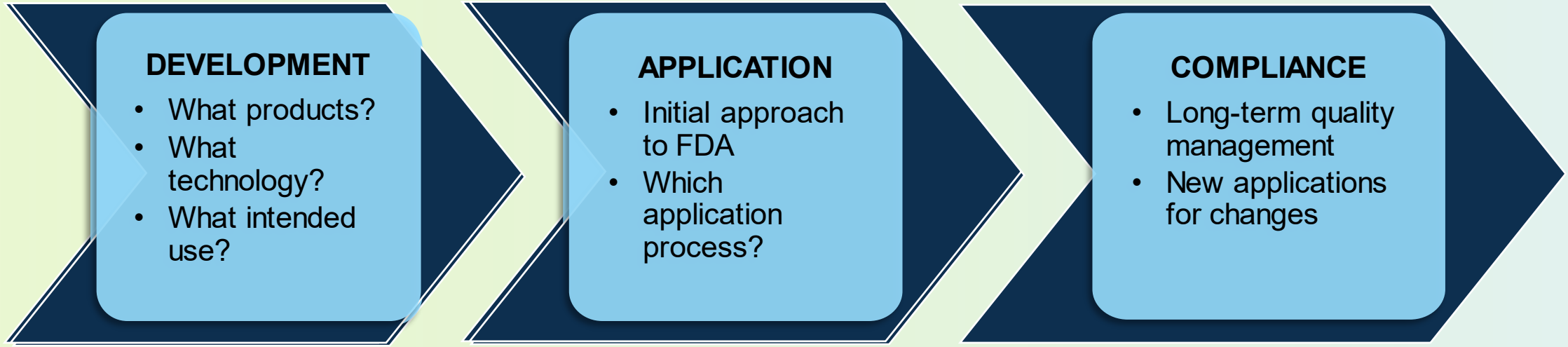
Medical Device Regulatory Case Study
InMotion Medical Remote Monitor System (RMS)

Regulatory Overview

To bring a medical product to market, an innovator needs to understand the entire commercialization process and manage multiple tasks related to early-stage research and development, clinical trials, regulations, and reimbursement. The goal of receiving U.S. Food and Drug Administration (FDA) approval is a major milestone in leading a new technology to commercial success. Innovators developing new medical products need to become familiar with the regulatory processes that may be applicable to their drug, device, or biologic so that they can successfully navigate the approval process.

Key Elements of a Regulatory Strategy

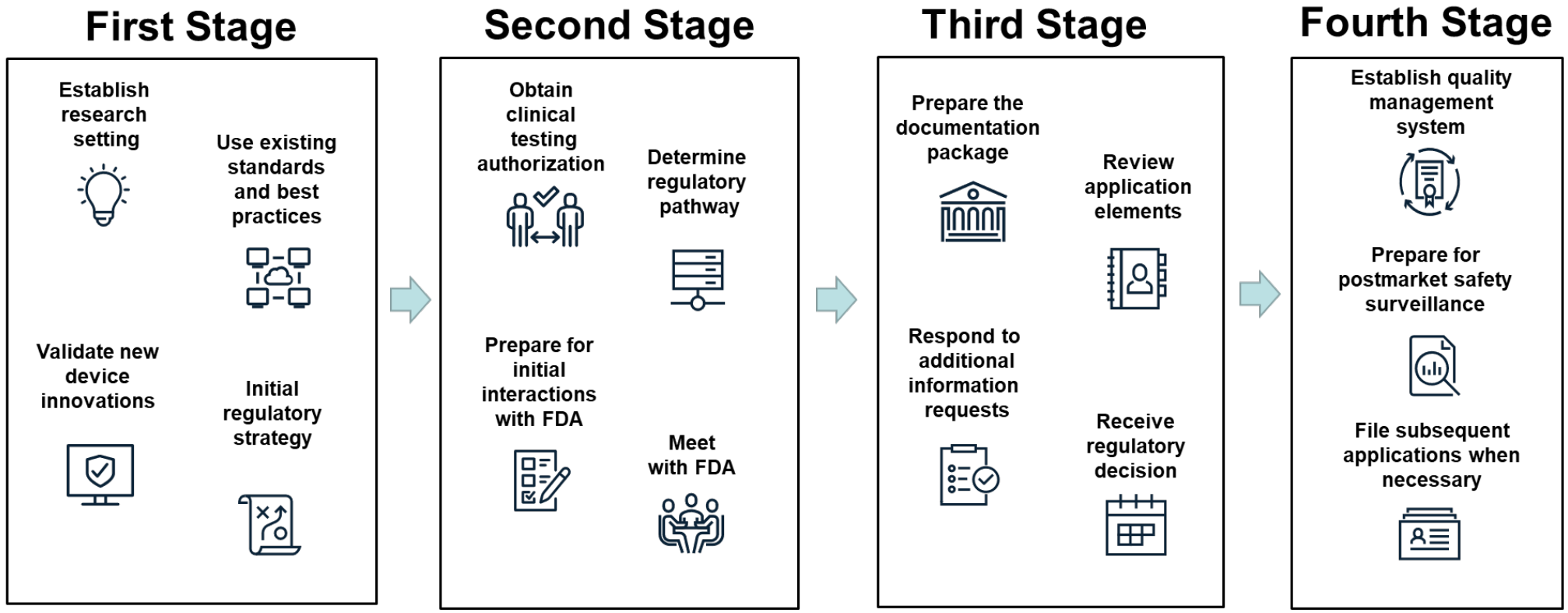


Regulatory Strategy Activities Roadmap

This case study breaks down the process described in our *Regulatory Knowledge Guides*. It will take you step-by-step through a process innovators may follow to develop a strategy for FDA market authorization. We'll walk through each step from the innovator's point of view. Aspects of the process may be conducted together, roughly in tandem. Each slide presents one aspect of a particular stage of the process.

(0 - 36 months)

(3 - 6 years)



Introduction to CEO and Product

Dr. Huan Ademola is an experienced physician with expertise in tremor and stroke patients. He is also the principal investigator of an R01 grant, focused on monitoring patients with tremors and at risk for stroke, from the National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke. Huan and colleagues recently formed a company called InMotion Medical, in continued collaboration with their research lab that is part of the East Olympic hospital's clinical research program. The first product that InMotion Medical intends to commercialize is a suite of non-invasive camera and stimulus-based tremor and stroke monitoring tools. Huan leads the technical development, while Rodolfo Miracle leads the business and operations as CEO. Rodolfo has led several medical device companies to commercialization.

What will InMotion Medical need to do to navigate regulatory requirements and legally market their device?

Here's some background on the device being developed as part of the R01 grant

Product Description:

- The tremor and stroke monitoring system under development is called the Remote Monitoring System (RMS).
- The RMS is a camera and stimulus-based system that allows for the monitoring of tremors and strokes of patients in the field of view which then drives specific nerve stimulus.
- The unique innovation of RMS is the combination of a non-invasive camera-based technology and external non-invasive nerve stimulus with the intended use of tremor and stroke monitoring and management.

Why tremors and strokes?

- According to the NIH, tremors are one of the most common neurological disorders that impairs quality of life and can lead to disability and social handicap. It affects nearly 1% of people worldwide.
- A non-invasive remote management and monitoring tool could aid in improving quality of life for those living with tremors and get care to those at risk for stroke sooner to improve patient outcomes.

First Stage

First Stage

- Establish research setting
- Use existing standards and best practices
- Validate new device innovations
- Initial regulatory strategy

Second Stage

- Obtain clinical testing authorization
- Determine regulatory pathway
- Prepare for initial interactions with FDA
- Meet with FDA

Third Stage

- Prepare the documentation package
- Review application elements
- Respond to additional information requests
- Receive regulatory decision

Fourth Stage

- Establish quality management system
- Prepare for postmarket safety surveillance
- File subsequent applications when necessary

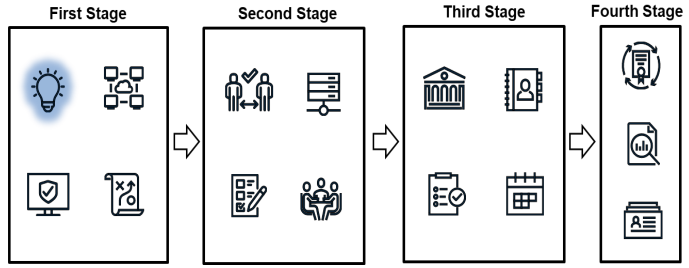
First Stage: Establish Research Setting

Huan begins the transition of his innovation and research to commercialization and forms a company called InMotion.

Within the clinical setting, Huan has made many strides with patients in treating varying degrees of tremors with nerve stimulation and seeing promising results. His clinical outcomes and observations are also being confirmed by other research [1, 2]. With such promising outcomes for his patients, Huan believes that with some additional development, more patients could benefit from this kind of treatment.

Huan has been treating patients through a large research hospital system and has leveraged its considerable available research resources, including a motion capture system. Huan and his team collaborate to demonstrate the feasibility of identifying the necessary nerve stimulant from quantifying a patient's movements through motion capture rather than relying on direct visual patient assessments. As Huan further understands the technological capabilities, he also sees the potential to leverage the motion capture system to identify patients at higher risk of stroke.

Huan reaches out to Rodolfo Miracle, who has been in the medical device industry for many years, to work with him to transfer the image processing and motion tracking technology from the research hospital setting. After several discussions with the hospital administration, they come to an agreement and form InMotion to develop the device.



Key questions:

- How has the technology been developed?
- What corporate structure should the new venture take?
- What non-clinical non-research expertise are needed to begin developing the technology into a device?

First Stage: Pre-Clinical Validation

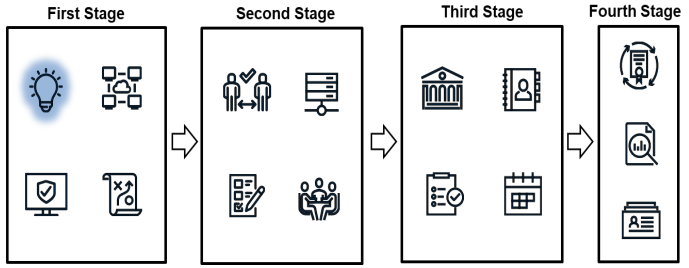
Huan and Rodolfo are initially focused on completing the first prototype of the RMS. They will need to ensure that they have identified all endpoints that will need to be validated as well as test and validate the underlying technology.

With years of experience in neurological practice, Huan is familiar with electrical nerve stimulation and what clinical endpoints are looked at when diagnosing someone with tremors and the warning signs for strokes.

Huan refers to established standards and guidances for neurological devices to guide preclinical analysis. He works closely with technical experts in camera design, image processing, and motion tracking to take these clinical endpoints and translate them into technically identifiable visual markers. Huan also works closely with nerve experts to ensure the proper stimuli is being applied.

Initial preclinical analysis and testing follows consensus standards. Testing includes simulated identified clinical endpoints and validating that the RMS correctly detects and identifies the visual markers. Furthermore, the nerve stimuli component of the device is tested to ensure it is performing as intended and in accordance with IEC 60601-2-10.

Once the first prototype and underlying technology are validated, Rodolfo refines the product development and prototyping of the RMS to prepare it for clinical testing.



Key questions:

- Do the endpoints that are chosen to support the device's validation have clear clinical basis?
- Has the team finalized the technological design and intended use?
- Does the device perform and function as intended under controlled non-clinical conditions?

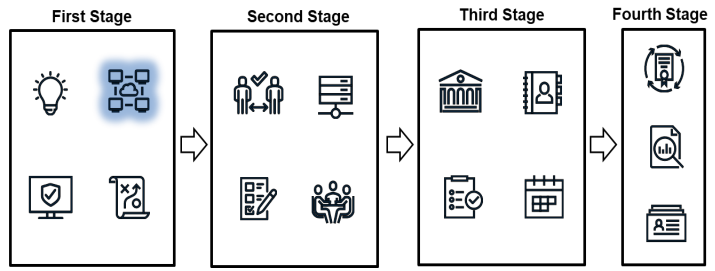
First Stage: Initial Regulatory Strategy

To understand what clinical testing will be needed for the RMS, it is important to first gain a high-level understanding of the potential regulatory pathway the device will be evaluated through.

Rodolfo is aware that most devices are cleared through FDA's 510(k) regulatory pathway. He brings in regulatory consultant, Lior Aelius, to identify a potential predicate that might give them guidance based on prior device's validation and testing. As with any device, the combination of intended use and technological characteristics determine the risk profile and controls needed to validate the safety and efficacy of the device.

Using the 510(k) database, Lior identifies several devices that are indicated for tremors and/or stroke but use different kinds of technologies. He also identifies several other camera-based devices and nerve stimulus devices that use similar technology as the RMS but have different intended uses. However, it does not seem that any existing marketed device in the U.S. has leveraged a camera and stimulus-based technology for tremor and stroke detection and management.

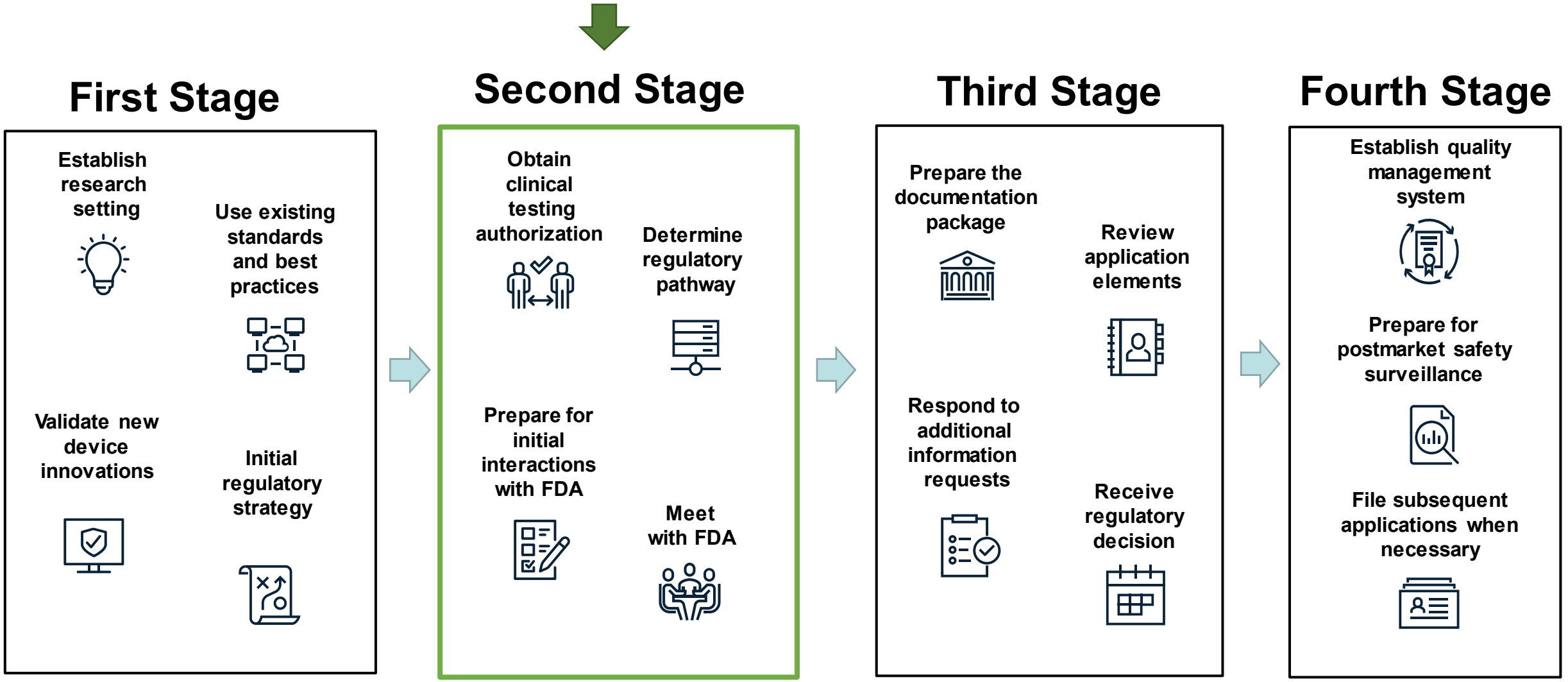
With no existing potential predicate, Rodolfo and Lior understand that the clinical validation strategy will need to be novel and unique and likely require a De Novo. Validation methods used for similar camera and nerve stimuli-based systems may provide initial guidance, however, they will have to be tailored to address any specific concerns of safety and efficacy related to tremor and stroke.



Key questions:

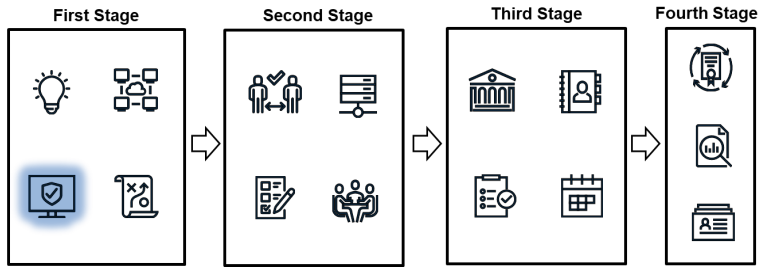
- What common aspects of the device's performance have well-understood test methods?
- Has FDA issued guidance relevant to this kind of device?
- What is unique about the device that will impact its validation strategy?

Second Stage



Second Stage: Obtain Clinical Testing Authorization

With the understanding that a new validation plan will need to be designed to support the safety and efficacy of the RMS, Huan and Rodolfo begin to discuss the clinical testing plans with an Institutional Review Board (IRB).



Given their historical association with the hospital, Rodolfo contacts the hospital's IRB to understand what additional requirements InMotion will need to validate the RMS device.

Rodolfo submits an initial clinical trial plan to the IRB to test the use of the RMS to identify patients with tremors and monitor risk of stroke. The IRB reviews this initial submission and, after a few conversations with the InMotion team, the IRB determines that the device's intended use may pose significant risk to patients.

The testing plan outlines how detection from the camera component of the device will inform the nerve stimuli component. A primary endpoint of the clinical study will be to measure the difference between patients that were monitored and linked with a nerve stimuli component and those that were solely monitored. The IRB has concerns around the nerve stimuli aspect of the device and any potential adverse effects it may have on patients.

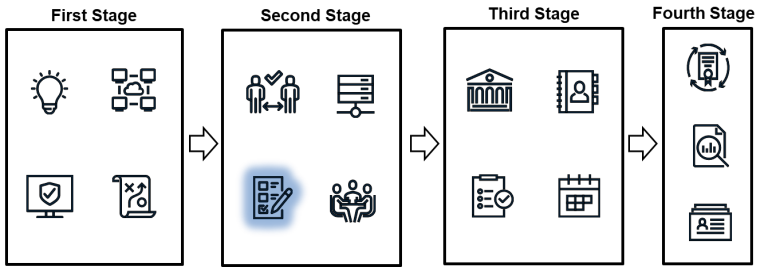
The IRB asks that InMotion reach out to FDA to determine if an Investigational Device Exemption (IDE) will be needed to fully study the safety and efficacy of the RMS.

Key questions:

- Has an IRB authorized clinical research and validation of the device?
- Does the clinical trial plan present enough significant risk to patients where an IDE needs to be obtained by FDA?

Second Stage: Prepare for Initial Interaction with FDA

After discussing their device's intended use and validation plan with the IRB, the InMotion team understands that they will need to obtain approval from FDA to clinically validate their device innovations.



As the InMotion team prepares to reach out to FDA, Lior is brought up to speed on the device's technology and validation strategy.

To best understand the full scope of the road ahead for the IDE, Lior uses both the De Novo database and the PMA database to identify devices with similar technologies and levels of risk as the RMS.

Specifically, since there is no potential existing similar devices, Lior filters his search based on products cleared by the Center for "Devices and Radiological Health," and specifically those reviewed by a "Neurology" panel.

Lior begins by outlining the IDE application process with Huan and Rodolfo. Due to the limited review timeline, the IDE application does not allow for much feedback or interaction with the FDA. Therefore, Lior suggests that InMotion submit a pre-submission request to ask questions about the company's plans for an IDE, also known as a pre-IDE or Q-submission.

Guided by the anticipated IDE Submission, Lior outlines what information the InMotion team will need to obtain before the first FDA meeting. Primarily, Lior reviews previous clinical trials and existing cleared medical devices to understand what clinical testing standards and details will need to be included in the pre-submission meeting request.

Key questions:

- What relevant supporting evidence and materials need to be obtained before contacting FDA?
- What information is most critical to receive from FDA before the upcoming regulatory application?

Pre-Submission for an IDE (Pre-IDE) Content

Pre-submissions, also known as Q-submissions, are characterized by the questions included on the cover page of the submission. Though the questions themselves may be brief, they should refer to supporting materials and plans FDA can review provide feedback.

Outline of pre-IDE content and questions to include on cover page. Submission should include:

- Detail of indication for use and intended use of the device
- Supporting regulatory background on similar devices that have been reviewed by FDA (for 510k pathway), or if no applicable predicates, devices with similar levels of risk to understand if it will be Class II (De Novo) or Class III (PMA)

For question 1, ask: Does FDA agree with the proposed device classification and regulatory pathway? (will help understanding of regulatory path) **Submission should include:**

- Expected and intended benefits of the device, including patient population
- Details of materials, including safety testing, of device as well as potential risk and mitigations put in place for these risks

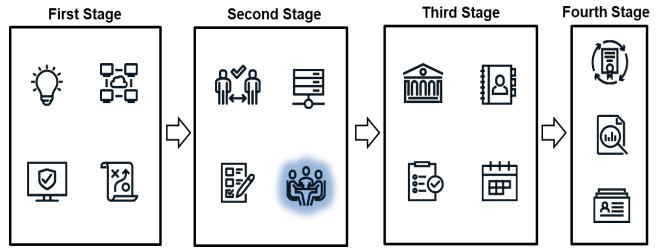
For question 2, ask: Does FDA agree that potential benefits outweigh potential risks of the device and that safety considerations have been thoroughly considered? **This second question allows FDA to comment of suitability for clinical human testing. Submission should include:**

- A detailed outline of the clinical trial plan including approval/discussions with IRB
- Include endpoints intended to be captured, and provide supporting justification for why these are appropriate endpoints, including intended population size plus expected endpoint outcomes and "what success looks like"

Finally, for question 3, ask: Does the potential benefit of the device, along with safety information, together with the testing plan seem suitable for an IDE and support a future marketing application? **The final question brings everything together to obtain feedback on the immediate next step and if the testing plan will down the road support a regulatory pre-market application, as specified in the first question.**

Second Stage: Meet with FDA

After thoroughly researching regulatory requirements and aggregating the necessary documentation, it's time to submit the pre-submission package to FDA's Center for Devices and Radiological Health (CDRH) and meet with FDA.



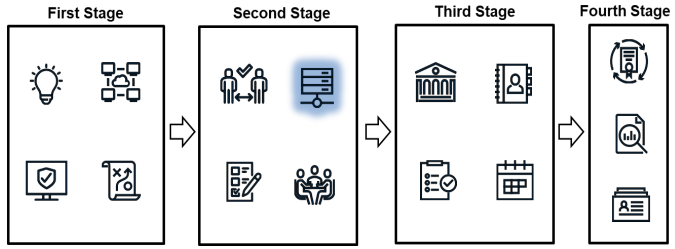
- Lior prepares the pre-submission and submits it online to CDRH. Shortly thereafter, FDA proposes a few one-hour meeting options, roughly 75 days out, for FDA and the team to meet.
- Two days before the scheduled meeting with FDA, the team receives FDA's written feedback on their pre-submission. The short timeline was expected, and the team is ready to address FDA's feedback. FDA responds to Question 1 with concerns around how the indications for use may be too broad to confirm a regulatory pathway. The inclusion of both tremor treatment and stroke risk is of additional concern to FDA. However, for Questions 2 and 3, FDA generally agrees with the InMotion's plans out. Lastly, FDA states that the product is ready for an IDE but add several references the InMotion team should review before starting a clinical trial.
- The InMotion team prepares a presentation outlining FDA's responses and asks clarifying questions based on FDA's feedback of Questions 1 and 4. They focus on getting additional clarity on the materials FDA provided in its pre-submission feedback. FDA has thoroughly read and internally discussed the submission materials; therefore, it is not useful to re-present previously reviewed content. The team knows FDA will generally not provide feedback on any new information presented during the meeting.
- After the meeting, the InMotion team submits meeting minutes to FDA to add to the pre-submission file. FDA will either accept the minutes or provide amendments to reflect differences in meeting take aways.

Key questions:

- What to expect for the pre-submission?
- Based on FDA's written feedback before the meeting, what is the best use of time for the face-to-face discussion?

Second Stage: Additional Meeting with FDA

As the clinical testing is underway, word is spreading about the RMS. Rodolfo and Lior begin planning to submit a request for breakthrough device designation (BDD) for the RMS from FDA.



Rodolfo reads a recent announcement about how BDD have helped medical devices gain market access faster. Huan and Rodolfo speak with other NIH innovators and hear that obtaining a BDD may aid in obtaining additional capital investments to develop and test the device by highlighting the substantial innovation the RMS presents. Rodolfo also notes that a BDD should be requested before a formal regulatory marketing submission and obtaining one may also accelerate the review timeline for future FDA submissions. Lior outlines for Huan and Rodolfo the criteria for obtaining a BDD.

After searching again through existing marketed device databases and following the BDD guidance, Lior concludes the RMS is innovative and no similar alternatives exist for treating tremors nor identifying risk of stroke. Lior also conducts an additional research on selecting appropriate regulatory pathways and a regulatory consult with the NIH SEED office.

Seeing that the RMS qualifies through both BDD criterion, Lior prepares a request for a BDD via a Q-submission to FDA. This would be a separate and new pre-submission focusing on the BDD. He ensures that the pre-submission includes a description of the device, proposed indication for use, regulatory history of the company and device, supporting evidence of how the device meets the BDD statutory criteria, and what marketing submission is intended for the future.

Key questions:

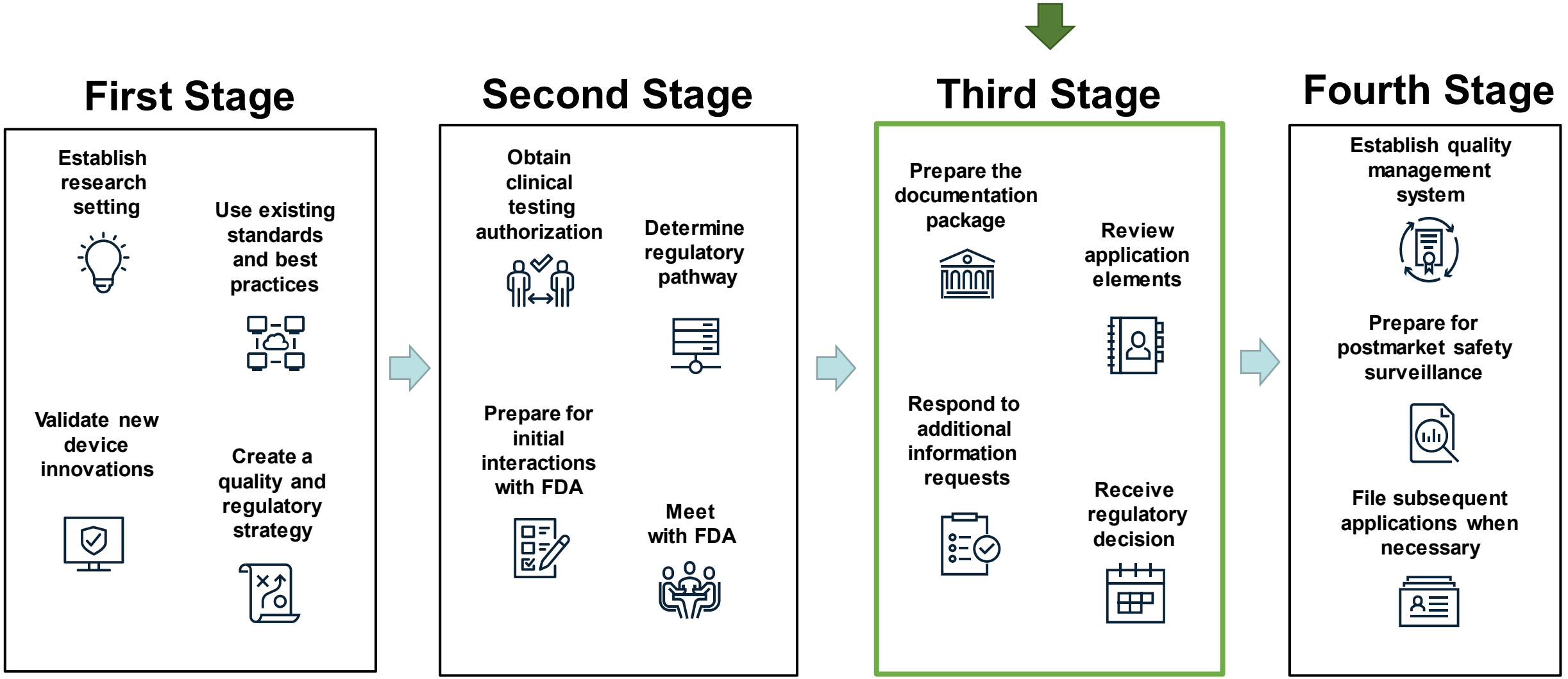
- What additional resources and designations does FDA provide for devices?
- What regulatory pathway will be most appropriate for the product?

The Breakthrough Device Designation Criterion

Criteria	Description	Refer to Guidance
First Criterion	The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions	Section III.B.1
Second Criterion	The device also meets **at least one** of the following:	
	a. Represents Breakthrough Technology	Section III.B.2.a
	b. No Approved or Cleared Alternatives Exist	Section III.B.2.b
	c. Offers Significant Advantages over Existing Approved or Cleared Alternatives	Section III.B.2.c
	d. Device Availability is in the Best Interest of Patients	Section III.B.2.d

- As part of the request for BDD, it is the innovator's responsibility to provide supporting evidence that their device meets the two criterion.
- For the RMS, the first criterion is clearly met through evidence and citing reference to tremor and stroke affects on quality of life and mortality.
- As for the second criterion, though it may be possible to provide supporting evidence of more than one of the options, clearly supporting at least one is the priority.
- Since there are other devices that treat tremors, which subset of a, c, or d InMotion decides to cite will depend on building their strongest case. Lior decides that highlighting the improved outcomes of the device compared to existing devices treating tremors supports c, as well as d.

Third Stage


First Stage
Establish research setting
Use existing standards and best practices
Validate new device innovations
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Second Stage
Obtain clinical testing authorization
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Third Stage
Prepare the documentation package
Review application elements
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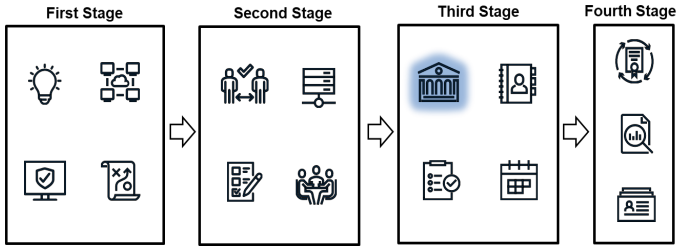
Receive regulatory decision
Fourth Stage
Establish quality management system
Prepare for postmarket safety surveillance
File subsequent applications when necessary

Third Stage: Prepare the Documentation Package

After many months on continued development and evaluation, the InMotion team is getting ready to put forward their submission to FDA. Unlike Lior's prior experiences with 510(k) submissions, this will be Lior's first De Novo submission. To ensure the RMS submission goes as smoothly as possible, Lior recommends the team have a pre-submission meeting with FDA to prepare for the upcoming De Novo submission.



Unlike a 510(k), where the focus of the submission is on an evaluation of substantial equivalence based on an existing device, a De Novo submission focuses on the special controls put in place to make a benefit-risk determination and that ensure the device is both safe and effective. Hiroki Larissa, an FDA Engineer, is appointed to lead the review of the RMS pre-submission. Hiroki recognizes that as an eventual De Novo, it will be up to him to work collaboratively with the InMotion team to ensure the special controls are appropriate.

As part of the pre-submission, Lior outlined the existing history of the device, including the BDD and validation that has been done to date for the RMS. The key question driving the pre-submission is to ensure FDA agrees that a De Novo is the right path and that there is no appropriate predicate device available to submit a 510(k). Innovators have two options when submitting a De Novo request to have a new device classified into class I or II either: a) initially submit a 510(k) and receive a letter of No Substantial Equivalence (NSE) or b) obtain feedback and concurrence from FDA to directly submit a De Novo.

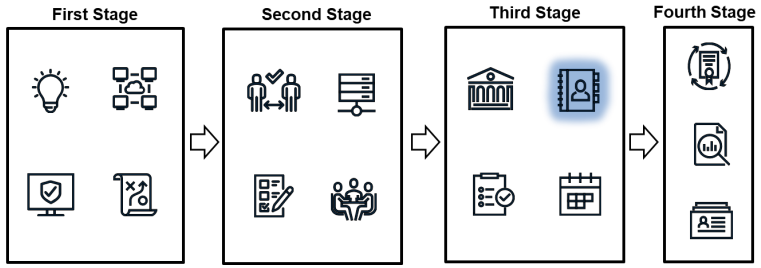
It is essential to obtain FDA concurrence that the device is low or moderate risk and that the proposed special controls are appropriate

Key questions:

- Is the De Novo the right regulatory pathway?
- Do the special controls reasonably assure safety and efficacy of the device?

Third Stage: Review Application Elements

With FDA input via the pre-submission meeting, InMotion can submit its official De Novo request for market authorization. Lior has FDA feedback indicating that the De Novo is appropriate and that he does not need to initially submit a 510(k) and wait for a not substantially equivalent decision.



Lior puts together all the necessary elements of the De Novo which include:

1. A coversheet clearly identifying the request as a "Request for Evaluation of Automatic Class III Designation" under 513(f)(2) De Novo request.
   - A novel device that is deemed inappropriate for a 510(k) pathway would by default be classified as a class III device. The aim of the De Novo request is to 'down-classify' a device to class II and establish the appropriate special controls that would then guide future 510(k)s.
2. Administrative Information, such as the device's intended use, prescription use or over-the-counter use designated, etc.
3. Device description, which includes but is not limited to technology, proposed conditions of use, accessories, and components.
4. Classification Information and Supporting Data as outlined and incorporating the right evidence to help FDA make a benefit-risk determination.

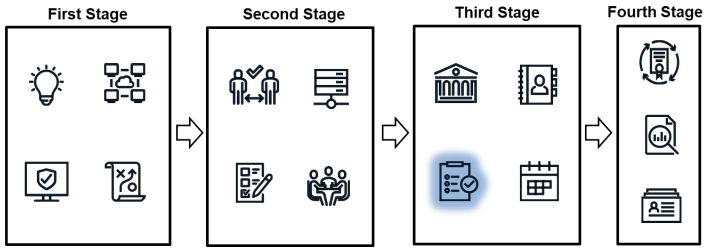
Upon verification of all these elements, Hiroki sends a formal email to Lior letting him know the application has been accepted and is proceeding with his review.

Key questions:

- Has all pre-submission FDA feedback been incorporated into the application?
- Does the submission have all the essential elements for a De Novo request?

Third Stage: Respond to Additional Information Request

Hiroki conducts an initial review of the submission and sees that InMotion addressed all comments from the pre-submission and accepts it as passing acceptance review. Hiroki gathers an FDA panel of experts for the device's substantive review where a significant concern emerges which prompts Hiroki to reach out to InMotion about deficiencies.



Specifically, by including stroke risk identification within the indications for use, several reviewers are concerned about the device's risk level. Though the underlying technology is the same, the additional indication may be an issue for the De Novo submission. However, Hiroki and the review team still feel that the rest of the RMS is a class II designation.

FDA sends InMotion an additional information request and puts the application on hold for up to 180 business days or until a response and supporting documentation are provided.

As part of this request, FDA suggests that the InMotion team consider limiting the device's indications to a single targeted condition. This would entail revising the indication for use.

- (**Original**) camera-based monitoring system and non-invasive nerve stimuli for tremor and stroke monitoring and management
- (**Updated**) camera-based monitoring system and non-invasive nerve stimuli for tremor monitoring and management.

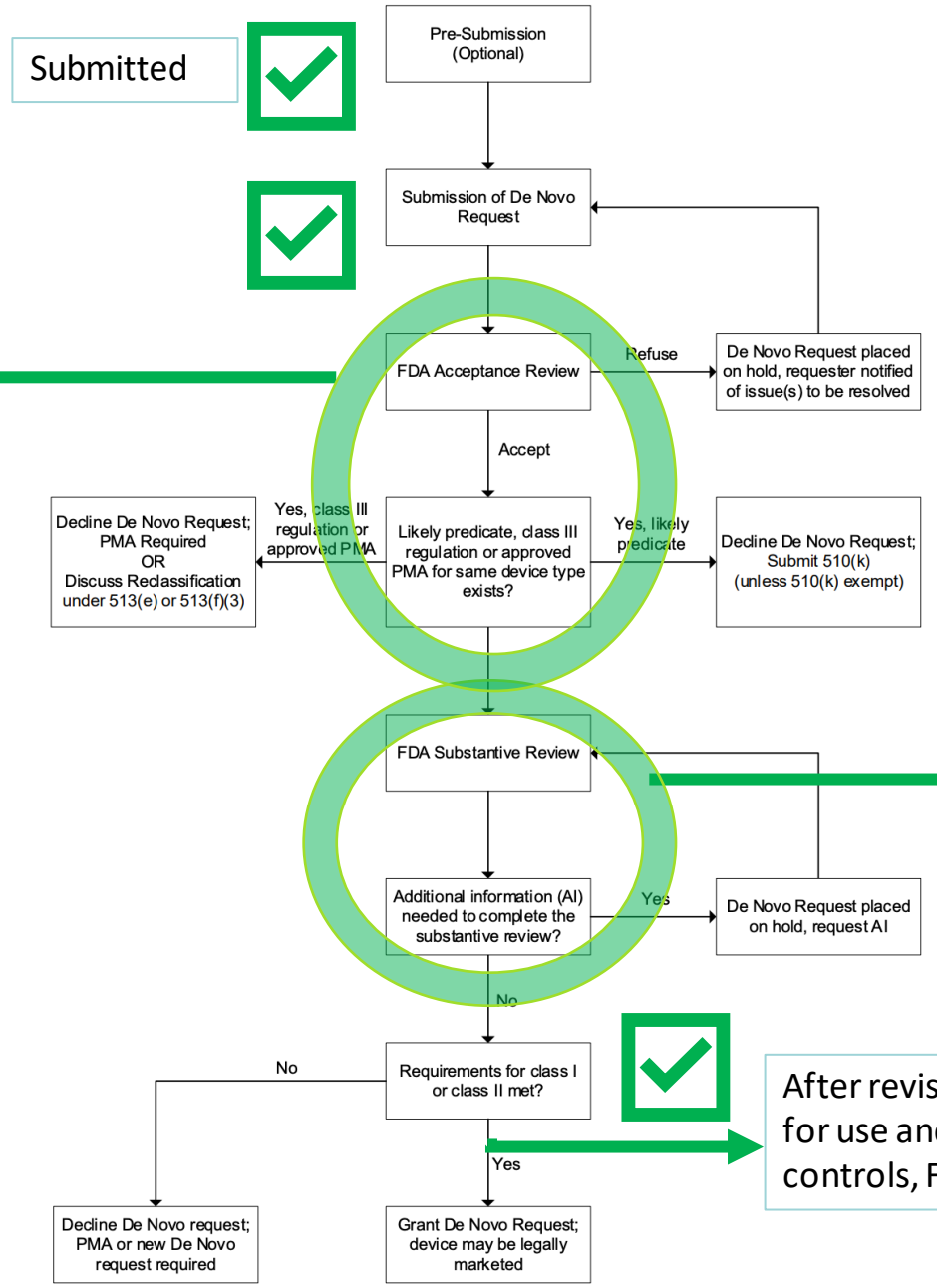
Otherwise, with the inclusion of the stroke monitoring and management elements FDA suggests that the special controls may not be sufficient, and that the device may be a class III device.

After discussing the implications of the potential change (e.g., it may impact device's reimbursement), the team revises the indications for use and removes the stroke elements.

Key questions:

- Are the device indications appropriately defined and fully supported by the submission?
- What implications might there be to changes made to the device during the review process?

De Novo Flowchart



Having a pre-submission allowed these parts of the review to be streamlined.

Hiroki and the FDA team communicated their concerns around the indications for use that were revised with mutual agreement.

After revising the device indications for use and refining the special controls, FDA grants the De Novo.

Third Stage: Receive Classification and Approval Decision

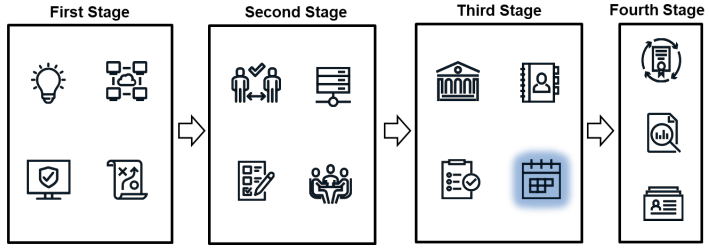
Lior and the rest of the InMotion team submit their responses and provide supporting documentation to address the Additional Information Request.

Upon receipt of InMotion's supplemental information, Hiroki reconvenes the original group of subject matter experts within FDA. They review the updated device description, intended use, and indication for use along with other clarifications and supporting data. In general Hiroki and the rest of the review team find the information to support the statements made in the submission. Hiroki continues to engage the Lior and InMotion team to finalize the special controls based on the updated device description and indications for use.

Once all the review team's concerns are addressed, Hiroki compiles a full review of the submission, including memos from each of the subject matter experts, and provides a recommendation to classify the device as class II and approve it for the U.S. market. These review documents are kept internal to FDA.

The completed file and recommendation is reviewed by managers and the director of OHT5B: Neuromodulation and Rehabilitation Devices who approve the device and create a new three-letter product code that will become the basis for any future 510(k)s.

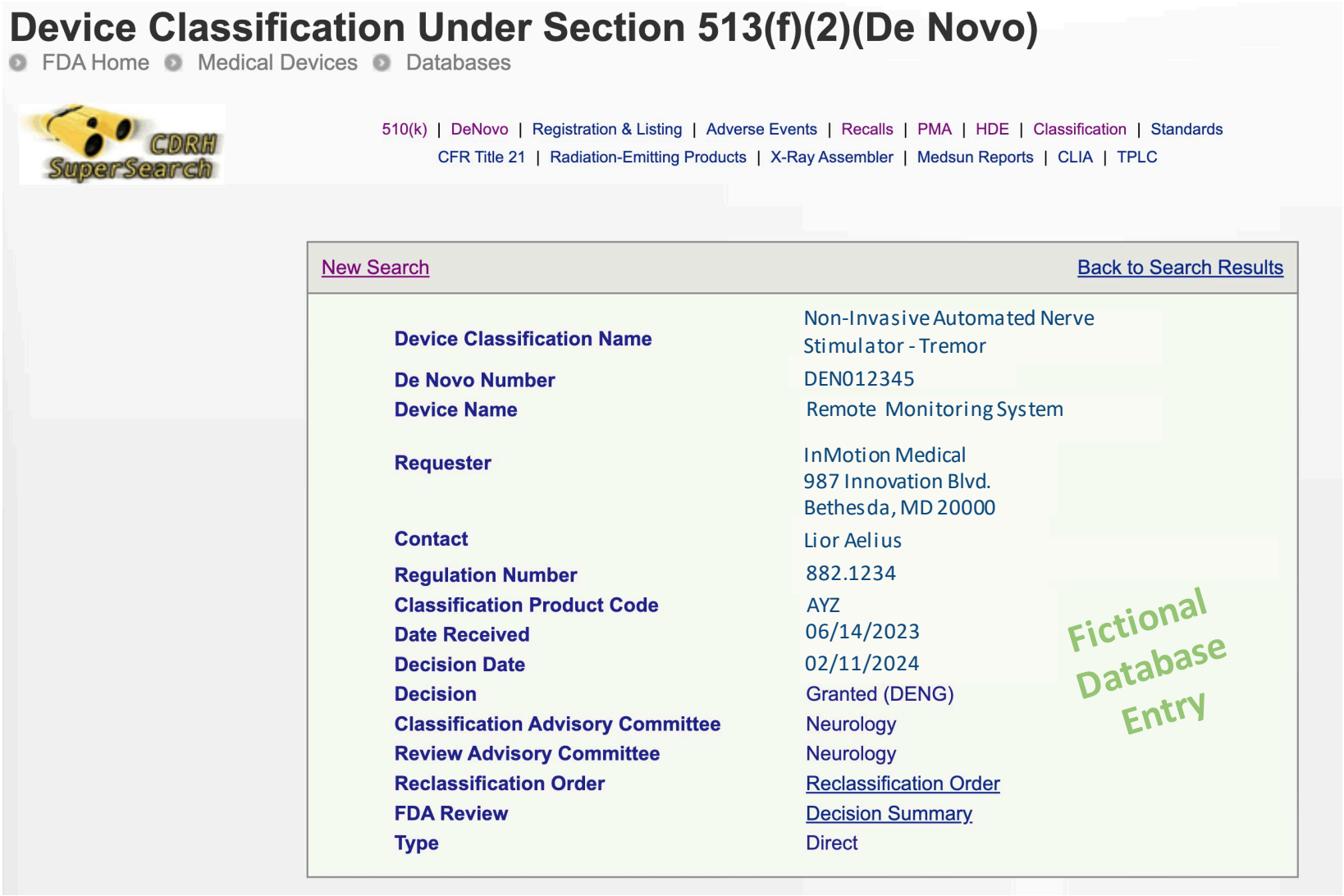
Within 180 review days of the submission, excluding the time between the additional information request and FDA's receipt of the response, Lior and the InMotion team receive the classification and approval letter from FDA that are made public.



Key question:

- Is there a plan in place for post-clearance regulatory and manufacturing activities (e.g., quality management, adverse event reporting, registration and listing)?

Decision Letter and Addition to De Novo Database



Device Classification Under Section 513(f)(2)(De Novo)

FDA Home ◉ Medical Devices ◉ Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

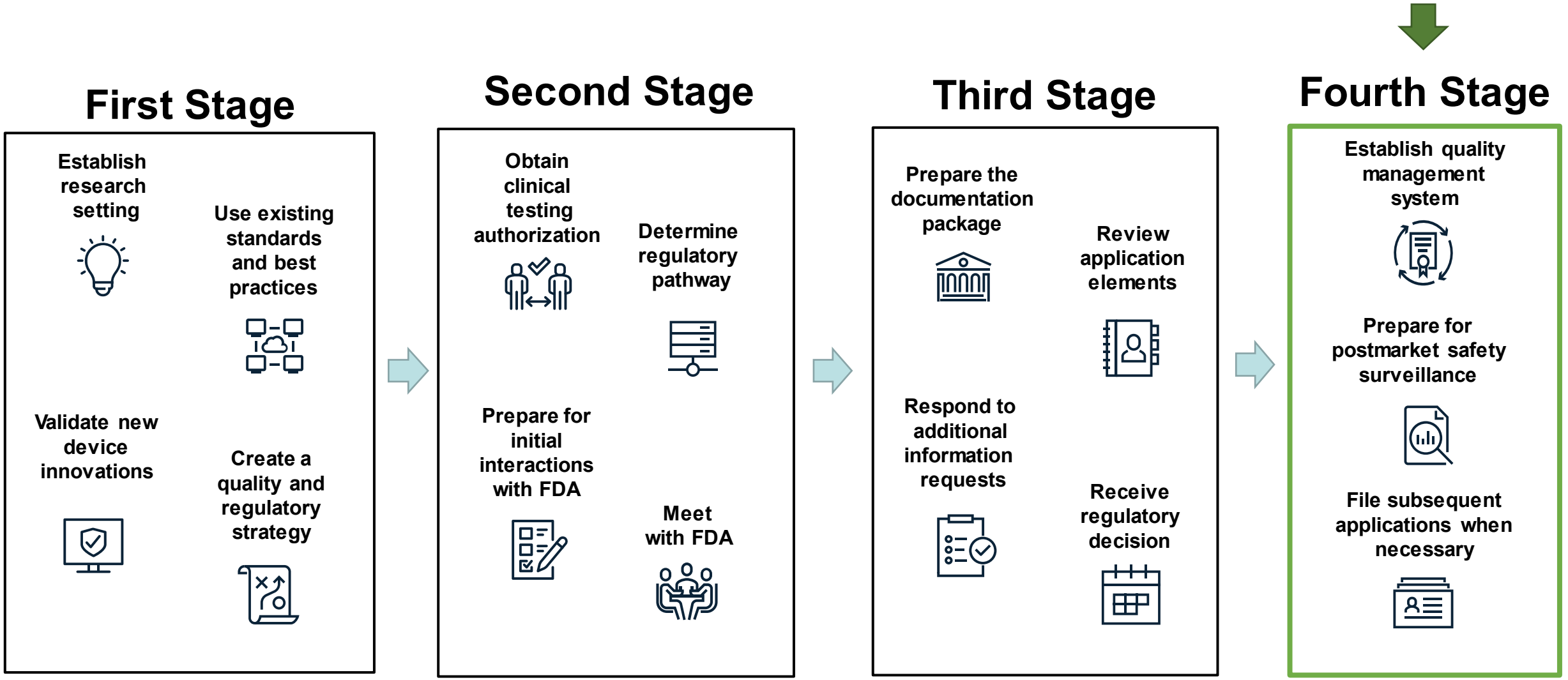
New Search | Back to Search Results

Device Classification Name	Non-Invasive Automated Nerve Stimulator - Tremor
De Novo Number	DEN012345
Device Name	Remote Monitoring System
Requester	InMotion Medical 987 Innovation Blvd. Bethesda, MD 20000
Contact	Lior Aelius
Regulation Number	882.1234
Classification Product Code	AYZ
Date Received	06/14/2023
Decision Date	02/11/2024
Decision	Granted (DENG)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Reclassification Order	Reclassification Order
FDA Review	Decision Summary
Type	Direct

Fictional Database Entry

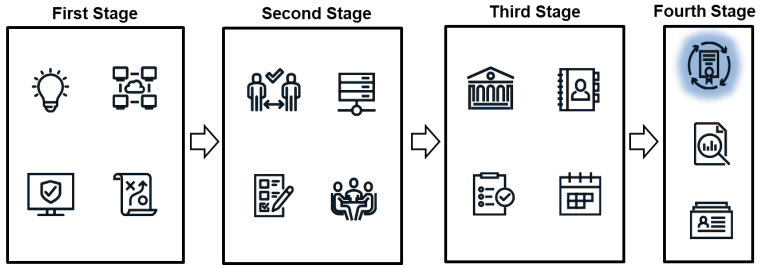
- After the device is approved, Acoustic Imaging Labs receives an official approval letter for the De Novo and decision summary.
- The De Novo is then added to FDA's De Novo database along with the reclassification order creating the new device classification and the decision summary.

Fourth Stage



Fourth Stage: Establish a Quality Management System

While the InMotion team celebrates their De Novo, Rodolfo and Lior are examining the next steps in legally marketing the device. Medical device manufacturers are required by the Code of Federal Regulations (CFR) to utilize and maintain a Quality Management System (QMS).



The goal of the Quality Management System is to ensure consistent medical device quality by requiring manufacturers have robust processes in place for design, production, and delivery of their products. Lior explains - as the registered manufacturer of the RMS the team's records may be inspected by FDA. The QMS, its documents, and its integration into manufacturing/management logistics, will be the focus of an FDA inspection.

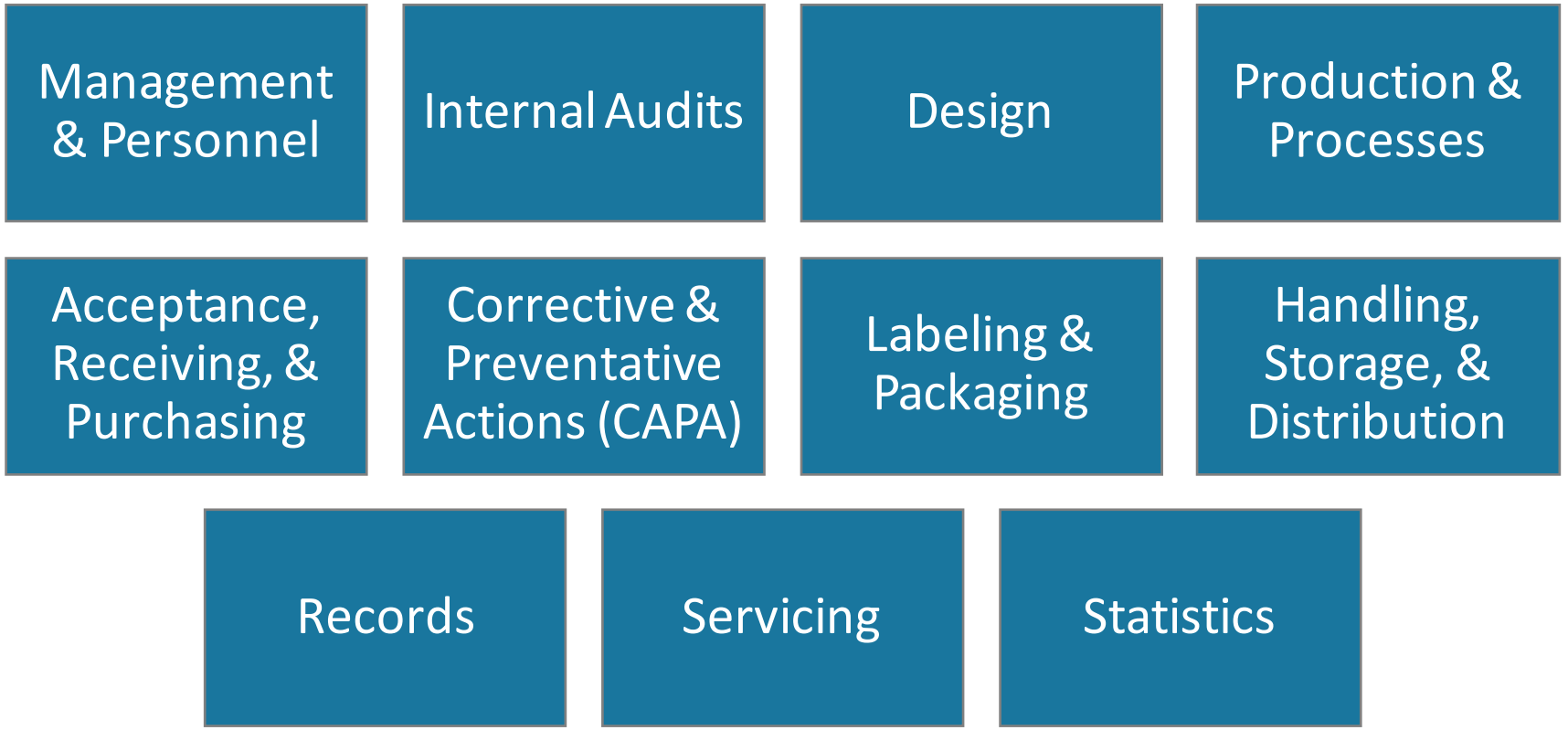
The Quality System Regulation contains 15 subparts describing required quality assurance processes. These cover a wide range of items including acceptance and receiving, complaint handling, design controls, packaging, and more.

The Quality System Regulation explains *what* needs to be done by the QMS, but not *how* to do it. The InMotion management team must develop – and iteratively improve – a QMS to meet their needs and ensure consistent quality. As a novel device, InMotion also leverages documentation from their De Novo on QMS elements to ensure the device continues to be safe and effective.

Key questions:

- How was a QMS outlined in the pre-market submission?
- Does the QMS address all controls specific to the novel device?
- Would the QMS be ready for review in the event of an FDA inspection?

Overview of QMS Elements Required by 21 CFR 820



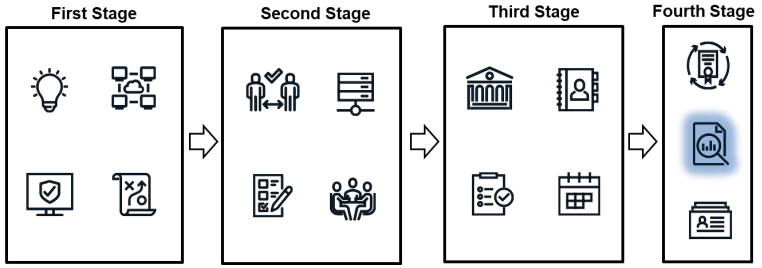
Fourth Stage: Prepare for Post-Market Safety Surveillance

Now that a De Novo has been granted for RMS and they are about to begin marketing their device, the InMotion team needs to implement systems for post-market monitoring requirements.

All medical device manufactures involved in the distribution of devices must follow post-market requirements once a device is on the market. This includes having systems and protocols in place for documenting adverse events.

FDA has outlined Mandatory Reporting Requirements that all manufacturers must be aware of to understand when to report an adverse event to FDA.

As a novel device, it is not yet known what a signal indicating a trend of adverse events for the RMS may look like. Though the target is always to mitigate all reported issues with a device, there is typically a consistent level of reported issues with any device. Therefore, InMotion must carefully review all complaints and incident reports to establish known issues and rates of types problems that occur. Understanding underlying rates allows InMotion to identify deviations that may require corrective and preventative actions (CAPA) or initiate any potential recalls.



Key question:

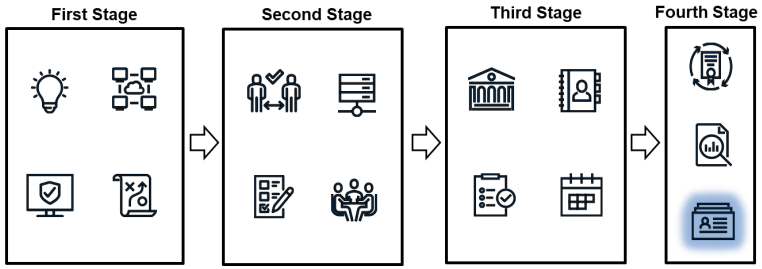
- Is there a plan in place for post-clearance regulatory and manufacturing activities (e.g., quality management, adverse event reporting, recalls)?

Fourth Stage: File Subsequent Applications When Necessary

With the issuance of a De Novo designation, FDA established a new product code and regulation. This paves the way for future devices with the same intended use and technology basis to leverage this submission as a predicate and use the 510(k) pathway. Accordingly, Huan has been leading their developers to augment the RMS with additional functionality. With their fully functioning QMS in place, the InMotion team begins to consider how functionality of the RMS can be expanded in a subsequent 510(k).

The key aspects of deciding when to submit a 510(k) for product improvements are described in the corresponding FDA guidance document. For the RMS, the changes introduce new functions for integrating wearable motion tracking which have low, but nonetheless new, risks for InMotion to mitigate. Thus, they decide to file a subsequent 510(k).

In comparison to the De Novo, with the special controls already established under the new product classification, the 510(k) allows a relatively smaller documentation package and faster timeline to a clearance decision.



Key questions:

- Does the change introduce new risks or does it necessitate a modified risk control measure?
- Could the change significantly affect clinical performance?
- Can the data (related to the change) be evaluated with concise or well-established methods?

InMotion Press Release

The following is a fictional portrayal of what success for the RMS may look like

For Immediate Release

FDA Grants InMotion's Novel Remote Monitoring System for Patients with Tremors

Bethesda, Maryland, January 12, 2024

InMotion Inc. is pleased to announce their Remote Monitoring System (RMS) has been reviewed and authorized to be marketed by the U.S. Food and Drug Administration (FDA). The RMS is the first and only device for accurate non-invasive assessment and improvement of tremors. The innovative RMS assesses patients' movements and tremors and provides neural stimuli to reduce tremors.

"Today's announcement marks an important step forward for technology-assisted ultrasound imaging," said Rodolfo Miracle, InMotion's CEO. "By being able to non-invasively assess patients and guide the right targeted stimuli needed, we can deliver exactly what each person needs to have the best outcomes and reduce the burden tremors have on so many people."

InMotion Inc. came out of East Olympic hospital's clinical research program. Established in 2015, they are collaborating with their clinical and commercial partners to develop a first-of-its-kind suite of non-invasive monitor and treatment for tremors that provide patient specific treatment based on each person's movements and biomarkers…

SUMMARY

Summary: By Stage

First Stage

- Establish research setting: Leverage existing connections and funding resources when setting up research team and environment.
- Pre-Clinical Validation: Though a device can rely on many existing technologies with known validation methods, novel technological aspects of the device should be validated as thoroughly as possible.
- Create a quality and regulatory strategy: Having the right start for a regulatory strategy can be critical in navigating these requirements.

Second Stage

- Obtain clinical testing authorization: Maintain IRB approval and contact FDA if significance of risk is uncertain.
- Prepare for initial interaction with FDA: Document the approach to testing the device for safety/efficacy and ask several questions of FDA for concurrence.
- Meet with FDA: Obtain direct feedback from FDA on the highest priority areas of uncertainty. Focus on outstanding issues.
- Continue to engage with FDA: As the device continues to mature in development, do not hesitate to meet with FDA again to obtain feedback on critical decision points from FDA.

Third Stage

- Prepare the document package: Do not underestimate the volume and complexity of documentation required to justify safety/efficacy and/or substantial equivalence.
- Review application elements: Be direct and focus on the device's unique aspects.
- Respond to additional information request: Expect that FDA will request more information and be prepared to respond quickly.
- Receive regulatory decision: Celebrate a successful market authorization! If needed, meet with FDA to ensure the next submission goes smoothly.

Fourth Stage

- Establish a quality management system: Ensure that the manufacturing and management and quality processes are compliant. Anticipate future FDA inspections.
- Prepare for post-market safety surveillance: Report adverse events to FDA and providers as necessary to ensure safety.
- File subsequent submissions when necessary: Submit subsequent market authorization applications when the device has substantially changed.

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