MDDAP
Body of Knowledge

Contents

Program Background

High-Level Overview

The Case for Quality Voluntary Improvement Program (VIP), a Food and Drug Administration (FDA) supported initiative, leverages the Medical Device Discovery Appraisal Program (MDDAP), which is a tailored version of the Capability Maturity Model Integration (CMMI) framework, as the standard maturity model by which medical device organizations measure their capability to produce high-quality devices and increase patient safety. The FDA adjusts their engagement activities and submission requirements for participants in recognition of program engagement, which includes an annual MDDAP Evaluation Appraisal. Maturity levels are not used in the program. There are no known incompatibilities between quality system regulations and the CMMI framework; however, the appraisal also includes areas of the facility beyond the Quality Management System (QMS), which contains the primary functions of a medical device organization under regulation.

Program Details

The FDA launched the Case for Quality in 2011 to elevate the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.

The FDA established the Case for Quality following an in-depth review of device quality data and feedback from regulatory and industry stakeholders. The FDA's analysis flagged manufacturing quality risks. It also showed that firms that manage those risks by driving quality organization-wide are more productive, with fewer complaints and investigations, and often benefit from lower quality-related costs than their competitors.

In other words, investing in quality pays.

Firms with an established quality culture are able to avoid quality failures and shift the resulting freed resources to accelerate device design, innovation, and market introduction.

Dr. Jeffrey Shuren, former director of the FDA's Center for Devices and Radiological Health (CDRH), outlined the Case for Quality's role in advancing solutions to ensure patient access to high-quality medical devices and the FDA's commitment to their shared goal of improving patient outcomes.

A cultural shift of this magnitude demands the engagement of regulators, industry, providers, payers, and patients. In 2014, the FDA enlisted the Medical Device Innovation Consortium (MDIC) to foster a new level of collaboration between the agency and industry in a far-reaching Case for Quality movement.

In 2018, an MDIC working group launched a VIP pilot designed to leverage a proven maturity model, the CMMI framework, to enable medical device organizations to better understand, measure, and improve their capability to produce high-quality devices and ultimately increase patient safety.

CMMI appraisal results are leveraged by organizations to drive targeted continuous improvement activities throughout their facilities. In 2023, 88% of program participants reported an above average or excellent experience with the appraisal, and 93% reported that the appraisal identified opportunities to improve product quality.

In May of 2021, MDIC's Case for Quality collaborative community (CFQcc) announced the transition of the VIP from a pilot to a full program. Manufacturers who participate in VIP provide supplementary data to the FDA that can help simplify the review of submission activities. The FDA will adjust each manufacturer's engagement activities and change submission requirements. **Figure 1** outlines the potential VIP-specific regulatory opportunities for manufacturers.

Figure 1: Regulatory Opportunities

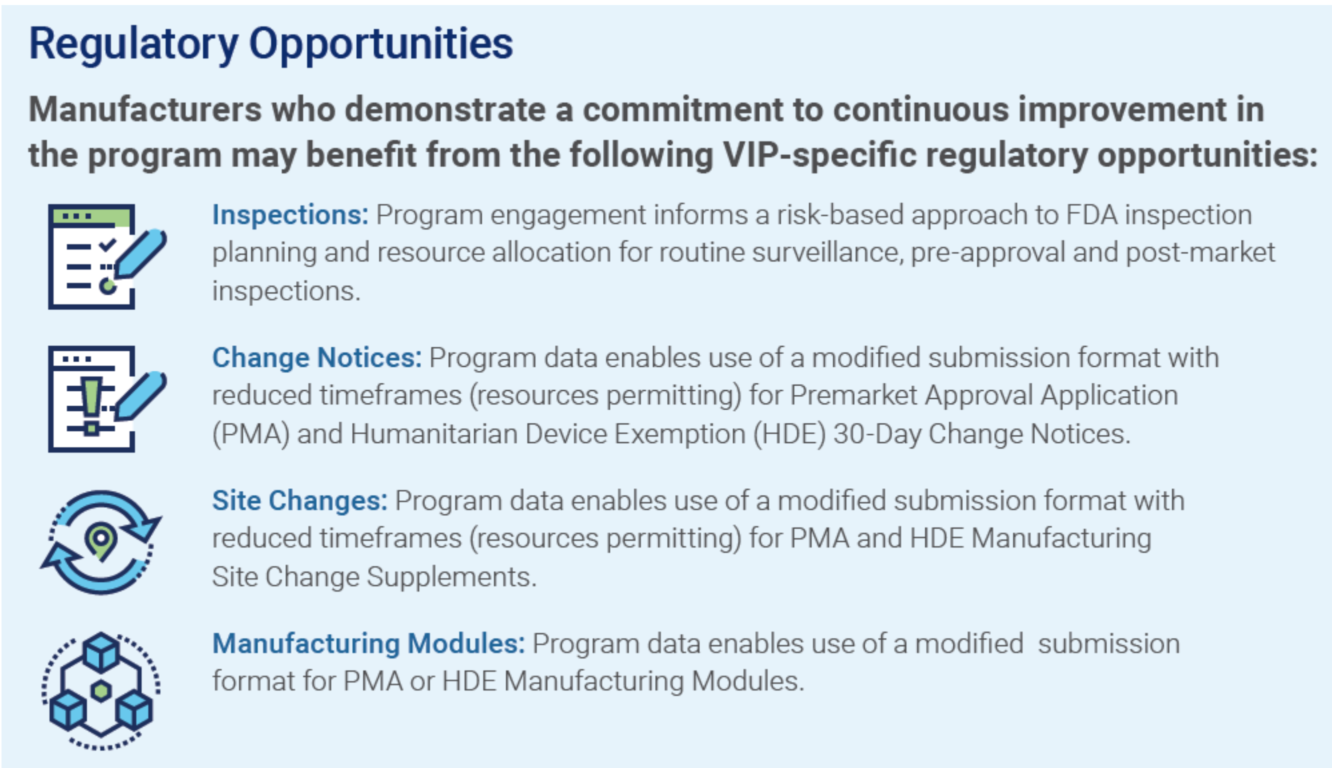


Figure 2: Program Timeline

2011
- FDA launched the Case for Quality (CfQ) to elevate the focus of all medical device stakeholders.

2014
- CfQ management transitioned to MDIC, enabling facilitation of a larger CfQ collaborative community.

2015
- CfQ formed a Maturity Model Working Group (MMWG) to determine if industry could leverage an existing maturity model to improve practices.
- MDIC contracted with Deloitte to study 22 different excellence models that concluded CMMI was the best fit for the initiative.

2016
- The MMWG conducted a Proof-of-Concept Pilot for CMMI in the medical device space for three facilities.
- Stakeholders were invited to observe the activities.

2017
- The MMWG created a set of sub-groups with a cross-section of representatives to develop a full pilot framework. Some representatives became early adopters.

2018
- MDDAP launched with 10 sites, growing to 35 by year end.
- Survey results indicated positive feedback from participants.
- FDA noted performance improvements in participating sites and the ability to maximize Agency resources.

2020
- The pilot began the transition into a formal program.
- ISACA expanded MDDAP services to a virtual environment and began development of the VIP Portal to manage datasets.

2022
- ISACA onboarded and trained the first group of FDA users in the VIP portal.
- VIP became recognized by the FDA through formal Draft Guidance.

2023
- Continued enhancements and evolution though ongoing improvement efforts to increase program scalability.
- Investigating new opportunities to provide more value from the program to everyone involved.

VIP Appraisers

VIP leverages a tailored version of the CMMI framework called the Medical Device Discovery Appraisal Program (MDDAP). In MDDAP, only Evaluation Appraisal types are used and have pre-defined, program-specific tailoring requirements. The following is an overview for appraisers delivering MDDAP services.

Certification Pathways

Internal ATM

Figure 3: Path to Become an Internal ATM

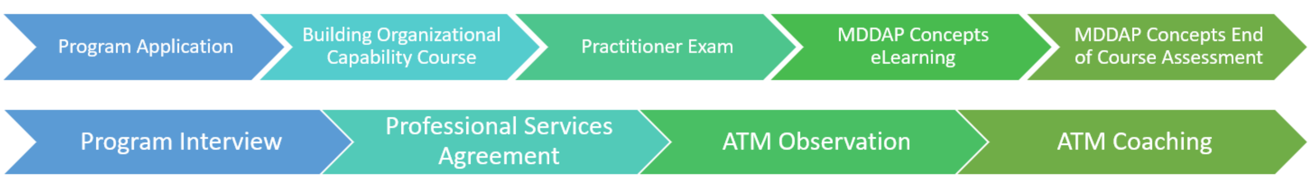
Path to become an Internal ATM:

- **Key Pathway Components**—To obtain the Internal Appraisal Team Member (I-ATM) certification, Candidates must first complete an apprenticeship wherein they participate on MDDAP Appraisals as extra team members to gain experience under the guidance of a coach. Then, they are eligible to participate on an MDDAP Appraisal as a core team member (where the core team is the minimum number of appraisal team members required to complete the appraisal scope). The path for I-ATMs is illustrated in **figure 3**.

ISACA ATM/ATL

Figure 4: Path to Become an ISACA ATM/ATL

Path to become an ISACA ATM:



Path to become an ISACA ATL (after ISACA ATM):

- **Key Pathway Components**—ISACA ATMs must pass a program interview and sign a Professional Services Agreement prior to completing an ISACA sponsored ATM observation on an MDDAP Appraisal.
- Individuals must achieve renewal requirements for maintaining the ISACA ATM/Appraisal Team Leader (ATL) certification. The paths for becoming an ATM or ATL are shown in **figure 4**.

Observations and Coaching

ATM Observation

I-ATM and ISACA ATM Candidates must successfully complete training and certification prerequisites before they can be observed. For ISACA ATM Candidates, the observation is considered an unpaid activity; however, travel expenses will be covered up to a certain amount (which varies by appraisal).

ATM observations require ATM Candidates to participate as an "extra" team member on an MDDAP Appraisal with an ATM Observer. ATM Candidates are responsible for leading exactly one discussion session for exactly one Practice Area (PA). They are also responsible for drafting the results for their assigned PA and building consensus around the final set of results. Finally, ATM Candidates must also participate in team discussions and retrospectives.

Once an ATM Observer has been assigned to the ATM Candidate, the Observer will schedule an introductory call to align on the details and expectations of the observation. ATM Observers can only conduct an observation for one Candidate per appraisal.

After the appraisal, the ATM Observer will complete the ATM Observation Report. Then, the ATM Observer and Candidate will meet to discuss the feedback and comments (i.e., what the Candidate learned, improvement opportunities, etc.). The ATM Observer will submit the ATM Observation Report and their recommendation to ISACA within 10 business days of the appraisal. ISACA will review the Observation Report and make a final decision to certify, coach, or fail the Candidate.

ATM Coaching

If there are areas indicated in the ATM Observation Report where the ATM Candidate can benefit from additional coaching, the Observer will provide ISACA with a coaching plan recommendation for the Candidate to complete with an ATM coach. If ISACA decides to coach the Candidate, then an ATM coach will be assigned work with them through the approved coaching plan. Several ATM coaches may be leveraged across multiple appraisals to support the Candidate.

Examples of coaching tasks include but are not limited to:

- Candidate reviews documentation (process documents, check lists, glossary terms, videos, etc.).
- Candidate shadows a more experienced ATM/ATL who performs appraisal tasks (discussions, notes, etc.).
- Candidate is monitored while performing appraisal tasks.
- Candidate discusses topics and questions with the coach (e.g., common misconceptions the coach has seen with other Candidates).

Candidates undergoing coaching are often referred to as “apprentices” undergoing an “apprenticeship.” I-ATMs may only participate as an extra team member during this apprenticeship, which is typically completed after two or more additional appraisals.

- **Second Appraisal**—Lead discussion session for two to three PAs
- **Third Appraisal**—Lead discussion session for three to five PAs

ATL Observations

Until there is a standalone MDDAP ATL certification (which is slated for the beginning of 2025), achieving the CMMI Lead Appraiser certification is a prerequisite to becoming an MDDAP ATL. ATL Candidates must first participate in a minimum of five MDDAP Appraisals as an ATM, including observation and apprenticeships, to qualify for ATL observation. For ISACA ATL Candidates, the ATL observation is a paid activity with travel expenses covered up to a certain amount (which varies by appraisal).

Prior to completing their ATL observation, the ATL Candidate must submit an MDDAP ATL Application. Once approved by ISACA, the Candidate will lead an MDDAP Appraisal with an ATL Observer. The Candidate is responsible for all the activities completed by the MDDAP ATL role, including all pre-appraisal and post-appraisal activities.

After the appraisal, the ATL Observer will complete the ATL Observation Report. The ATL Observer and Candidate will meet to discuss the feedback and comments (i.e., what the Candidate learned, improvement opportunities, etc.). The ATL Observer must submit the ATL Observation Report to ISACA within 10 business days of the appraisal. ISACA will review the Observation Report and make a final decision to certify, coach, or fail the Candidate. If the Candidate does not fail their observation, they will participate in their first check point with the appraised site alongside an ATL coach.

ATL Coaching

If there are areas indicated in the ATL Observation Report where the ATL Candidate can benefit from additional coaching, then the ATL Observer will provide ISACA with a coaching plan recommendation for the Candidate to complete with an ATL coach. If ISACA decides to coach the Candidate, an ATL coach will be assigned to work with the Candidate through the approved coaching plan. Several ATL coaches may be leveraged across multiple appraisals to support the ATL Candidate.

Appraiser Resources

MDDAP Appraiser Collaboration Site

ISACA ATMs and ATLs (hereafter "appraisers") will have access to the MDDAP Appraiser Collaboration SharePoint site after completing their Professional Services Agreement (PSA). This site provides appraisers with a variety of materials, resources, and updates about MDDAP. Materials and resources include but are not limited to:

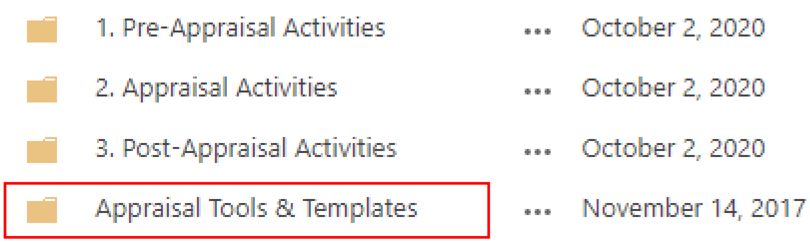
- Appraiser Meeting Minutes
  - Presentation slides and notes from each monthly appraiser meeting
- CAS Tools
  - Instructions and templates for adding appraisals to the CMMI Appraisal System (CAS)
- VAD Activities
  - Virtual Appraisal Delivery (VAD) training, guidelines, etc.
- MDDAP Service Provider Travel Policy
  - Defines standards and guidelines for business travel for all traveling on behalf of ISACA
- VIP Portal
  - Provides availability for MDDAP Appraisals

Any questions can be noted as a discussion entry in the MDDAP Appraiser Collaboration SharePoint site. The ISACA team and other appraisers will review and respond accordingly.

Tools and Templates

MDDAP tools and templates are provided to appraisers through the ISACA-hosted SharePoint site (shown in **figure 5**). These documents must be downloaded to be edited and should be imported into the CAS and VIP Portal where appropriate. Tools and templates are provided to ensure a consistent experience for participants and MDDAP appraisal team leads and members. The tools and templates are used by the appraisers and, in some cases, completed templates are provided to participants of the appraised organization (e.g., a heatmap, final results presentation, etc.).

Figure 5: Appraisal Tools and Templates



When delivering appraisals on behalf of ISACA, ISACA systems must be used to host appraisal artifacts, as they are secure, collaborative environments. No other platforms should be used. Anyone who has trouble accessing an ISACA system should reach out to the ISACA team for assistance. If artifacts are being reviewed, the recommendation is to use the appraised organization's digital sharing systems (e.g., Dropbox, Box, SharePoint) and for the team to receive "view only" access to limit risks to confidentiality.

Any change requests or errors requiring correction to any of the tools, templates, guidelines, etc., should also be noted as a discussion entry in the MDDAP Appraiser Collaboration SharePoint site. The ISACA team will review, triage, and act on these accordingly and communicate any and all changes to the appraisal community as necessary.

Specific instructions on how to use these templates and tools are provided within the tools or in other training material as appropriate.

CAS

All appraisals must be submitted in the CMMI Appraisal System (CAS). The ATL will generate an appraisal record in CAS and enter all pertinent information. ATMs are required to provide an electronic signature for the confidentiality/non-attribution and appraisal plan summary sections prior to the appraisal start date. After the appraisal, ATMs will be required to sign the Final Findings. Refer to the CAS – ATL Instructions.

Expected Engagement

Meeting Attendance

All certified and Candidate appraisers are expected to attend the MDDAP Appraiser meeting regularly and review any missed information via meeting minutes and/or recordings. ATLs are required to attend 50% of these meetings, which are generally one hour long. Meeting attendance is recorded, and MDDAP appraisers who are engaged in the meeting and the MDDAP appraiser community are eligible to earn one continuing professional education (CPE) credit for each live meeting attended for the renewal of their CMMI-credentialed certifications.

Individuals are also expected to actively participate in discussions (either live on the call or in discussion posts), sharing their insights and lessons learned with the larger group. Some may even contribute their expertise and skillsets to support the development of the program. At the very least, appraisers who wish to continue in the program must understand and adhere to changing processes and policies.

Certified and Candidate ATMs are expected to attend MDDAP ATM meetings regularly and review any missed information via meeting minutes and/or recordings. These MDDAP ATM meetings provide a space for ISACA ATMs and I-ATMs to discuss specific needs and questions, review and collect feedback on proposed changes, and build a community in which they can learn from one another. Anyone who has applied to be an ATM or I-ATM and is eligible to complete an ATM observation (i.e., has passed the Practitioner Exam and completed the MDDAP Concepts eLearning course) will be invited to this meeting series. These meetings generally last 30 minutes.

Occasionally, ISACA will bring in guest speakers to present on specific topics. ISACA may also offer periodic ATM training. All meeting invitees are encouraged to use SLIDO to propose topics or questions to help tailor each meeting agenda.

Updating Availability

Appraisers are expected to provide their availability via the calendar in the VIP Portal at least three months in advance; this allows ISACA to appropriately manage the program's capacity and assign teams. Refer to the Team Member Assignments section below for more details.

Note: ATLs can only lead 18 MDDAP Appraisals per calendar year and participate on an additional six MDDAP Appraisals as an ATM. ATMs can only participate in 24 MDDAP Appraisals per calendar year.

Contracting With ISACA

Statement of Work (SOW) Process

After an ATL submits the Appraisal Information Submission Form, ISACA will assess the information provided and identify ATMs to assign to the appraisal. Upon signing an appraisal SOW with the customer, ISACA will create an appraisal SOW for the ATL and ATMs. The SOW can take a week to go through legal approvals before being sent to the contracted appraiser. The contracted appraiser or their sponsoring company's Business Point of Contact (BPOC) must sign the SOW to commit to delivering appraisal services on behalf of ISACA. Once the contracted appraiser or their BPOC signs the SOW, ISACA will countersign, and an executed SOW will be sent to both the contracted appraiser (and their BPOC, if applicable) and ISACA.

MDDAP Appraisal SOWs outline expectations and deliverables for the appraisal, along with the compensation for the engagement. SOWs include language on health and safety protocols, along with a release and liability waiver. ISACA will provide $1,000 per day as a consulting fee for ATMs, $1,250 per day as a consulting fee for ATLs, and additional compensation for travel stipends (refer to the Travel and

Stipend Process section below and the Pricing and Compensation Guideline for more information). Please reach out to ISACA for any questions.

Note: For ISACA ATM Candidates, the observation is considered an unpaid activity; however, there is no observation fee due to ISACA, and travel expenses will be covered up to $2,400.

Appraisal Shifts

MDDAP Appraisal SOWs are written for both onsite and virtual appraisals. If an appraisal shifts to virtual last minute (see also "Appraisal Shifts" in Risk Mitigation), the appraiser will not receive an updated SOW. Instead, they should not invoice for the travel stipend indicated in the SOW. If appraisers have non-refundable costs, they can reach out to ISACA. ISACA will determine whether the costs are in line with the travel stipend and provide approval/rejection and next steps.

Purchase Order (PO) Process

For each MDDAP Appraisal, the appraisers will also receive their own specific PO, which they will include on their invoice to ISACA when submitting all necessary documents following appraisal completion. After accepting an appraisal, in addition to creating the appraiser SOW, ISACA will create a PO number for the specific appraisal engagement. ISACA will not begin the PO process until the SOW is signed. This typically takes about a week to complete and be approved. After the PO number is created, ISACA will send it to the appraiser via email.

Vendor Addition

All appraisers require ISACA to add their company as a vendor in the PO system. Upon ISACA requesting to add the company as a new vendor, ISACA Accounts Payable will send an encrypted email from the ISACA Accounts Payable department containing an Automated Clearing House (ACH) and a W9 form (for US vendors) or a Wire form (for international vendors). It is important to note that sometimes these emails may end up in spam or "junk" email.

ISACA cannot approve a company as a vendor without this information. Once an appraiser completes and signs the form(s), they should return them to ISACA Accounts Payable by replying to the encrypted email. To avoid delays with payment processing, invoices should be sent directly to accountspayable@isaca.org and include the PO number on the invoice.

Travel and Stipend Process

Within the MDDAP Appraisal SOW, there will be instructions on booking travel to the appraisal through ISACA's travel provider, TRAVELINK. There will also be a Travel Code that will need to be provided to TRAVELINK in order to book the travel. ISACA occasionally sends information for booking travel early. Appraisers should make every effort to book travel as far in advance as possible.

TRAVELINK counselors are available Monday through Friday from 6:00 a.m. to 10:00 p.m. CST and on weekends from 10:00 a.m. to 9:00 p.m. CST at 1-866-301-3011 or isacatravel@travelink.com. More information can be found in ISACA's MDDAP Service Provider Travel Policy.

Please see Risk Mitigations for full details.

Reimbursement for COVID tests

Appraisers should work closely with the ATL and site point of contact (POC) on any onsite requirements or parameters (proof of vaccination, COVID testing, restriction on onsite capacity, etc.). Those who need to get a COVID test to travel onsite or during the appraisal should notify ISACA. ISACA may provide reimbursement; to receive reimbursement, appraisers should submit the receipt to ISACA following approval. Refer to COVID Guidelines.

Testing Technology

Technology usability should be tested ahead of appraisals, and a backup technology option should be available. If an appraiser is unable to use video, they should still use audio for the appraisal.

Visas

Appraisers traveling to another country to perform appraisal activities should review all required visa information for their country.

If appraisers require a visa letter from ISACA in order to obtain a visa for MDDAP work, they should contact ISACA.

Invoice Process

Appraisers must provide an invoice to ISACA (addressed to accountspayable@isaca.org) within 10 days of completing MDDAP activities for an appraisal or check point. One invoice with one PO should be submitted at a time to avoid any payment delays. ISACA must receive the entire appraisal team's invoices to request final payment from the client.

Payment will not be submitted to the ATL unless all required steps have been completed, which includes the following:

- Appraisal
  - Appraisal is submitted to CAS and approved by ISACA
    - Appraisal artifacts uploaded to CAS include:
      - The schedule
      - Heatmap Tool
        - The appraisal information tab is complete
        - FDA heatmap is complete
        - PAs are characterized with notes
        - PAs match plan and reappraisal rationale
      - Results Presentation
  - Lessons Learned survey is completed
  - Correct versions of the tools have been used
- Check Point
  - Check Point Report submitted in the VIP Portal
    - Submitted as a Microsoft Word document; refer to the Check Point Report Template
    - Performance Metrics (required starting six months after the baseline appraisal)

- Reappraisal Rationale (for year 2 and beyond)
  - Submitted as a Microsoft Word document; refer to the Reappraisal Rationale Template
  - Facility Establishment Identification (FEI) number
  - Explanations are complete

Professionalism and Consulting

There is an expectation of professionalism for appraisers involved in the program. When appraisers are contracted to execute services on behalf of ISACA for MDDAP, the expectation is that they now represent ISACA. Appraisers may not solicit MDDAP clients.

Appraisers should not promote activities related to their own personal or business interests while delivering services on behalf of ISACA. However, if an MDDAP client contacts an appraiser directly to request additional services, that appraiser is welcome to oblige.

Appraisers must always inform ISACA when doing paid work for an MDDAP Participant. If ISACA learns an appraiser performed paid work without notice, it is grounds for removal from the program. If any appraisal team members own direct stock or investments in a company being appraised, this must be indicated as a potential Conflict of Interest (COI) in the CAS plan; however, ISACA does not need to be directly informed.

Delivering an MDDAP Appraisal

For a high-level overview, refer to the MDDAP Infographic.

Phase 0

In MDDAP, the ATL's responsibilities begin when ISACA assigns them to an appraisal. Assignment is determined by a number of factors, including but not limited to availability, certification requirements, team experience requirements, observation needs, geographic location, and history.

However, before the ATL is assigned, there are a few touchpoints between ISACA, the FDA, and the participating facility that provides context. First, the facility must submit an application with information such as the site location, approximate number of products, and the point of contact (POC). ISACA reviews this application for completion before submitting it to the FDA; the FDA then reviews the applicant facility's history to determine whether there are any active official actions indicated or issues surfaced in an inspection that requires the facility to take official action. If the organization passes the FDA's review, a congratulatory email is sent to both the facility POC and ISACA, and the facility becomes accepted into the program.

ISACA will reach out to the POC to welcome the facility to the program, provide high-level information (such as the program's intent and flow), and schedule their "onboarding" call. The onboarding call is intended to include the POC and ISACA Sales. The purpose of this one-hour call is to review:

- The background of the program
- What the program endeavors to achieve
- The difference in approach from other regulatory activities
- The scope and reasoning of the baseline appraisal
- Overview of the intake/scoping calls and their purpose
- An example schedule and how that schedule is determined
- An example heatmap and how to interpret the results (no minimum "score" is required)
- Overview of the checkpoint activities and their purpose
- Overview of the participant meeting and its purpose
- Cost expectations and legal review (specifically for confidentiality)

By the end of the onboarding call, all attendees should have a good understanding of what is expected of the facility and what they can expect from the program.

At this point, the facility could still opt to de-enroll from the program, at which point only ISACA's and the FDA's time has been invested. Therefore, ISACA will not assign an ATL until the organization has signed a master services agreement (MSA) and the Program Fee SOW. Signing the MSA allows ISACA to engage in providing paid services, and signing the Program Fee SOW officially enrolls the facility in VIP while covering the cost of ATL intake and scoping activities (among other things) should the facility later choose to de-enroll without receiving an appraisal.

Once these two documents are signed, ISACA will review ATL availability against the facility's targeted appraisal timeframe and make an assignment. Additionally, a separate introductory email will be sent to the ATL and the facility POC to complete the handoff.

Phase 1

Getting to Know the Assigned Site(s)

Prior to meeting with an assigned site, an ATL should conduct some research. A site's FEI number can be used to find information on the [FDA's Establishment Registration and Device Listing] website. This website will show an assigned site's registered devices and whether they are considered a manufacturer, contract manufacturer, distributor, etc. This will give ATLs a sense of the type and variety of products and services delivered by the assigned site(s). Additionally, ATLs should complete an online search to find the company's website and review its full product portfolio, services, history, culture, locations, and other compliance accomplishments. This will provide the ATL with a deeper sense of the site's identity and other broader nuances to consider.

Remember, one of the primary goals of MDDAP Appraisals, especially in the first year but on an ongoing basis, is to build trust and transparency between the participating site(s) and the program facilitators (ISACA, ATL, ATMs, FDA, and MDIC). If the site has sibling site(s) enrolled, seek guidance from their sibling site's first-hand experience; otherwise, ISACA can coordinate mentorship from an industry peer. If a site or site's organization has a trained I-ATM, consider adding them to the appraisal team.

Medical device organizations are very adept at completing audits and inspections. Appraisers must foster an open and welcoming environment so that appraisal participants feel comfortable sharing information that would not typically be included in a compliance activity. Building trust can be a challenge at any point in a participant organization's journey as new individuals are brought into the activities, especially in the first year. An appraiser's demeanor must remain conversational rather than interrogational.

For new sites, ATLs may consider scheduling introductory sessions for the team and site. These sessions are meant to enable site participants to build a rapport with the team and understand that the goal of the appraisal is to help the site. Examples of activities for these sessions include:

- Ice breakers—Introduce team members and site participants (and make it fun).
- CMMI PAs—Discuss the value of PAs and practices and connect it back to the organization and individual contributor work.
- Organizational overview—Cover information such as the organizational structure, overall processes, site philosophy and culture, corporate objectives cascading into specific objectives, product introduction, and floor plan.
- MDDAP overview—Discuss what MDDAP is and how an MDDAP appraisal differs from an FDA audit.
- FDA involvement (optional)—Consider asking FDA to join preliminary sessions to share their expectations and intentions and why trust is critical.

Sampling

The ATL is responsible for scheduling an intake call with the POC using the [Intake Call Template] as a guideline to appropriately sample and scope the appraisal activities for the facility. Presently, product and function sampling (instead of project sampling) is primarily used to identify the sample. The products sampled should represent the majority of products and processes in the facility; this can be accomplished by considering where there are key distinctions in the processes for manufacturing products.

For example, perhaps an organization has the following distinct products and processes:

- **70% Product Family A**—Two distinct processes
- **25% Product Families B and C**—One shared process distinct from Product Family A
- **5% Product Family D**—Similar process to Product Families B and C, with minor distinction

In this scenario, it would be fair to sample two products from A (one for each distinct process), one product from either B or C, and no products from D.

Types of processes to consider whether there are notable distinctions include but are not limited to:

- Manufacturing new vs. legacy products
- Manual vs. automated product manufacturing
- Components vs. finished products

Submitting the Intake Call and Scoping Form

Intake Call and Scoping

Newly assigned ATLs conduct an intake call with the VIP participant as the first step in the appraisal planning process. There is an optional MDDAP [Intake Call Template] that can help ATLs facilitate these initial calls. The purpose of the intake call is for the ATL to better understand the attributes of the facility being appraised (such as the organization's objectives, pain points, structure, products, etc.) so that an appropriate appraisal plan and schedule can be defined. The ATL should share their notes with the ATMs selected later so they can become familiar with the organization ahead of appraisal activities.

The Intake Call Template provides approximately 24 questions or prompts for collecting this information. The template is typically used in a teleconference between the ATL and representatives from the appraised facility. The ATL seeks to understand a variety of attributes, such as (but not limited to) the number of products manufactured at the location, the number of different processes performed at the site in the manufacturing of those products, the FDA risk classification of those products, the number of employees at the facility, and the organizational structure. The template serves as a guide for the ATL to determine what scoping is most appropriate, an expected team size, and any other considerations necessary for the appraisal. **Figure 6** highlights examples of scoping considerations.

Organizations should consider which projects, departments, functions, products, and/or processes most closely align with their business objectives and could be sampled. As organizations move further along in their reappraisal journey, they should consider looking at the following:

- Challenging areas or processes that have been newly implemented to help identify continuous improvement opportunities
- Areas of strength to see how that success could be applied across other parts of the business

Based on the organization's needs, a narrowed scope can be applied to the entire appraisal or specific PAs. If a narrowed scope is chosen, the ATL should work with the appraisal team to target questions that cover that specific scope.

If multiple functions, departments, projects, products, or processes are chosen for a PA, the ATL should assess the number of discussion sessions required for PA evaluation. Consider the following:

- If projects or products do not follow the same governing processes, it may be appropriate to split them into separate discussion sessions.
- If multiple functional levels with personnel reporting relationships are required to address a specific PA, it may be appropriate to split them into separate discussion sessions.

Figure 6: Examples of Scoping Considerations		
Project	• New technology adoption • Process improvements • Reorganization	• Automation • Corrective and preventative actions (CAPA)
Function or Department (within QMS)	• Research & development (R&D) • Supply planning • Operations • Quality	• Engineering • Clinical • Environmental health & safety (EHS) • Supplier quality or development
Function or Department (outside QMS)	• Information technology (IT) • Finance • Marketing	• Customer services • Human resources (HR) • Subcontractor relationships

Product Lines	• Finished goods:
	  o Implant
	  o Catheter
	  o Combination devices
	• Production line type:
	  o Manual
	  o Automated
	• Product class:
	  o I, II, or III
		• Subassemblies
		• Components
		• Packaging
		• Labeling
		• Production volume:
		  o High
		  o Low
		• Product maturity:
		  o Legacy product
		  o New product

Transactional QMS Processes	• Non-conformance • CAPA	• Complaint-handling
Business Processes	• Project management • Change management	• Supplier management • Strategic alignment

A few additional notes on the intake call and scoping include:

- The ATL can use the Intake Call Template to compile information needed for the appraisal plan and CAS upload.
- The customer may already have knowledge and experience with MDDAP and may have completed the template already.
- For multi-site appraisals, refer to the MDDAP Multi-Site Guidelines.

Reappraisal scoping considerations include the following:

- Before determining the reappraisal approach, the organizational unit (OU) should consider that changes in the appraisal may impact the reappraisal size and, therefore, cost, duration, and resources.
- When large or many changes are made to the criteria, scope, appraisal team, and/or participants, a reappraisal can affect the score and feel like a Year 1 appraisal.
    - I-ATM can help increase the trust, engagement, and accuracy of the reappraisal.
- It is important to strike a balance between the familiarity of the team year over year to make progress on existing threads and getting new perspectives to identify missed opportunities or additional insights.

Appraisal Target

MDDAP has a predefined view for a participant's first year and required PAs for out years.

Baseline Appraisal View

Every organization's first MDDAP Appraisal is considered their "baseline" appraisal, allowing the FDA to get a baseline view of the organization's capabilities at the start of their continuous improvement journey in the pilot.

As of this document's date, the scope for a baseline appraisal must be as follows (shown in **figure 7**).

Figure 7: Baseline Appraisal Scope

Practice Area (PA)	Practice Group Level (PGL)
Estimating (EST)	2
Planning (PLAN)	2
Monitor and Control (MC)	2
Configuration Management (CM)	2
Managing Performance and Measurement (MPM)	2
Requirements Development Management (RDM)	2
Process Quality Assurance (PQA)	2
Technical Solution (TS)*	3
Product Integration (PI)*	3
Governance (GOV)	2
Implementation Infrastructure (II)	2

*Note that TS and PI are appraised to PGL3, whereas all other PAs are considered PGL2. The reason for this is that the industry is doing well in these two development-specific PAs. Therefore, the FDA wants to see if the industry continues to do well at higher levels of capability. If so, the FDA may consider removing TS/PI from the baseline view.

Reappraisal View

The goal of a reappraisal is to provide value back to an OU wherever it needs it. OUs should work closely with their ATL to identify reappraisal criteria and scope that will help them along their continuous improvement journey. ATLs can utilize the Reappraisal Guidelines for requirements and best practices.

For all reappraisals, three PAs are considered core to MDDAP (shown in **figure 8**).

Figure 8: Core MDDAP Practice Areas

Practice Area	Practice Group Level
Managing Performance and Measurement (MPM)	≥2
Governance (GOV)	≥2
Implementation Infrastructure (II)	≥2

This means that all reappraisals must include the following:

- **Managing Performance and Measurement (MPM)**—Ensures that all levels of the organization understand how to measure success, track their performance against their targets aligned with the organizational objectives, and make adjustments when necessary
- **Governance (GOV)**—Ensures that leadership clearly sets the strategic goals and objectives, communicates them to all levels of the organization, and provides the resources necessary for teams to be successful
- **Implementation Infrastructure (II)**—Ensures that teams have clear and up-to-date processes in place and the support needed to fulfill the required activities to achieve the organizational goals and objectives through process definition and improvement

All other available PAs are considered elective. This includes all PAs within the Development (DEV), Services (SVC), Suppliers (SPM), Virtual (VRT), Safety (SAF), Security (SEC), Data (DATA), and People (PPL) Domain Views. The scope size of an MDDAP Reappraisal should be similar to the baseline appraisal; however, even this range can be flexible on a case-by-case basis.

Any ATL (in any domain) can lead an appraisal if only the core CMMI PAs are in scope. These include:

- Configuration Management (CM)
- Decision Analysis and Resolution (DAR)
- Estimating (EST)
- Causal Analysis and Resolution (CAR)
- Governance (GOV)
- Implementation Infrastructure (II)
- Managing Performance and Measurement (MPM)
- Monitor and Control (MC)
- Organizational Training (OT)
- Peer Reviews (PR)
- Planning (PLAN)
- Process Asset Development (PAD)
- Process Management (PCM)
- Process Quality Assurance (PQA)
- Requirements Development and Management (RDM)
- Risk and Opportunity Management (RSK)
- Verification and Validation (VV)

An ATL is required to be certified in a domain to lead an appraisal with PAs in that domain. Domain-specific PAs include:

- DEV-specific PAs
    - Technical Solution (TS)
    - Product Integration (PI)
- SVC-specific PAs
    - Continuity (CONT)
    - Incident Resolution and Prevention (IRP)
    - Service Delivery Management (SDM)
    - Strategic Service Management (STSM)
- SPM-specific PAs
    - Supplier Agreement Management (SAM)
- VRT-specific PAs
    - Enabling Virtual Work (EVW)
- SAF-specific PAs
    - Enabling Safety (ESAF)
- SEC-specific PAs:
    - Enabling Security (ESEC)
    - Managing Security Threats and Vulnerabilities (MST)
- DATA-specific PAs
    - Data Management (DM)
    - Data Quality (DQ)
- PPL-specific PAs
    - Workforce Empowerment (WE)

There are options for MDDAP ATLs who lack the credentials to lead an appraisal with domain-specific PA(s). These include:

1. The ATL can remove any PAs from a non-credentialed domain from the appraisal.
2. ATL can add PAs from a credentialed domain to the appraisal.
    a. ISACA can assign a credentialed ATL for the other domain PA(s) as an ATM.
    b. Note: There are exceptions for multiple domain appraisals, wherein the Lead Appraiser does not need to have ATL credentials for all domains. Instead, a Lead Appraiser of a multi-domain appraisal only needs to be credentialed for one of the domains and can have separate credentialed ATL(s) for the other domain(s) join the team as ATM(s).
3. ISACA can assign a credentialed ATL (who is also an MDDAP ATL) to lead the appraisal.
    a. The current ATL would become an ATM if qualified in the domain.

High Maturity

Due to additional requirements for high-maturity practices, an organization's reappraisal scope must be limited to Practice Group Level 3 (PGL3) practices; exceptions will also be considered on a case-by-case basis.

Reappraisal Rationale

When determining the reappraisal scope, the ATL must use the Reappraisal Rationale Template. Reappraisal Rationales must be reviewed and approved by the FDA.

Appraisal Details Submission

Before every MDDAP Appraisal, ATLs must submit the team size, appraisal dates, I-ATM details, etc., at least 12 weeks prior to the appraisal start date for ISACA review. For MDDAP Appraisals being delivered in 2024, ATLs should continue to use the Survey Gizmo form. For MDDAP Appraisals being delivered in 2025, ATLs must submit the information in the VIP Portal calendar event. This form can be shared by the ATL with ISACA ATMs and I-ATMs assigned to the appraisal upon request. Timely submission is required to complete all subsequent steps (including team assignments, SOWs, booking travel, etc.). If the ATL has trouble obtaining information from the site in a timely manner, they can contact ISACA for assistance. Refer to the Appraiser Compensation Guidelines for full details.

If submitting appraisal details for a reappraisal, the Reappraisal Rationale must also be submitted. ISACA will then submit the rationale to the FDA for review. The FDA has three business days from the time ISACA submits the rationale to review and provide feedback. If there is no response, the rationale is considered auto-approved and the ATL may proceed with planning. More often than not, the FDA will only respond if there is feedback. If feedback is provided, information will be relayed to the ATL. At that point, the ATL may be asked to resubmit the rationale for the FDA to review again.

Sometimes, the reappraisal rationale changes. In that case, the ATL should submit an updated copy to ISACA, which will then submit the updated version to the FDA.

Appraisal SOW

After confirming the appraisal details provided, ISACA will generate an SOW for the ATL. Refer to the Statement of Work (SOW) Process for more information.

Team Member Assignments

Appraisal details give ISACA context for how many ISACA ATMs and I-ATMs are needed for the appraisal. The team member size should be appropriate for the scope of the appraisal. An appraisal can have a mix of ISACA ATMs and I-ATMs. The site must identify any participating I-ATMs no later than 12 weeks before an appraisal. No changes to I-ATM participants can be made within six weeks before the appraisal. Refer to Appraiser Compensation Guidelines for full details.

Each MDDAP appraisal team must include at least two people whose combined experience includes ATL CMMI knowledge and three years of medical device experience (or experience on three MDDAP Appraisals). More than one appraiser enables the team to maintain accountability and objectivity throughout appraisal activities. All Year 1 Appraisals are required to have a minimum core team size of three appraisers (one ATL and two ATMs).

A fully qualified I-ATM can take the place of one ISACA ATM. The number of I-ATMs on an MDDAP Appraisal may not exceed 50% of the core team (the group of individuals minimally required to successfully complete the appraisal activities). Extra team members, such as MDDAP ATM Candidates completing their observation or apprenticeship, do not count towards the 50% rule for the core team. Refer to the MDDAP Team Composition examples.

Extra ATMs have fewer responsibilities than the core team members, who will take on those additional responsibilities if necessary. These mitigation steps reduce risk to the appraisal schedule and quality, as ATM Candidates are still being vetted to become full ATMs.

Team size is impacted by a number of factors, including but not limited to the variety and volume of products, number of full-time employees (FTEs)/part-time employees (PTEs), complexity of work, number of organizational functions in scope, number of PAs selected, and PGLs.

ISACA assigns the ATL to an MDDAP organization's appraisal. Then, based on the core team size and other appraisal criteria (language, model domains, etc.), ISACA sends a recommended list of eligible and available ATMs to the ATL for selection. MDDAP ATMs and ATLs must provide their availability in the VIP Portal.

ISACA will look at how many ISACA ATMs are needed and begin contacting available appraisers. Factors that can be considered for assignment include:

- Previous appraiser for site (relationship, history, understanding of facility)
- Availability (most common conflict)
- Team experience requirements
- Other appraisal considerations (from the Sponsor, facility, or ATL)
    - Example: New ATL needs someone who meets medical device experience requirements
- Domain experience
    - Example: Reappraisal looking at SVC PAs needs SVC experience
- Candidate requiring observation (in order of date eligible for observation)
- Geographic/travel costs

Note: ATLs and sites can make team member requests for ISACA's consideration; however, not all requests can be fulfilled. ISACA retains all scheduling authority, and neither the ATL nor the site may contact ISACA team members directly to request their participation in an appraisal. Where possible, ISACA tries to provide consistency year-to-year and site-to-site within an organization, but it can also be beneficial to bring in new perspectives occasionally.

Appraisal PA Assignments

After ATMs are assigned and introduced, the ATL should schedule an initial call prior to the appraisal to review team member experience and assign PAs to the appropriate individuals. The PA assignment limitations for Candidates and apprentices include:

- **Candidate**—Must lead exactly one discussion session for one PA
- **Apprentice (Second appraisal)**—Must lead discussion sessions for two to three PAs
- **Apprentice (Third appraisal)**—Must lead discussion sessions for three to five PAs

Drafting the Appraisal Plan

The purpose of the appraisal plan is to identify the scope, criteria, resources, risks, schedule, conflicts, and other necessary logistics for the MDDAP Appraisal. The planning process is performed by the organization or OU and the ATL.

The appraisal plan should be driven by what is of greatest value to the site and should consider the number of sites and practices being appraised, products and/or projects being sampled, processes being evaluated, and Objective Evidence (OE) being reviewed.

The plan includes the objectives, appraisal team information, PAs selected, scope (projects, products, etc.), risks, logistics, and results. MDDAP Appraisals strive to consider the appraised organization as holistically as possible to provide insights not just within individual projects but also where cross-functional teams or processes intersect. Refer to the MDDAP Participant Considerations to better understand how participants may be selected.

Refer to the CAS - ATL Guidelines.docx for explicit instructions to enter and submit MDDAP Appraisals in the CAS.

Schedule

A typical MDDAP Appraisal schedule is five days:

- Day 1—Kick-off and site tour
- Days 1-3—Discussions between team and site
- Day 4—Follow-up and preliminary results sessions
- Day 5—Executive brief, results presentation, and lessons learned

Additional logistical considerations are required for virtual appraisals. The delivery method (virtual, onsite, or hybrid) must be determined at least eight weeks prior to the appraisal start date. If the site is unsure whether they can accommodate an onsite appraisal (whether due to COVID, inclement weather, etc.), then ISACA will shift to virtual. When possible, sites should switch to virtual instead of rescheduling their appraisal date. The goal is that appraisals are distributed evenly throughout the year to make sure enough ATMs are available. Refer to the COVID Guidelines and Risk Mitigation Strategies for more details.

Appraisal Plan Reviews

Phase 1 must be complete in CAS before submission of the appraisal plan. ATL Candidates are required to have their appraisal plan reviewed by ISACA no later than four weeks prior to the appraisal start date. ISACA may provide feedback for the ATL Candidate to update or incorporate details in the plan. Once a new MDDAP ATL submits a total of three consecutive appraisal plans with minor or no edits from the quality team, they are no longer required to submit plans for review. On rare occasions, an ATL may no longer be required to submit their plans for review after one to two consecutive reviews with minor or no edits. ATL that is currently engaged in coaching may be required to submit more plans for review.

Gathering Evidence

- OE includes artifact review and affirmations (examples of OE are shown in **figure 9**).

    - Artifact review involves reviewing documented evidence.
    - Affirmations are verbally communicated to explain how people do their work.
    - Some OE can fall into both categories (e.g., demonstrations and tours).
- The intent of OE outside of discussions is to improve the accuracy of the appraisal team's assessment and provide additional support and insight into how the work is done.
- During Year 1 and 2 appraisals, OE includes discussions, tours, and sometimes demonstrations (e.g., tools, products, etc.).
    - Ad hoc artifact review may be performed to provide further insight into the organization.
    - Some organizations may need time to become more familiar with the program and appraisal approach; therefore, artifact review may not be appropriate.
- By the Year 3 appraisal, OUs are encouraged to consider if including artifacts in their OE review would be beneficial and support their appraisal objectives.
    - ATLs and Site Coordinators/Sponsors should consider having a conversation with the participants around the intent of artifact review and clarify its distinction from an audit (i.e., there is no backroom, it does not have to be perfect, and it should be presented as is).
    - Additional days of OE review (e.g., artifact review) or "OE days" may be required prior to the appraisal so that the team can review the materials. OE review occurs throughout the appraisal itself, but OE days involve reviewing documents before the appraisal.
        - Artifact review is not just about reviewing artifacts but also taking notes and using the information to prepare questions prior to the onsite meeting.
        - Note: Adding additional days or OE days increases the time and cost of the appraisal. The ATL should set expectations with the site up front on the value of OE days and how they can be beneficial. If the site does not want to incur the cost, then the appraisal scope should be reduced to compensate for incorporating OE days into the appraisal itself.
            - OE days should reflect the accurate amount of time the appraisal team needs to complete the review, which should be relayed to the site. OE days can be spread over one or more weeks that align with individual team member and site availability.
    - Any agreed-upon estimated and actual OE days will be included in the appraisal plan via CAS, and the cost will be included in the Participant and Appraiser SOWs.
- Appraisal teams should plan for how OE requests will be managed and processed during the appraisal.
    - Organizations should consider a combination of curated information and live discussions.
- OE collection should generally not be limited to QMS OE.

Figure 9: Examples of Objective Evidence (OE)			
Type	Example	Value	Considerations
Affirmations	Organization Overview/Tour *(required)*	Can provide understanding of the site flow, dynamics, and culture	• An agenda may be provided to optimize time with people/processes. • Multiple tours throughout the week may be beneficial; follow up with individuals in a discussion session.

Figure 9: Examples of Objective Evidence (OE)			
Type	Example	Value	Considerations
			• Tours may be performed remotely.
	Discussions *(required)*	Can inform the appraisal team how the work is performed by the people who do it	• OU and ATL should have conversations to identify appropriate participants for the discussions based on appraisal objectives, scope, and criteria.
	Product Overview *(required)*	Improves understanding of the type of products manufactured at the facility	• A live demo, allowing hands-on experience with the devices, may be more effective than a presentation.
	Site Meeting Observations	Provides visibility into candid conversations and how information flows up and down through the OU	• Join management level meetings (e.g., tiers) and follow the logical thread through the organization (e.g., lowest to highest). • Avoid having the site rearrange their work around the appraisal team.
Affirmation and Artifact Review	Tools Demo	Improves understanding of the tools that are used at the facility	• Live demos on how various tools and systems (e.g., configuration management, project management, production planning, etc.) are used. • These may be performed with a specific PA in mind (e.g., Project Management tool for PLAN, EST, MC).
Artifact Review	Organizational Chart *(required)*	Can help the team understand the participant dynamics and overall organizational structure	• Some of these artifacts are needed for the planning of the appraisal and may be requested ahead of time during planning sessions. • Artifacts may come up during discussion sessions that may be reviewed immediately or revisited at later time.
	Quality Plan and/or Manual	Can help define scope and most organizations are eager to share	
	Master Index	Can help appraisal teams understand what kind of processes have been documented	
	Metrics, Definitions, Dashboards	Could be considered as part of the Performance Report	
	Recent Newsletter	Can inform culture and what's important to site	
	Project Plans, A3s	Can inform questions around project management	
	Management Review, Tier Boards	Can inform what measures are important to the site and how they track data and progress	
	Process Documents, Playbooks, Standard Work	Can inform how the work is planned to be done	

Documented OE

Begin conversations early:

- The site takes the lead on which OE would best provide the team with information regarding the PAs and organizational functions in scope.
- It can be shared over the site's virtual tool ahead of discussion sessions and/or shared in real-time during discussion sessions.
- Documentation is meant to be supplementary to conversations:
    - The team is not relying on documents as primary evidence nor reading everything.
    - The team is sampling information, which is why 90% is the maximum "score."

Tours

Tours are still intended to be a low burden activity for the site, not a grand production.

- The ATL is expected to provide the appraisal team with advanced notice for any tour requirements, e.g., a clean room where individuals must wear protective clothing or rooms with have entranced restrictions.
- For virtual appraisals, tour dry runs should be completed ahead of time to work out potential technical issues.
- The tour should include a view of manufacturing and other functional areas in scope.
    - If time is limited, new or different work should be the primary focus.
- If virtual, the tour can be completed live with video or pre-recorded with a live audio voiceover.
    - Pre-recorded tours may work better for showing manufacturing activities.
    - Live tours may work better for other facility areas. The following should be considered for live tours conducted virtually:
        - Multiple cameras
        - Camera stabilization to avoid motion sickness
        - Proximity to the microphone (especially if wearing masks, which can muffle audio)
- As needed, tours should be supplemented with photos, process flow documents, activity demos, etc.
    - If something is difficult to see live, the appraisal team can request the site to send a picture.
- A site layout should be provided ahead of the tour and referenced during the tour to orient the appraisal team.
    - Sites can work with the ATL to discuss and plan the pathway ahead of time.
    - Sites should consider accounting for extra time for discussion during the tour.

Organization Meetings

Organization meetings can include the line, management, or leadership. Viewing the structure and content for meeting relevant to the appraisal can provide valuable information to the appraisal team.

- If an organization meeting is occurring virtually or in-person, the appraisal team can join.
    - These meetings can also be pre-recorded, especially if the schedule is tight.
- If there is something exciting happening, sites should notify the team.
- It is useful to have an organizational chart available that is applicable to the appraisal.
    - It is also helpful to show reporting relationships and identify leadership to give perspective during discussions and ensure open communication.

Discussion and Validation Sessions
In discussion and validation sessions, confidentiality and non-attribution agreements apply. There is no recording or note-taking permitted.

- Preparation
    - Participants should be reminded that they do not need to prepare for discussion sessions.
        - The appraisal team will learn more if participants do not have prepared answers.
    - Participants should be encouraged to highlight both positives and issues.
- Room management
    - The Site Coordinator can join the session early to verify all identified attendees are present and that no additional personnel are in attendance. Coordinators must leave before the discussion or validation session begins to maintain confidentiality and non-attribution.
        - It is beneficial to identify backups ahead of time so the Coordinator can contact them if an identified attendee is no longer available.
    - If virtual, the session may be co-located (it is helpful for the Coordinator if most staff are onsite) or privately located (it is helpful if large numbers of staff are working from home).
- Time management
    - Multiple participants talking over each other should be avoided. Discussion can be supplemented with the chat feature as needed.
    - Discussion sessions should be kept to six people or less; validations should have 15 people or less to allow for more interaction.
    - It is important to schedule enough time for each session, especially when multiple PAs are grouped for the discussion.
- Approach management
    - Presentation time should be limited to a total of no more than 30 minutes across all presenters, with the remaining time designated for discussion.
        - If possible, the site should provide any presentation materials ahead of time.
    - People should be encouraged to ask clarifying questions or raise concerns in validation.
    - It is beneficial to group discussion session attendees into larger validation groups.

Two-Question Survey

Two weeks before the appraisal is scheduled to be delivered, the ATL should solicit a set of questions from the Appraisal Sponsor to be asked through a Two-Question Survey. The ATL creates and sends the survey to the appraisal site participants. If the ATL is unable to create the survey, ISACA has the ability to create the survey and provide a results link. The Two-Question Survey is distributed during the appraisal week, and results are provided to the organization during the final results presentation. While it is a requirement for Year 1 appraisals, it is not a requirement for reappraisals.

- Benefits of the survey
    - The Site Sponsor may choose to utilize the survey for questions they want to ensure are anonymous.
    - Survey responses may jog new ideas, achieve synergy across teams that brings to light issues or opportunities, and/or provide a pulse check.

    - The questions help people think about their work in new ways.
- Logistics
    - The questions may change year over year.
    - More or less than two questions may be asked.
    - The ATL or Site Coordinator may distribute the survey.
        - Distribution by the Coordinator prevents the survey from going to spam folders.
    - Survey platforms should be tested with each organization to ensure accessibility.
    - The survey may be distributed to anyone identified by the Site Sponsor (e.g., appraisal participants, the entire OU being appraised, all office professionals).
        - If the ATL distributes the survey and participants outside of the appraisal plan are requested for feedback, an additional list of email addresses must be provided.
    - Survey results must be scrubbed to remove illicit language and/or specific names and roles that may be attributable.
    - Site Sponsors may choose how the survey results are provided to the organization. This can include but is not limited to:
        - Presented during the final findings to the organization
        - Printed out for review for the organization
        - Provided separately to the organization at the discretion of the Sponsor
- Site Sponsors may choose to forego the survey if they already use several survey platforms within their organization.

Standard baseline questions include the following (and can be modified per the Sponsor's request):

- If you were to start this organization over from scratch, which activities/behaviors would you keep?
- If you were to start this organization over from scratch, which activities/behaviors would you avoid, and what would you do differently?

Standard reappraisal questions include the following (and can be modified per the Sponsor's request):

- What has been the most impactful process improvement(s) in the last 12 months?
- Last year, we asked you what activities/behaviors you liked and would stop or alter. We think we either acted on your suggestions or, at a minimum, communicated why we could not alter or stop a specific process. If we fell short of your expectations, please give us another chance to effect positive change by telling us what we missed.

Phase 2

Tools and Templates

When possible, the ATL should prepare tools and templates prior to the appraisal. The general purpose of each template is provided below. Specific instructions are provided within the tools or in other training materials as appropriate.

Appraisal Kick-Off

The purpose of the Kick-Off Presentation Template is to provide a standardized set of slides that the ATL can use to present at the start of the onsite phase of the appraisal. This presentation is given to appraisal participants, typically as the first official scheduled event of the appraisal. It provides information to the participants from the appraisal plan, such as the appraisal scope and the schedule. It also contextualizes other topics, including what MDDAP and the Case for Quality are; the differences between MDDAP Appraisals and typical regulatory audits or inspections; what the CMMI framework is; the expectations for discussion sessions; what the Two-Question Survey will be (if used); and what appraisal results will be shared with the FDA. The kick-off presentation can be shared with the appraised organization through the Site Coordinator or Appraisal Sponsor, who can then distribute it to other members of the organization at their discretion.

Facilitate Discussion Sessions

The purpose of the Discussion Script Templates, also called discussion prompts or discussion questions, is to provide a standardized mechanism by which ATMs can capture notes and facilitate discussions. These templates provide a consistent context for the purpose and intent of the conversation and help initiate the discussion and facilitate closing remarks.

Discussion facilitators are not expected to follow the question prompts verbatim; rather, the template is intended to be a quick reference tool for ATMs to frame the conversation appropriately and ensure they are addressing all the practices within a PA. Facilitators are encouraged to customize their questions based on the organizational context and appraisal scope and may seek guidance from the ATL.

Each team member taking notes should keep their own discussion script document to capture the contents of the conversation. Discussion scripts can be captured digitally or printed out and captured manually (at the discretion of the ATL and ATMs). Discussion script outputs are stored in the Discussion Questions folder in the Appraisal Activities folder of the Appraisal Engagement SharePoint site. I-ATMs should be reminded that the notes are not just for individuals; they are meant to help the team reach consensus and must be clear and complete.

Demonstrations, tours, and presentations are all considered discussion sessions where questions can be asked. ATMs must take notes during all discussion sessions. Notes should be complete and timely. ATMs are responsible for ensuring that enough OE has been collected (via discussion sessions and/or artifact review) for all practices within their assigned PA(s).

A discussion script template should be dedicated to each PA. Some PAs may be combined if they align with a functional process at the organization being appraised (e.g., EST, PLAN, and MC are often combined for project management functions). There is no standalone discussion script for II, as there is a section for II-related questions on the processes being assessed at the end of each PA script template.

Team members should try to ask questions that encourage open and transparent dialogue and allow and invite other team members to ask additional questions. Mini-teams are not encouraged during MDDAP Appraisals; rather, it is recommended to include all team members in discussion sessions to establish full team consensus for appraisal results. However, there may be use cases where it is appropriate to schedule concurrent discussion sessions that enable the team to divide the work and fit more activities into the appraisal schedule.

Unlike other appraisal artifacts that are produced, all discussion scripts and related notes are destroyed at the close of the appraisal. This is a step to further assure confidentiality and non-attribution for appraisal activities. This activity is facilitated by the ATL.

Drafting Appraisal Results

Each team member (including the ATL) with PA assignments is responsible for drafting the initial results for their PAs and capturing this information in the MDDAP Appraisal Tool and Heatmap. The purpose of this tool is to provide a document where:

- Appraisal results and evidence are noted for the processes reviewed in the appraisal (against relevant PAs)
- Characterizations of practices are captured based on the appraisal team consensus for the processes reviewed in the appraisal (against relevant PAs)
- A view of practice and PA scorings in views that are appropriate for both the organization and the FDA is provided

The heatmap tool is a Microsoft Excel spreadsheet with tabs dedicated to each PA. The organization being appraised will be provided a master copy of this heatmap. Therefore, the document should be reviewed and "scrubbed" before any transfers to ensure there is no data saved that can be attributed to any individuals.

Draft entries should include a characterization for each practice: Satisfied (meets practice intent), Partially Satisfied (sometimes meets practice intent), or Deficient (does not meet practice intent). Refer to the MDDAP Scoring Guide.

MDDAP is an Evaluation Appraisal type, which is not required to provide practice characterizations for the sampled projects or support functions. MDDAP Evaluation Appraisals also do not assign a capability or maturity level rating or a practice group or PA rating to appraised organizations.

Team members should include the evidence considered when providing a characterization. If the characterization is Partially Satisfied or Deficient, the team member must also include result statements describing the opportunity. Team members can also optionally include any strengths or notes related to their PA.

Result statements should be clear, actionable, and demonstrate the value of addressing opportunities. Results statements should avoid using absolutes, specific examples, and suggested solutions. Possible result types include:

- **Strengths**—Rare exemplary areas
- **Opportunities**—Gaps (required for non-Satisfied practices)
- **Notes**—Neither strength nor opportunity
    - **Warning**—No gap against the model but an observation that the current implementation may cause risk

- **Benefit**—No strength, but there may be an improvement project underway that should be expanded to other areas to further benefit the organization

Appraisal results are owned by the appraised organization, and leadership is encouraged to prioritize only the responsive actions that are most valuable.

Team Consensus

Although drafting the appraisal results is typically an individual team member activity, the entire team must build consensus around the results, which will be shared with the site for validation. MDDAP leverages the thumbs up ("I will support it"), thumbs down ("This is not my first choice"), and thumbs sideways ("I can live with it") technique. All team members must give a thumbs up or sideways for a characterization and corresponding result statement to be accepted for validation.

Validation

The purpose of the Validation PowerPoint Deck is to provide a standard mechanism for the appraisal team to present preliminary results to the organization being appraised. This session enables the appraisal team to understand if the appraisal results are accurate (the organization may provide additional evidence), can be understood a month from now (clear and actionable), and avoids any hot-button words.

The validation deck is divided into two sections: (1) setting expectations for the validation session and (2) reviewing each PA included in the appraisal. At the discretion of the ATL, multiple validation sessions may be held to assure confidentiality. For example, the ATL may elect to have different validation sessions for management staff and individual contributors. Alternately, different validation sessions could be held with a focus on each PA with participants who attended that initial session.

Validation sessions are held only with participants who were a part of a discussion or information-collecting session during the appraisal. Those who have not been a part of those sessions are prohibited from participating in the validation sessions.

Validation sessions are still an information-gathering activity and ATMs are expected to collect notes on the appraised organization's responses to preliminary observations. This collection of notes not only includes verbal feedback provided but any body language noticed (e.g., nodding in affirmation or scrunching forehead if not understanding).

The ATL uses the deck to guide the session, noting that while the observations against the model are what the appraisal team wants to discuss, the appraisal team will not define specific solutions to any observation in this session or commit to any specific language changes to any noted observation. While strengths are not required to be validated, the appraisal team and site may find value in validating all opportunities, notes, and strengths.

This activity is unique compared to a typical audit or inspection and begins the transition of result ownership to the organization. ATLs typically facilitate these validation sessions; however, ATMs should be encouraged and prepared to speak to their result statements if questions arise. Site staff may also answer questions. All final results must first be validated. The validation deck is not delivered to the appraised organization.

Delivering Final Results and Executive Session

Executive Session

The ATL must present the final results to the Sponsor, who may choose to include additional key members from leadership. The benefits of this additional session include securing buy-in from leadership, ensuring the results are understood, and beginning to transfer results to the Sponsor. The ATL should prepare the Appraisal Disclosure Statement (ADS) for the executive session. It may be helpful to remind the Sponsor that they will be called upon to share some words. Consider scheduling next steps (e.g., a one-year roadmap for a Sponsor-prioritized process improvement plan focused on the highest value and biggest impact opportunities).

Final Results

The purpose of the Final Results Presentation PowerPoint Deck is to provide a standardized mechanism to present final results to the organization being appraised. All draft results should be updated as appropriate, with team consensus, based on the feedback from validation sessions. Results are delivered by the ATL to the organization. Anyone in the organization may be invited by the Sponsor to join this final session. If the organization leveraged a Two-Question Survey, then those results are also presented to the organization.

Phase 3

Lessons Learned

The ATL will also facilitate a retrospective meeting with the appraisal team and site to discuss what went well and what could be improved. These lessons learned should be submitted via a Lessons Learned Survey (which can be after the appraisal is conducted). This survey allows ISACA to monitor program quality and ultimately get closer to our shared goal of increased patient safety.

Feedback Forms

Each team member is required to complete feedback forms in CAS for all other members of the team. This feedback allows ISACA to monitor appraiser performance to ensure they are continuing to provide valuable appraisals or investigate recommendations for improvement. The data from these forms will be provided in the individual's CAS profile after five feedback forms have been submitted for that individual. Feedback is updated monthly to ensure anonymity. It is recommended that all appraisers look at their feedback to continually improve their skills.

Post-Appraisal Survey

The week after the appraisal, ISACA will send the Site Sponsor and/or Coordinator a survey link to share with all appraisal participants. Sponsors and Coordinators are encouraged to get at least a 50% response rate, as the data will be used to evaluate their satisfaction and experience with the program and the performance of the appraisal team. However, the 50% is not a requirement. Participants are highly encouraged to share ideas for improvement opportunities in this survey as well.

Appraisers are also provided report links with a summary of this data to show their ATM and ATL (if applicable) feedback so they can continually improve their skills for the program.

CAS

ATL must submit the CAS record to ISACA’s quality team for review. Once the appraisal is approved, the results summary will be sent to the FDA, which enables a participant’s regulatory benefits in the first year (and ongoing in out years).

Upon completion, the ATL must ensure that all notes are destroyed and all OE is returned to the organization (if applicable).

Check Point Process

On a quarterly basis after the first appraisal, the ATL will facilitate a check point with the Site Sponsor and other key stakeholders. ATLs should reference both the Check Point Guidelines and Template.

During the first check point (typically three-months post appraisal), the ATL should have a discussion with the site about the performance metrics (including what they are) and the information to collect and go over as required for submission. Starting in the second check point (typically six-months post appraisal), ATLs must begin collecting performance report metrics from the site. ATLs should reference the Performance Report Process and submit the check point and performance metrics to the VIP Portal by referencing the Check Point and Performance Report Guide.

Resources

Below is a comprehensive list of program resources available for review.

Program

- Program Overview—This document provides a high-level overview of the VIP.
- Program Landing Page—This is the centralized website for information on the VIP, including eligibility, benefits, case studies, and more.
- FDA White Paper—This white paper documents the success of the VIP Pilot, which was launched in 2018.
- FDA Final Guidance—This document outlines the FDA's formal support for VIP.

Appraiser Pathway Information

- I-ATM Pathway–This document details the requirements for becoming an Internal ATM.
  - Associate / Practitioner Directory–This directory shows all certified ATMs and their renewal date.
- ATM and ATL Pathway—This document details how to become an MDDAP ATM/ATL.
- Courses
  - Building Organizational Capability Courses—This page lists all Building Organizational Capability (BOC) courses for practitioner ATMs by instructor and date. This certification covers all CMMI PAs.
  - Foundations of Capability Courses—This page lists all Foundations of Capability courses by instructor and date. This certification is a prerequisite for serving on an MDDAP appraisal team for Development or Services domain appraisals only.
  - Building Development Excellence Courses—This page lists Building Development Excellence courses by instructor and date. This certification is a prerequisite for serving on an MDDAP appraisal team for Development domain appraisals only.
  - Building Service Excellence Courses—This page lists Building Service Excellence courses by instructor and date. This certification is a prerequisite for serving on an MDDAP appraisal team for Services domain appraisals only.
- Renewals
  - Associate Renewal—This page provides information on the CMMI V3.0 Certified Associate Exam Retake or Renewal.
- Practitioner Exam—This page provides information on the CMMI Certified Practitioner Exam, which must be passed every three years to maintain the Practitioner Certification.
- MDDAP Concepts E-Learning—This page includes the MDDAP Concepts E-Learning course, which must be completed by anyone who would like to become an ATM on an MDDAP Appraisal, including any VIP participants or current CMMI ATMs.
  - MDDAP Concepts Retake Assessment—This page provides details on the MDDAP Concepts Retake Assessment.

Guidelines and Policies

- COVID Guidelines—This document provides guidelines in the event an appraisal needs to shift from an onsite appraisal to a virtual appraisal due to COVID-19. It includes special logistics and considerations for the planning and appraisal process to ensure a smooth appraisal.

- Rainy Day Policy—This document's goal is to create an open dialogue for ISACA, the FDA, and participants to work together on addressing concerns that arise during program participation and lay the grounds for program removal.
- Risk Mitigation Policy—This document provides different risk mitigations procedures regarding virtual appraisal shifts, team member emergencies/removals, and contacting ISACA for escalations.
- Reappraisal Guidelines—This document is a tool to help guide appraisers and participants when considering reappraisal criteria and scope that will help them along their continuous improvement journey.
- Check Point Guidelines—This document is a tool to guide appraisers and participants when considering quarterly check points and performance metrics.
    - Performance Report Process—This document is an overview of the Performance Report process, including the background, approach and timing, data sharing, and program requirements.
- Multi-Site Guidelines—This document is a tool to guide appraisers and participants when considering multi-site appraisals and determining whether a multi-site appraisal is a good fit for an organization.
- MDDAP Roles and Responsibilities—This document outlines the roles and responsibilities of key stakeholders for MDDAP Appraisals.
- Participant Considerations—This document serves as a guide for Sponsors and Coordinators in selecting participants.
- Scoring Guide—This document serves as a guide on scoring MDDAP Appraisals and why scoring can differ each year.
- MDDAP Service Provider Travel Policy—This document provides parameters for booking travel for MDDAP Appraisal activities taking place on behalf of ISACA and is applicable to MDDAP service providers only. All travel is subject to this Travel Policy unless explicitly approved by ISACA.
- ATM Playbook—This is a quick guide and easy reference document for any appraiser functioning in the role of an ATM on an MDDAP Appraisal.
- CMMI Policies—ISACA, in the administration of the licensed product suites, has established policies related to the training, certification, and delivery of official CMMI services. MDDAP Service Provider Travel Policy

Templates and Tools

- MDDAP Appraisals Tools and Templates—This folder contains all the standardized MDDAP tools and templates (both required and optional) used for the delivery of MDDAP Appraisals.
- Intake Call Template—This is an optional template for the first call with a new site to understand their organizational structure for sampling purposes.
    - FDA Site—This is an FDA website that provides the ability to search for site information by FEI number.
- Reappraisal Rationale Template—This is a required template to justify the appraisal criteria for any MDDAP Reappraisal.

- Appraisal Scope Information Form Submission—This is the survey tool for submitting appraisal criteria and scope information for MDDAP Appraisals being delivered in 2024 for ISACA to provide a quote to the customer and assign an appropriately experienced appraisal team.
- Appraisal Plan Word Template—This is a guideline for items to consider when planning an MDDAP Appraisal.
- Kick-Off Meeting Template—This is a required template to be used when initiating the MDDAP Appraisal Phase 2 with a VIP participant.
- Discussion Questions—This folder contains a series of optional template prompts and a note-taking structure for conducting MDDAP Appraisal discussions.
- Validation Template—This is a required template to be used when validating preliminary results during MDDAP Appraisals. It should not be delivered to VIP participants.
- Appraisal Tool and Heatmap—This is a required template to be used when characterizing practices and documenting supporting evidence during an MDDAP Appraisal.
- Final Results Template—This is a required template to be used when delivering the final MDDAP Appraisal results to a VIP participant.
- Check Point Template—This is a required template to be used when conducting quarterly checkpoints with VIP participants (outside of the quarter during which the MDDAP Appraisal is conducted).
- Lessons Learned Survey—This is a required survey to be completed by the appraisal team at the end of every MDDAP Appraisal.
- ATM Observation Form Template—This is a required template to be used when conducting an observation for any MDDAP ATM Candidate.
- ATL Observation Form Template—This is a required template to be used when conducting an observation for any MDDAP ATL Candidate in 2024. A new form will be made available in 2025 for the standalone MDDAP ATL certification.

CAS

- CAS System—This link redirects to the CMMI Appraisal System (CAS); appraisers can use CAS to access past appraisals, create records for new appraisals, and submit documentation for completed appraisals.
    - CAS Instructions and Tools—This SharePoint file location stores all current CAS resources and documents for appraisers.
        - Resource Estimate—This document provides an approximate expectation of hours needed to support an appraisal, broken down by contributor role.
    - CAS Tutorial—This recording from the September 2021 Monthly Appraiser Meeting provides a walk-through of CAS for MDDAP Appraisals.
        - CAS – ATL Instructions—This document provides instructions and guidance for MDDAP ATLs using CAS.
        - CAS Participant Instructions—This document provides instructions and guidance for MDDAP participants using CAS.
    - CAS Quality Review Times—The ISACA quality team’s “Our Commitment to Quality” page provides ISACA’s purpose and promise, helpful links to policies, appeals, complaints, and tips webpages, insight into appraisal review timelines, and ethics and compliance information.

VIP Portal

- VIP Portal—This is the link to the VIP Portal system login page. The VIP Portal has a calendar used by ISACA to align appraiser availability to appraisal opportunities based on monthly/quarterly updates provided by appraisers regarding their weekly availability.
- Check Point and Performance Report Guide—This document is a guide on how to submit check points and performance metrics in the VIP Portal system.

General

- MDDAP Appraiser Collaboration SharePoint Site—This SharePoint file location stores all current MDDAP appraiser resources and documents.
    - Appraiser Meeting Minutes—This folder contains historic meeting minutes from the Monthly Appraiser Meeting calls between ISACA and the MDDAP Appraiser Community.
        - Appraiser Meeting Topic Submission—This link redirects to a form where appraisers can anonymously submit questions and/or topics they would like ISACA to speak to in upcoming Monthly Appraiser Meetings.
    - VAD Resources—This folder contains various tools to aid in supporting virtual appraisal activities, including a VAD training recording and presentation, COVID guidelines, and even Zoom backgrounds.

Regulatory Benefits

- Regulatory Benefits Overview—This document provides a brief overview of the different program benefits.
- Regulatory Benefits Q&A with FDA—This document provides FDA answers to common regulatory benefit questions.
- Streamlined 30-Day Change Notice—This document details the streamlined 30-Day Change Notice regulatory benefit.
- Streamlined Site Transfer—This document details the streamlined site transfer regulatory benefit.
- Streamlined PMA manufacturing module—This document details the streamlined PMA manufacturing module regulatory benefit.

Medical Device Context

The following are freely available resources that are not affiliated with MDDAP:

- Top 100 Medical Device Acronyms & Terminology You Need to Know
- 21 CFR 820 (Quality System Regulation)
- QMS (Quality Management System)
- FDA's PMA Supplements and Amendments: When and How to Use Each
- Ultimate Guide to Corrective and Preventive Action (CAPA) for Medical Devices

Acronyms

- MDDAP—Medical Device Discovery Appraisal Program
- ISACA—Information Systems Audit and Control Association
- CMMI—Capability Maturity Model Integration
- ATL—Appraisal Team Lead
- ATM—Appraisal Team Member
- I-ATM—Internal Appraisal Team Member
- CAS—CMMI Appraisal System
- VAD—Virtual Appraisal Delivery
- PSA—Professional Services Agreement
- SOW—Statement of Work
- PO—Purchase Order
- PA—Practice Area

ISACA MDDAP Team

MDDAP Appraisers and Participants should direct their questions to the correct individuals on the MDDAP Team. In the list of MDDAP Staff Roles, there is information on the ISACA MDDAP Team, including individuals' contact information and primary responsibilities for the MDDAP program. It is imperative that the correct person is contacted in order to ensure timely responses.