

# *maestro* 2.X

*Orchestrating Advanced Solutions  
to Exploit Integrated Clinical Data*

## **MAESTRO 2.X**

### **Case for Change Strategy**



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# 1 INTRODUCTION

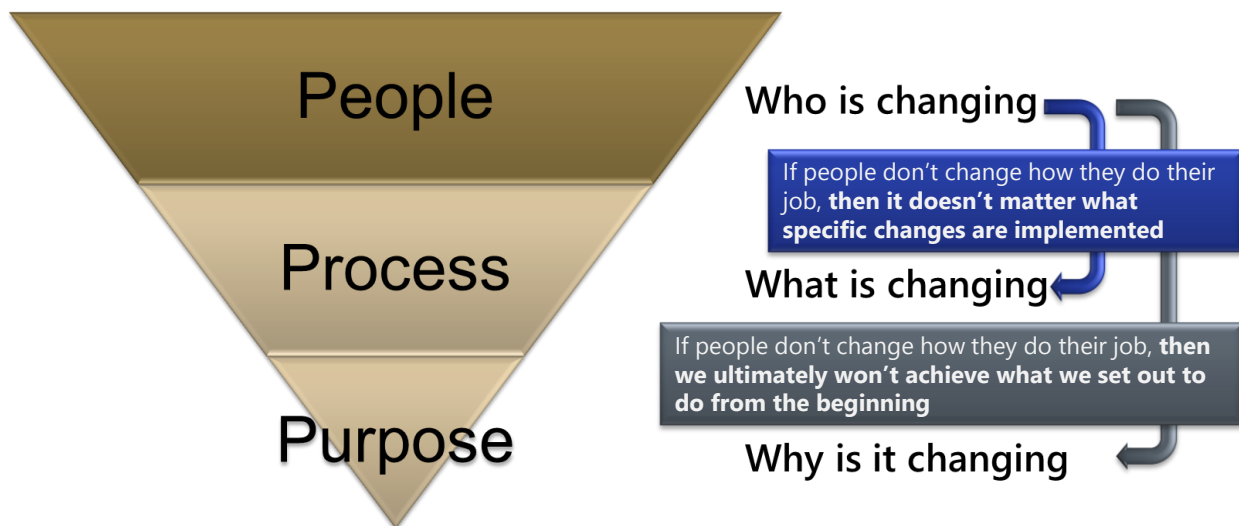
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Change Management encompasses a variety of activities and processes. The objective of Change Management is to ensure that the introduction of and transition to new procedures, processes, systems, workflows, and organizational structures occurs smoothly with a minimum of unanticipated impact on business and the affected individuals. And just as importantly, ensure that the change is successful.

Change happens one person at a time; the individual unit of change. Whether it is 15 people adopting a new process or 150 people using a new technology, an initiative is only successful if everyone is adopting and using their new process or tool. There are three people-centric factors that impact a transition:

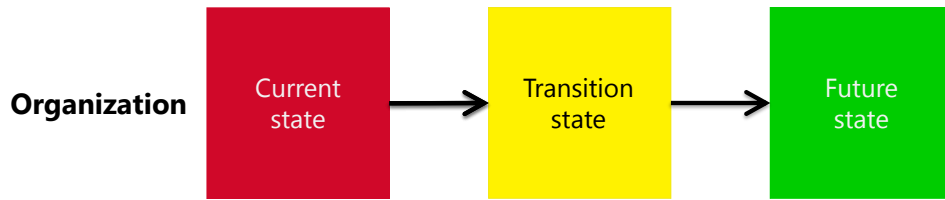
- Speed of adoption
- Ultimate utilization
- Proficiency

The Case for Change address all three of these by creating awareness, providing communication to set and manage expectations, encouraging necessary training, and establishing a clear path for transition. It targets the people-centric issues of change.

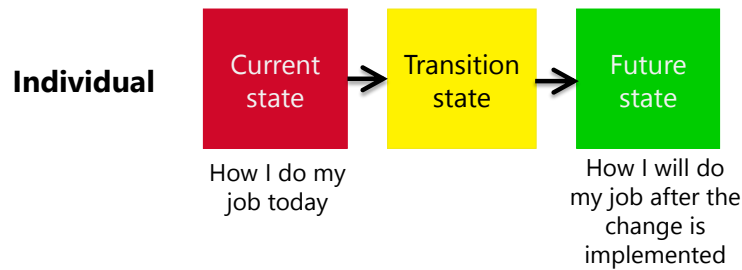


The Case for Change focuses on individual and group messaging, along with tools and techniques that are used to develop communication tactics, designed to make sure people-centric issues will not impede adoption, utilization, and proficiency. The Case for Change delivers messaging to individuals and groups to create incentives and motivation that will foster these while minimizing or reducing the impediments that could hinder them.

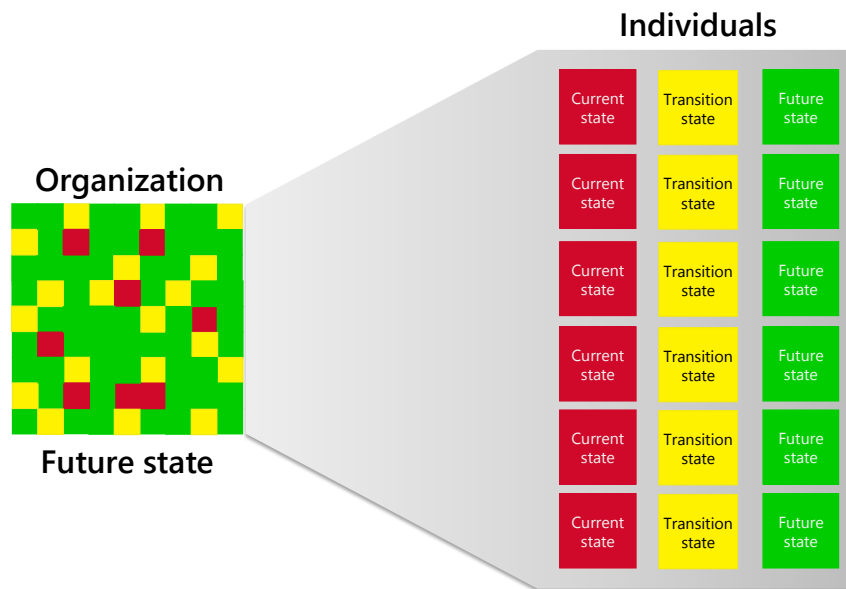
Change is usually viewed from an organizational perspective. There is a current state, how things are now, and a future state, the way we want things to be. During the change, there is a temporary transition state. The Case for Change tries to minimize the length of that transition state and reduce its impact.



However, it is important to remember that the individuals in the organization impacted by the change also have those same three states.



Ultimately, the organizational future state may be a collection of individual change states. The Case for Change, by addressing individuals and small groups, helps reduce pockets of slow adoption, low utilization, and substandard proficiency.



One of the major objectives of Case for Change is make sure that each individual is committed to the change that they will make the changes when they occur, continue using their new processes and/or systems, and develop a high level of proficiency with them. To accomplish this, the Case for Change must have targeted messaging that is communicated to the right people at the right time.

There is an old saying, “communicate early, and communicate often”. This is good, useful advice but you have to know what to say and when to say it. That is what the Case for Change provides. It starts with the vision and expands it into specific messaging content

and delivery tactics that can be used for awareness, communication, stakeholder management, training, and transition.

The MAESTRO vision:

*“Maestro will orchestrate advanced solutions to exploit integrated, standardized clinical data by incrementally delivering enhanced data visualization and analytics tools that support operational effectiveness and improved decision making.”*

The vision statement addresses two broad benefit categories, operational effectiveness and improved decision making. It does not address the specific benefits that will encourage acceptance at an individual or small group level. The Case for Change focuses on that need.

## **2 WHAT IS THE CASE FOR CHANGE**

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As mentioned previously, the Case for Change has two components, messaging and tools/techniques. The messaging is the content. The tools/techniques help determine the tactics for distributing and conveying those messages as well as the timing. The Case for Change is assembled from these two components. Assembled is the key word. There is no single Case for Change. The Case for Change is not a single document, presentation, or artifact. It is dynamic and repeatable in a variety of formats and flavors.

The Case for Change is not an action plan. It is a flexible, tactical approach that makes sure that every audience and individual to the change receives clear, understandable information about the coming change and why they should embrace it.

The Case for Change is not the Business Case either. Although the Business Case is one source for messaging content included in the Case for Change, the economic or operational justification in the Business Case is usually not focused enough to provide the necessary incentive and motivation for individuals.

The Case for Change is a dynamic assembly of persuasive communications, in multiple forms and formats, which can be directed to a group or individual with a clear, focused, timely message that answers the question “what’s in it for me”. The purpose of the Case for Change is to have an accessible inventory of messaging content that is vetted and available to be assembled into customized messages for regular and ad hoc communications. That content is used through the Case for Change tactics to be communicated through a variety of media, forms, and formats.

The Case for Change is executed iteratively. Analysis is needed to identify audiences and develop focused messaging content. The delivery of that messaging content produces results and feedback that are analyzed. This may result in the messaging content being modified, being sent again via another channel, or a combination of adjustments. This iterative execution will occur over the entire MAESTRO 2.X program and throughout each release.

## **2.1 DYNAMIC MESSAGING CONTENT INVENTORY**

The Case for Change content inventory will include both components and assembled content. The components will be reusable items that can be assembled into content. The items will be the building blocks for all assembled content. This inventory will include the basic MAESTRO brand elements such as graphics and templates. Another component will be reusable text organized into useful categories. For example, the inventory could include lists of MAESTRO benefits, features, user success stories, process descriptions, use cases, and roadmaps and other diagrams. Although not part of the inventory, another component to messaging development will be information coming from related projects such as Unify. This type of incoming information may create needs for new messaging.

The inventory will grow through each MAESTRO release. Some content items will come later as release components are finalized. For example, a short video clip of a super user demonstrating and talking about the benefits of a particular MAESTRO feature will have to be created later in the release timeline.

Assembled content includes targeted presentations, newsletters, flyers, posters, online demos, recorded events, and support materials for live events. This inventory will grow also with each MAESTRO release as communications are created and distributed. The assembled content is also reusable in that it can be revised and updated for redistribution or distribution through a new channel.

## **2.2 CASE FOR CHANGE TOOLS/TECHNIQUES**

The assembled messaging content needs to be received by the audience. In order to determine what, when, and how to communicate, the needs must be understood. This is where the tools/techniques come into play. These are assessments, analysis, methods, and means to learn more about the audiences and their specific needs. Additionally, it also includes the assessment of the content itself and the delivery mechanism. Is it the right content? Does it meet the audience's need? Is it being communicated in the best way?

Tools/techniques includes a lot of reassessment and monitoring. Content is always being assessed for accuracy and making sure it is still current and relevant. Audience needs must be monitored and reassessed. The most obvious example of this is the audience's needs after the change has occurred. There are other times when an audience's needs may change. These must be identified and the Case for Change assembled to address those needs.

There are also built in opportunities to incorporate feedback from each release. Lessons learned and customer feedback can be used to update messaging content and delivery methods.

## 3 WHAT'S INCLUDED IN THE CASE FOR CHANGE

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The Case for Change is dynamic. New messaging content will be added to the library continually. Effectiveness of the messaging and delivery will continually be reassessed. As necessary both content and delivery mechanisms will be expanded and/or modified. Some of the initial Case for Change components and approaches have been identified. These are detailed in the following sections.

### 3.1 CASE FOR CHANGE MESSAGING

Messaging created to support the Case for Change will follow these guidelines:

- Messaging will be targeted for one or more audiences
- The more specific the audience the more specific the messaging
- All messaging, regardless of objective, should include a “what’s in it for me” component
- Audiences will receive messaging in a variety of media and venues to ensure they receive the messaging and that it is reinforced
- Audiences will receive progressively more detailed messaging the closer they get to the change that impacts them
- Audiences will continue to receive Case for Change messaging after their change

Messaging content will begin being assembled at a high-level and gradually expand in detail as each MAESTRO release progresses. Some initial sources of messaging content include:

- MAESTRO Tagline
- MAESTRO Vision Statement
- MAESTRO Business Case
- MAESTRO Roadmap
- Interviews with Stakeholders
- Why MAESTRO Customer Statements
- MAESTRO Solution Testimonials

This initial content will focus on MAESTRO awareness and overall program benefits. It will provide the context for more detailed messaging content. Messaging content is needed for each MAESTRO release. That content will need to be adapted and tailored for different MAESTRO user groups, business units, and other audience segments.

An example of this is a specific MAESTRO release. A release will have a certain capability that is being provided. That capability has a business function that it provides. Associated with that is one or more benefits to the users of that capability and business function. If a capability addresses more than one business function and audience, the benefits provided may be different. This will require customization of the messaging.

Initial sources for the more detailed messaging content include:

- As-is processes
- To-be processes
- Use cases
- Stakeholder interviews
- User testing

As releases progress there will be the potential to gather more content through feedback from user demos or testing and from the user acceptance testing process. Also, during and after implementation, stakeholder interviews will provide content for follow-on messaging.

### 3.2 CASE FOR CHANGE TOOLS/TECHNIQUES

There are several artifacts and tools from the MAESTRO 1.1 release that will serve to jumpstart the 2.X release activities. The process of identifying stakeholders has already started. The list of 1.1 stakeholders served as a starting point for that effort. Currently identified stakeholders are organized into various groups and categories.

The Change Agent Network (CAN) and MAESTRO User Group (MUG) are still in place although they have been inactive for some time. Both are going to be re-engaged not only for their original purposes but as sources of information relevant to change management, communication, training, and transition.

To begin the process of understanding who we will be communicating to, and what types of messaging will be important, an iterative process will be initiated to understand the high-level MAESTRO benefits and the specific needs of the stakeholders who will receive those benefits. The initial objective is to build a matrix that maps stakeholder needs to MAESTRO benefits. During the early iterations this will be done at a high level. Subsequent iterations will develop more detailed and specific depictions of the needs and benefits. The two tools that will be used in the process are Feature / Function / Benefit analysis and Stakeholder Persona Descriptions.

The Feature / Function / Benefit analysis will identify all MAESTRO 2.X features to be delivered by release, the specific function(s) of those features, and the benefit(s) of the functions. As an example of feature / function / benefit analysis, consider a snow scrapper with a wide blade. The feature is the 27 inch wide blade. Its function is to move more snow. The benefit is finishing faster. This same type of breakdown will be completed for the MAESTRO 2.X release components.

A feature can have more than one function and provide more than one benefit. The functions and benefits can also vary by audience. The table below presents preliminary feature / function / benefit statements for MAESTRO. Note that the features are components delivered in different MAESTRO releases.

| Feature          | Function  | Benefit   |
|------------------|---|---|
| Content Data Hub | <ul style="list-style-type: none"> <li>• provides a single location to manage &amp; store clinical safety data that is made available to end-users</li> </ul> | <ul style="list-style-type: none"> <li>• data standardization aligned with regulatory guidelines</li> <li>• clinical data in an industry-standard format to support user analysis / reporting</li> <li>• compressed submission timeline by pre-generating required deliverables (data package)</li> </ul> |



| <b>Feature</b>                     | <b>Function</b>  | <b>Benefit</b>  |
|------------------------------------|--|---|
| Visualization & Analytics / SAFIR  | <ul style="list-style-type: none"> <li>interactive visualization tool with advanced graphical capabilities to facilitate safety data review</li> </ul> | <ul style="list-style-type: none"> <li>direct access to the clinical safety data without requiring the support of Biostatistics &amp; Programming</li> <li>fully interactive</li> <li>user friendly with easy navigation through the reports</li> <li>built in library of validated report templates ready-to-use</li> <li>templates designed for both signal detection and safety review</li> <li>enhanced graphical capabilities permitting better data visualization compared to existing static reports</li> <li>easy export of graphs into PowerPoint presentations</li> </ul> |
| Compound Analysis                  | <ul style="list-style-type: none"> <li>exploit existing integrated clinical data for a compound, at any time from Phase I to Phase IV</li> </ul>       | <ul style="list-style-type: none"> <li>assess, document and characterize the safety profile for a compound</li> </ul>   |
| Benefit Risk Assessment            | <ul style="list-style-type: none"> <li>derive a potential benefit-risk ratio for a compound</li> </ul>   | <ul style="list-style-type: none"> <li>Improve internal Benefit / Risk analysis capabilities by enabling earlier and more effective decision-making around clinical development programs</li> </ul>   |
| Product Defense                    |  | <ul style="list-style-type: none"> <li>integrated clinical data readily available to respond to health authorities</li> <li>ability to respond to product claims quickly will restore consumer confidence and help to maintain brand image</li> </ul>   |
| Safety Analysis / Signal Detection | <ul style="list-style-type: none"> <li>assess, document and characterize the safety profile for a compound</li> </ul>                                  | <ul style="list-style-type: none"> <li>Safety data is available for analysis earlier in the timeline</li> </ul>   |

This preliminary compilation of features / functions / benefits will be reviewed by the MAESTRO team to flush it out and make sure that it is complete. It will also be reviewed by stakeholders, especially the CAN and MUG participants.

There are stakeholders who will receive the specific MAESTRO benefits. Stakeholders are already segmented into numerous audience groupings. There is obviously some overlap with many stakeholders in more than one group. The groupings will be used to create Stakeholder Persona Descriptions. A persona description is a generic, narrative "picture" of a member of a group. Personas are frequently used in design projects. The Case for

Change is in essence a design effort in creating on-going, focused communications and awareness messaging for the stakeholder audiences.

Most personas focus on the motivations, needs, wants, etc. of the representative actor. Creating Stakeholder Persona Descriptions for the Case for Change will focus on the actor's relationship and association with the MAESTRO features, functions, and benefits. Direct users of MAESTRO features such as Safir will have a different set of needs and priorities than other stakeholders such as their managers and executive sponsors.

Ideally, personas will be based heavily on interviews and direct interaction with representative stakeholders from each group. For large, homogeneous audiences questionnaires or focus groups may also be used. Additional insight for the construction of personas will be provided by the MAESTRO Change Agent Network (CAN). Review of existing stakeholder processes and systems will be completed also.

The personas will focus heavily on the stakeholder's motivations, needs, and wants. Another important component is their current "pain points". This is where they have real or perceived challenges in accomplishing their work. These do not have to be MAESTRO related. If they are challenges they may distract the stakeholder and impact the implementation of the change. Just as important is identifying other factors that may impact the stakeholder's ability to process the change. For example, is there specific information they must have, do they frequently multitask, do they have frequent interruptions, etc. Also, stakeholder audiences impacted by other systems such as Unify will be noted in their persona.

The personas will be reviewed and vetted by knowledgeable surrogate users such as:

- Domain experts / SMEs –often able to identify what might be valuable to users, how users might do a particular task, etc.
- Trainers – familiar with current tools, processes, and areas of concern and audience receptivity
- Immediate supervisors – able to offer feedback on what they are hearing from their staff and may have a broader view of issues that complements or conflicts that of their staff

The resulting personas will be an important tool for developing a common understanding of each stakeholder audience.

With the MAESTRO feature / function / benefit analysis and stakeholder personas, a Stakeholder Benefit Matrix will be created. This maps each stakeholder group to one or more benefits. Early versions will be high-level mappings. Additional detail will be provided through subsequent analysis. It is important to remember that any one benefit can be realized by more than one stakeholder group. They may or may not realize that benefit from the same feature / function set though.

There are two separate areas of this matrix that need to be investigated. First, more than one stakeholder group may be obtaining the same benefits. Does this mean they should be combined? Do they get their benefits from the same feature / functions set? Is their perception of the benefit the same?

The second issue is that any one benefit may impact two or more stakeholder groups. We need to determine if that are being impacted the same way and if their derived benefit is

from the same feature / function set. The answers to these questions will be important in mapping communications to the groups and/or communications about the features that drive the benefits.

Even the first iteration of the matrix will begin to provide messaging content for each audience. Audience specific benefit statements can be developed at this point although some of them may still be high level.

Additional analysis will be conducted to discover possible messaging content from existing documentation such as:

- As-is processes
- To-be processes
- User Stories
- Use Cases

This analysis will have the objective of exploring the stakeholder's experience as it is before their pending change and how it will contrast with their MAESTRO experience. This will provide messaging content to set stakeholder expectations and provide additional "what's in it for me" content.

## 4 DELIVERING THE CASE FOR CHANGE (CFC)

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The Case for Change is designed to bring meaning, understanding, and value to business people and users. It answers the questions, "why are we doing this", "when will it happen", "how will it work", "how does it impact me and my role", and "what is the value to me and the organization".

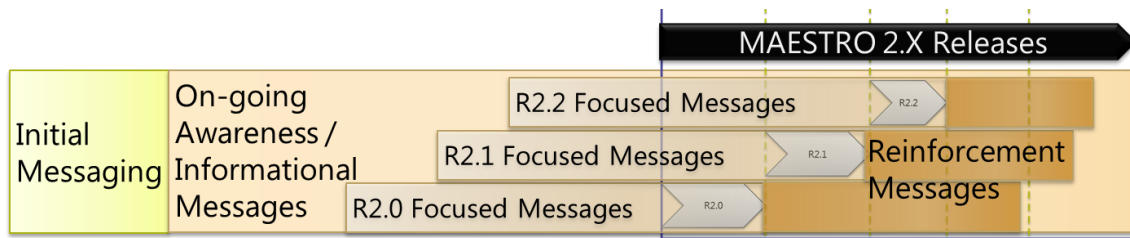
The Case for Change must be communicated to those who will be impacted. In addition to an initial messaging blitz to make the audiences aware of what is coming, there must be on-going communication that reinforces the Case for Change and builds on the MAESTRO story. These messages may delve more deeply into benefits, address timing/transition, or engage the audience with content that makes them more aware of what it means to them.

As releases are deployed there will be opportunities to communicate success stories and best practices. Even after the change has occurred, reinforcement messages are necessary to maintain momentum and continue to highlight the reasons for the change. Reinforcing the Case for Change after the change occurred helps ensure those impacted by the change know they have not been forgotten and that their buy-in and participation is important.

Both the Case for Change components, messaging and tools/techniques, will produce content for messaging. The tools/techniques component provides insight into particular needs and timing for the various audiences and MAESTRO 2.X releases. It also provides insight into the best approach for structuring the messaging. Tools/techniques help develop the tactics to be used in distributing and conveying the messaging content. This information will feed the MAESTRO 2.X Communication Plan which will have a detailed schedule of specific messaging campaigns, media, and methods.

The diagram below depicts how Case for Change messaging will be distributed throughout the entire MAESTRO 2.X Roadmap. Messaging is ongoing throughout the entire MAESTRO

2.X program and throughout each release. The MAESTRO 2.X Communication Plan will have details for overall and release specific campaigns that define when the campaign begins and ends, the media used within each campaign, and the intended objective.



The power of the Case for Change is that it can provide new messaging and repurposed messaging quickly to meet ad hoc needs. If there are pockets of resistance that need to be addressed, the inventory of content can be used to assemble a messaging campaign to address the issue. If new insights or benefits are discovered during deployment, that information can be assembled into a new messaging campaign using the existing inventory of templates and assembled content.

The MAESTRO 2.X Communications Plan will specify a number of campaigns to meet the awareness and communications needs of the program and releases. The Case for Change provides the assurance that unexpected needs can be addressed quickly and effectively.