

1. Under what mechanism were you able to accept delivery of the license from Medidata?

NCI received the licenses pursuant to a contract for software licenses, software maintenance, technical support, local installation support and other related activities awarded by the Department of Interior's National Business Center on August 10, 2009. While the award was ultimately protested at the U.S. Government Accountability Office, the award was not protested in the time frame that is required to stay contract performance pursuant to federal law. (Federal law does not require a stay of contract performance unless the contract is protested within a certain period of time after award. See 31 U.S.C. 3553(d)(3)(A).) As a result, Medidata performed some parts of the contract following the award date (August 10, 2009), and NCI, consistent with the awarded contract, received and utilized goods and services outlined under the terms of the contract during this time.

2. How and when was this accomplished?

Medidata provided a partially executed version of the software license for NCI and its authorized users as an attachment to its final proposal in response to the Government's solicitation. Medidata's proposal, including the software license, was accepted by the Department of Interior's National Business Center on August 10, 2009. Pursuant to the terms of the awarded contract, Medidata delivered the executable version of the software to NCI on August 13, 2009 and began performing the initial parts of the contract, since as noted above, there was no stay of contract performance during this period.

As noted, although the procurement in question was protested, contract performance was not stayed as the protester did not file in the time frame required to activate the stay. As courts have explained, "The purpose of the statute is to stop the contractor who was awarded the contract from proceeding with its performance pending the protest. Unless the agency receives the required notice, it cannot direct that performance be stayed. Once ten days have passed since that award, the contractor should be able to proceed without concern that the agency may later direct him to cease performing the contract." *McDonald Welding v. Webb*, 829 F.2d 593, 596 (1987). Since Medidata began performance of the contract in the absence of any required stay, NCI received, and paid for, some goods and services during this period. Although GAO ultimately issued an adverse decision against the Department of Interior, the license and commercial software were accepted by NCI prior to the time the protest was filed. Pursuant to the terms of the contract, NCI could not return the license or software despite the fact that a protest was filed at a later point in time. In addition, nothing in federal law prohibits an agency from utilizing goods and services provided pursuant to a contract that is not subject to a stay.

3. Are you deploying Medidata software now and what was done when with respect to deploying Medidata since the initial award?

A test instance of the software was installed at NCI starting in September 2009, on which NCI subsequently conducted testing and security scans. NCI was in the process of setting up a production instance of the software when Velos filed its protest in November 2010 and thus work on deploying the software at NCI was discontinued pending resolution of the protest.

In addition, several NCI-funded organizations became covered last summer under NCI's perpetual use license for the Medidata software. However, NCI stopped enabling access to the software under its license after Velos filed its protest. Now that the protest has been dismissed by the GAO, NCI plans to reach out to its awardees to confirm their interest in using the software and to facilitate execution of the required agreements.

The NCI Cancer Therapy Evaluation Program (CTEP) and the NCI Clinical Trials Cooperative Groups are planning to base their work for a centralized IT platform on this system; specific information regarding technical remote hosting and related deployment support will be provided as soon as it publicly available. In addition, other NCI programs will be exploring their options to support use of the software to further the data management needs of the NCI clinical research community.

4. Has Medidata made any improvements to its software since the initial award?

Yes. NCI always anticipated that, regardless of the software vendor that would eventually be selected, some customization of the commercial product would be required to facilitate integration with established standards and existing NCI tools and infrastructure that implemented these standards. Because contract performance following the second award was not stayed, Medidata made the following modifications in accordance with the terms of the contract:

- Creation of a Clinical Trial Object Data System (CTODS) with an Extract/Transform/Load (ETL) process to populate it
- Enhancements to the ability of Medidata software to integrate with the caBIG metadata repository (caDSR)
- Enhancements that allow patient-specific information to be used across multiple studies

5. How does this relate to two oppositions and findings by GAO?

Currently, there are no actions pending at the GAO. As noted, because the contract was not required to be stayed when it was awarded in August 2009, Medidata delivered various goods and services to the Government in 2009, including certain software licenses, prior to the GAO's disposition of the protest. However, because of the adverse GAO decisions, the vast majority of goods and services that were the subject of this contract have not, to date, been delivered or provided. After the most recent protest at the GAO, filed in November 2010, NCI determined that it would procure the remainder of the goods and services contemplated by the initial Request for Proposals directly. In December 2010, the Department of the Interior's National Business Center notified GAO of this development. As a result, the Department of Interior cancelled the procurement, and GAO dismissed the most recent protest as moot. NCI is currently engaged with procurement and contracting staff at the Department of Health and Human Services to determine how to procure requirements that have yet not been procured by the agency.

6. Are you currently contracting for installation and support services piece? How is this broken down?

NCI is not currently contracting for installation services or technical support services for the Medidata software. However, as noted above, NCI CTEP is planning to support the use of this software as part of a centralized IT network for the Clinical Trials Cooperative Groups. More information will be provided when it is publicly available.

7. How are you determining what research entities want to use the Medidata software?

Interested parties submitted letters of intent in December 2009. Now that the protest has been dismissed by the GAO, NCI will use standard NCI channels to determine which entities are still interested in using the software and receiving deployment support.

8. Are the research entities paying for the Medidata software or its deployment, or is NCI paying the cost?

Eligible research entities are not required to pay for a license to use the Medidata software. At this time, NCI is not supplying software maintenance, technical support or local installation support broadly across the NCI clinical research enterprise. However, as noted above, NCI CTEP is planning to support the use of this software as part of a centralized IT network for the NCI Clinical Trials Cooperative Groups. Organizations that do not want to wait for NCI deployment support should make private arrangements for deployment, maintenance and technical support at their own expense directly with Medidata.

9. What effect, if any, did the Velos protest have on the deployment of Medidata?

Bid protests are part of the federal procurement process, and the Government Accountability Office's consideration of such matters, as well as the Government's response to such matters, necessarily take time. The Velos protests have delayed the deployment of the Medidata clinical data management system software by interested participants in the NCI clinical research enterprise. In fact, one of the reasons NCI decided to cancel the procurement by DOI and bring the procurement in-house was to reduce any further delay.