple lots of the same strength should be tracked on the same DARF. DARFs are continuous records that may span many pages during the life of a protocol.

Protocol-specific DARFs are used to track agent disposition for multiple patients on the same study.

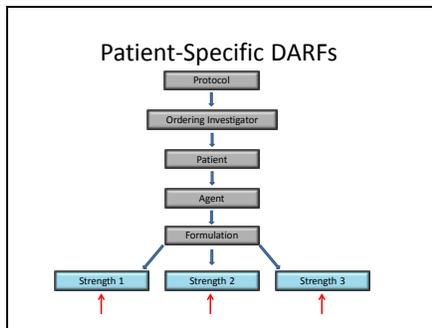
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Protocols that use patient-specific supplies (e.g. placebo-controlled studies) are tracked by protocol and by patient. Patient-specific supplies use the Julian date and order number as the lot number.

Refer to the protocol document if you are unsure whether agent supplies are patient-specific.

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Separate DARFs are required for each patient on that protocol. Each agent formulation for that protocol must have a separate DARF. Additionally, each strength for that particular agent requires a separate DARF.

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