U.S. Department of Veterans Affairs

CLOUT Process Guide

Establishing Clinical Limits of Use Tools (CLOUT) for Medical Devices and Technology

Developed by
VA National Center for Patient Safety
and
The Human Engineering Research Laboratories

A Partnership Among
VA Pittsburgh Healthcare System
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NCPS VA National Center for Patient Safety
Safer Systems • Safer Care

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Preface

Introduction

This guide provides an overview of the systematic process to establish clinical limits of use tools (CLOUT) for medical devices and technology. The overarching goal of developing these tools is to improve the prescription and/or usage of the medical devices and technology by appropriately classifying the available features and limits of safe operation.

The recommendations put forth in this document have been derived from work conducted by the Human Engineering Research Laboratories in collaboration with the Human Factors Engineering Division at VA National Center for Patient Safety.

Scope of Work

This process guide provides an overview of what is entailed in the development of CLOUT and sets expectations for individuals leading and supporting the work. The information provided in this document should be used as a general guide to initiate and plan the development of future CLOUT for other medical devices or technologies.

Scope

This document addresses wheeled mobility devices for adults, which include commercially available wheelchairs (manual and electric power), scooters, and other devices that are intended to provide at least temporary mobility using a wheeled base in either a seated and/or standing position. Standard wheeled mobility accessories (e.g., power seating functions, or anti-tip systems) are included within the scope. Custom accessories, such as custom molded seating systems and wheeled mobility devices for children, are beyond the scope.

Organization and Overview

This process guide includes examples from the development of CLOUT for wheeled mobility devices. It is divided into four sections in chronological order, each representing a critical phase of the recommended process (**Figure 1**).

Acknowledgments

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VA National Center for Patient Safety

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0: Planning	1: Project Charter	2: Research & Development	3: Share & Maintain
Identify Technology • Safety Risk • Lack of Knowledge • Prescription Issues	**Establish the Team** • Interdisciplinary • Clinical, Technical, and Administrative • Expertise and Knowledge **Establish the Project Mission** • Goal, Objectives and Scope • Stakeholders and Key Partners • Dissemination Channels • Target Document Outcomes • Product Testing Plan	**Deep Review** • Expanded Review of Literature, Medical and Product Performance Database, Regulatory, etc. **Product Testing** • Standards, Durability, and Performance • Usability and Clinical Performance **Writing and Designing** • Information Design • Mapping Product Features and Limitations • Develop Other Supporting Material	**Disseminate Clout** • VA Dissemination Channels **Establish Maintenance Plan** • Key Partners for Maintenance • Review Cycle As Needed

Figure 1 Phases of Clout Development

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Phase 0: Planning

In this planning phase, the VA National Center for Patient Safety (NCPS) identifies a medical device or technology with patient safety concerns and determines the method to support an appropriate multidisciplinary team to examine this device or technology as a CLOUT project. NCPS maintains oversight of the CLOUT project. Leadership for the project is designated by NCPS as an individual who is a VA employee, either internal or external to NCPS, or as a contracted consultant external to VA.

0.1 Identify the Medical Device or Technology

There are three main criteria that should be examined in order to determine whether a medical device or technology (hereafter referred to as "product") requires a systematic evaluation of its limits of use. These criteria include:

i. Risk to patient safety or health.

ii. Lack of knowledge or awareness of the product and its limitations.

iii. Issues with prescription and/or use of the product.

Past safety and performance issues with the product should be compiled and documented. Patient safety databases such as the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE), VHA Alerts and Recalls Website, (ARMS), Alert/Advisory Creation Tool (ACT), SPOT (not an acronym), and Joint Patient Safety Reporting (JPSR), can be reviewed for incident reports and safety concerns. Review of published, non-academic and government literature, including research studies and clinical practice guidelines, should be performed to identify product failures, results of product testing (laboratory and clinical), and best practices. If available, product repair and replacement data, and clinical or consumer feedback should be obtained.

Phase 0: Summary

Lead
- VA National Center for Patient Safety

Duration
- ~1 month

Key Activities
- Identify Clinical Technologies with Safety Risks

Key Outcomes
- Select Clinical Technology for CLOUT Development
- Designate project lead

Phase 1: Establishing the Scope

Phase 1 development begins with NCPS designating a project lead that will be responsible for the overall project management duties and will work closely with NCPS throughout the duration of the project.

Phase 1 also presents an opportunity for the newly enlisted team to develop a working relationship and a shared understanding of the project. The primary outcomes of this phase are a project mission that defines the overall goals, scope of work, target audiences and key stakeholders for the project, timeline, and methods of dissemination.

1.1 Establish the CLOUT Team

Team members include stakeholders internal to the Veterans Health Administration (VHA), and may also include stakeholder external to VHA who carry pertinent expertise.

Establishing CLOUT will require an understanding of the product and its prescription, medical benefits and client usage scenarios, and product information including durability, performance, and product life-cycle costs. A CLOUT team should therefore include a diverse mix of experts representing both clinical and technical areas relevant to the selected product. Below are the recommended criteria to help establish a successful collaborative team.

1.1.1 Team Size

The complexity and novelty of the product involved will determine the requirements for team size. For example, products that have no known testing standards may require a large engineering and testing team to develop and carry out those tests.

1.1.2 Team Composition

The complexity and novelty of the product involved also determines the team composition. Products that have safety concerns with their prescription may require a team with stronger clinician presence. At a minimum, the team should include members who represent clinical, technical, and administrative areas.

The clinical group may consist of practicing expert clinicians and/or expert clinical researchers. These individuals will be tasked with providing knowledge about how features of the technology, determined by design and performance, can or cannot be matched with the needs of the Veteran. They should also be able to understand the contexts in which use of the product in various scenarios may result in safety concerns. The clinical group assists in determining the depth and breadth of information provided in the CLOUT documents, ensuring that the information is clinically appropriate for the target audience. Additionally, the clinical team should lead clinical testing and/or focus groups with potential end users (e.g., other clinicians and Veterans) to objectively evaluate the product using an activity analysis framework. Clinical team members should be familiar with the use and prescription of the product under review. Clinical team members should be aware of the current best practices in the field and related research and clinical practice guideline literature.

The technical group should consist of engineers and/or technicians who are familiar with the technology. Technical group members will be tasked with determining performance expectations and contributing knowledge of existing test standards, regulatory requirements and results of product testing. To fill in knowledge gaps, the technical group may conduct product testing to evaluate product features, performance and durability. Technical team members should be familiar with the product under review, related technical research literature, and standards used to evaluate performance and durability. In certain situations, especially with novel products, the technical team may need to create and carry out new tests, protocols, and benchmarks to measure product durability and performance.

The administrative group may consist of project managers, technical writers, and/or graphic designers. These individuals may be tasked with overall project management, organization and write-up of information gathered across the teams, and/or data visualization.

1.1.3 Other Considerations in Selecting the CLOUT Team

The ability of the team to access information from published literature, product databases and product testing facilities can help facilitate the CLOUT process. These sources could include national and international databases (e.g., patient safety and product testing relevant to the technology being examined). Literature and databases may help the team understand the history and current state of the product being evaluated.

The team's access to a product testing facility could be helpful to establish limits of use for products for which complete performance and/or durability information is not readily available. Such a testing facility should have the ability to test the durability of a product as well as establish performance benchmarks.

1.2 Project Mission

The project mission developed in this phase will serve as a focal point throughout the project—providing a set of objectives and helping to manage the scope in subsequent phases. Thus, it is imperative that the team has a clear understanding of the reasons for undertaking the project and reach a consensus on its future direction.

The mission may have been established prior to the institution of the CLOUT team; nevertheless, the team should evaluate its merit and revise as needed. A clear mission is necessary to determine the project goals and scope, as well as the key stakeholders and primary and secondary target audiences. The scope of the project provides the breadth and depth of information to be included and ways to bundle this information for effective delivery. Establishing the channels for disseminating the project outcomes further improves the impact of the work done and ensures its utility.

1.2.1 Project Management Plan and Timeline

The CLOUT team should establish a project timeline and a clear communication strategy among internal team members (and external, as appropriate) for efficient completion of distributed tasks (e.g., tasks delegated to individual members; tasks executed in parallel or sequence).

The project management plan should include meeting frequency and agenda, consequently establishing meeting minutes and action items with time frames. The communication strategy should also include online tools for collaborative document review and editing to help with collective development of the CLOUT documents.

1.3 Recommended Phase 1 Activities

1.3.1 Preliminary Review

A preliminary review of information available to the team should help verify the goals and objectives of the project. This information may be sourced from research literature, clinical practice guidelines, team member experiences, preliminary data and other sources. Furthermore, the information gathered here could help refine the project mission.

1.3.2 Identify Stakeholders and Key Partners

Identifying the users of the CLOUT documents can greatly impact the clarity of the project mission and determine (and constrain) the scope. The primary audience should be the clinician who is involved in the prescription of the product (e.g., wheelchairs, prostheses) or who uses the product in patient care (e.g., surgery, acute care, rehabilitation or long-term care). Additional secondary audiences, if appropriate, should be clearly defined. Subsequently, as the team progresses through the development of CLOUT documents, availability of stakeholders who partner with the CLOUT team, will greatly improve the process of reviewing the work with them, and ensuring the output remains aligned with the needs of the audience(s). These stakeholders may include individuals with specific access to information or facilities not available to those within the team, such as those with particular areas of clinical or technical expertise or access to research databases or testing facilities.

1.3.3 Establish Target Outcomes

It is important to define the number and types of documents, and the properties of the documents early in the process. This ensures that style, organization, level of detail of information presented and the way it is communicated (graphics, visualization, or text) are agreed upon prior to development. The outcome of this project may be a single or multiple documents—digital and/or print—that set guidelines for clinical limits of use for the key audience(s). Based upon the targeted outcomes, a project timeline should be established that considers the effort needed to compile the documents and fill in information gaps.

The types and properties of the documents can remain a work-in-progress as the team progresses through the development phase. In order to establish the targeted documents and set of properties for the document, the team should consider the expected core experience provided in its usage, and draw inspiration from contemporary information designs that may be familiar to and used by the target audience(s).

The team should also consider the lifetime of the CLOUT document(s), specifically assessing how new products or research will be integrated to keep the information current and relevant. Defining a document framework upfront that allows for ease of future updates is beneficial. This target framework, like the target documents and properties, remains a work-in-progress. The final framework and properties should be established at the conclusion of the development phase (Phase 2).

The reach and utility of the project depends on how the documents developed are disseminated to the target audience. As part of the Phase I activities, teams should examine the communication formats and platforms recommended by VA NCPS. Considering the potential channels of communication can help determine the document properties, as well as the framework to revise and update the document.

1.3.4 Establish Testing Plan

In the case of technologies that are emerging or do not have adequate performance or durability data to create the CLOUT documents, the team must define a timeline that includes time for product procurement; development of new tests, protocols, and benchmarks as needed; and product testing to existing or newly developed standards and protocols.

Phase 1: Summary

Lead
- CLOUT Team

Duration
- ~2 Month(s)

Key Activities
- Identify Field Experts: Clinical, Technical, and Administrative Groups
- Evaluate Project Scope, Goals, and Objectives
- Identify Key Stakeholders and Key Partners
- Establish CLOUT Document Framework
- Examine Communication Channels for Dissemination
- Product Testing Plan

Key Outcomes
- Establish CLOUT Team
- Project Mission
- Project Timeline
- Targeted CLOUT Documents and Framework

Phase 2: Development of CLOUT

Phase 2 involves conducting an expanded review, testing the product, mapping its features and limitations, and producing the CLOUT documents.

2.1 Recommended Phase 2 Activities

2.1.1 Expanded Review

The team should build upon the preliminary review conducted in Phase 1. In this review, the team should review published literature, product testing and performance databases, existing performance standards, relevant regulatory requirements, product categorization and coding for reimbursement, clinical practice guidelines, position papers, consensus documents, stakeholder discussions, and expert reviews. The recommended set of objectives that guide this search include identifying: the medical benefits of using the product; safety and injury risks related to use of the product (based on design, durability, and clinical and environmental assessments); and best practices in product prescription, configuration and maintenance.

2.1.2 Product Testing

As described in Phase 1, products that are novel or do not have sufficient background evidence or well-defined testing methods may require additional laboratory testing to fully clarify their limits of use and related safety concerns. Furthermore, it should be noted that novel/emerging technologies may require additional design reviews, stakeholder discussions, and/or human testing.

Clinical evaluations using an activity analysis framework uncover safety risks associated with use of the product by potential end-users, examine the performance of the product under various usage scenarios, and identify limitations based upon the various levels of ability of potential users. Activity analysis is a practice commonly used by rehabilitation therapists (e.g., occupational and physical therapists) as a framework for assessing an activity while it is being performed.[1,2] This framework was designed to consider the activity as it could be conducted by any potential person. The framework has two components. First, product evaluation in a controlled laboratory space is conducted. This consists of evaluating requirements for product assembly and disassembly, installation or uninstallation of the product (if applicable), the interface of the product with the person using it (e.g., fit, comfort, seating and positioning support), the engagement or disengagement of the person with the product (e.g., transferring into and out of), the process of using of the product in an indoor controlled setting, and review of care, maintenance, and storage requirements. A collaborative clinical and technical team discussion or focus group using expert clinicians or Veterans who may use the product can be used to supplement the clinical information gathered.

The technical team evaluates the product using established standards, if available, or by developing and carrying out appropriate performance and benchmarking tests. Standards testing provides details on the nature of product performance and durability and safety issues that arise from it. Occasionally for some emerging technologies where the team has little experience with the product, non-destructive technical testing may need to precede clinical testing to ensure safety of the team evaluating the product. Destructive technical testing is done after all other testing information is gathered. For guidance on product testing, see the Appendix.

Case Study

In evaluating the limits of use of Action Trackchair, the CLOUT team conducted extensive tests with both clinicians and technical experts. The team began by evaluating the performance and durability testing reports provided by the manufacturer. The clinical and technical teams then conducted an activity analysis in an indoor use trial followed by guided discussion. The product was then evaluated in several selected outdoor tasks that exemplify typical usage scenarios (**Figure 2**). The guided discussions and hands-on examination of the product provided a comprehensive understanding of the Action Trackchair's benefits and limitations of use.

Figure 2 CLOUT Team Evaluating the Action Trackchair in an Outdoor Environment

2.1.3 Mapping Product Features and Limitations

The information gained in the extended review is used by the team to determine how product features (or lack of features) are related to safety and limits of use of the product. Mapping of product categories to product features and product limitations is one of the primary means of describing the clinical limits of use. The mapping can be visualized in several ways (see example provided below in **Figure 3** and **Figure 4**). The team must examine different formats to determine the most appropriate way to communicate the information to the appropriate target audience(s). Choice of appropriate formats must take into consideration the target document properties and framework set in Phase 1.

Product Features or Usage Limits	Product Categories		
	Category 1	Category 2	Category 3
Feature 1			
Feature 2			
Feature 3			
Feature 4			
Feature 5			
Feature 6			
Feature 7			

Red – unsafe to use.
Yellow – may have restrictions.
Green – safe to use.

Figure 3 A Sample Dashboard Showing the Mapping Between Product Categories and Features or Usage Limits. Mapping is Represented by Color Coded Cells

Category		Ultralight Rigid & Folding	High Strength Lightweight	Lightweight	Standard	Standard Hemi	Standard Heavy Duty	Tilt-In-Space	Recline	Transport
CMS K Codes		**K0005**	**K0004**	**K0003**	**K0001**	**K0002**	**K0006 K0007**	**E1161**	**E1225 E1226***	**E1038 E1039**
Wheelchair Weight (Lb.)		**< 30**	**< 34**	**34-36**	**> 36**	**> 36**	**NS**	**NS**	**NS**	**NS**
Seat Height (Inches)		**NS**	**NS**	**NS**	**≥ 19**	**< 19**	**NS**	**NS**	**NS**	**NS**
Device Features	Backrest Angle (C)									
	Seat Plane Angle (C)									
	Accommodate Seating/Positioning Items									
	Rear Wheel Position (C)									
	Front Rigging Position (C)									
	Seat To Floor Height (C)									
	Options & Accessories to Customize									
	Supports Tilt In Space									
	Supports Standing									
	Supports Seat Elevation									
	Standard Duty (≤ 250 Lb)									
	Heavy Duty (251-300 Lb)									
	Extra Heavy Duty (≥ 301 Lb)						K0007			E1039

① NS = Not Specified

② C = Customizable by Adjustability and/or Configurability

③ * = Only WC-19/WC-20 Compliant Wheelchairs

Red – common products in that category do not typically have that feature or are not typically clinically appropriate in that scenario.

Yellow – a limited selection of products in that category typically have that feature, or common products in that category have limitations and may not always be clinically appropriate in that scenario.

Green – most or all products in that category typically have that feature, or the most common products in that category are usually clinically appropriate in that scenario.

Figure 4 Excerpt from an Example Dashboard for Manual Wheelchairs

2.1.4 CLOUT Documents

The CLOUT document bundle should include a literature review, visual dashboards, and appropriate supporting documents such as product summaries, fact sheets, case studies, and/or testing reports. The literature review summarizes the important clinical factors related to use of the product, and the evidence guiding the selection of product features to meet the needs of a Veteran and prevent injury or medical complications. The dashboard is a primary visual tool which presents categories of the product in columns, indicates a list of product features as rows, and uses colors/symbols to indicate the extent to which product factors (e.g., customizable backrest angle), activity factors (e.g., part-time use), and environmental factors (e.g., outdoor mobility in the community) are representative of product categories. Supporting materials can highlight the importance of a limit of use. For example, case studies could be developed that present a particular scenario in which a Veteran uses a product in a specific environment that then creates potential safety issues or limits of use. Product summaries or fact sheets could be developed to describe features, usage, capabilities, performance expectations, and limits of use for discrete categories of the technology. Testing reports provide additional details about specific product limits of use that are detected through activity analyses and technical evaluation.

Phase 2: Summary

Lead
- CLOUT Team

Duration
- ~4 Month(s) + Additional Time for Product Testing, as Needed

Key Activities
- Expanded Review
- Product Research: Technical and Clinical Evaluation
- Mapping Product Features and Limitations
- Iteratively Build CLOUT Documents

Key Outcomes
- Final CLOUT Document Bundle

Phase 3: Disseminate and Maintain

Phase 3 represents the conclusion of the development phase and the start of the project maintenance phase. It begins with the dissemination of the CLOUT document through VA or other communication channels to reach the target audience(s) and concludes with establishment of a review and maintenance process to keep the document up to date with new information and insights.

3.1 Document Dissemination

The VA utilizes both electronic and print document distribution systems. As determined by the CLOUT team and the VA, the document should be optimized for the selected delivery system(s).

3.2 Document Maintenance

Research and development will undoubtedly continue even after the CLOUT documents are developed. Furthermore, clinical experience in working with products, especially for novel technologies, can significantly change based on patient-centered outcomes measured over the product lifecycle. New knowledge gained during this time may supplement or contradict information set forth in the CLOUT documents. Therefore, it is important that a document maintenance plan be established to ensure the CLOUT documents represent the latest in research and clinical thinking. CLOUT documents should be re-evaluated every 3 to 5 years to determine whether the documents should be 1) confirmed, 2) revised/amended, or 3) withdrawn. This follows similar processes used by standards organizations across several fields including the American National Standards Institute (ANSI)/The Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) and International Organization for Standardization (ISO). Furthermore, the CLOUT team should identify and establish ongoing relationships with key partners, such as professional organizations, who may lead or assist in maintenance of the document over its determined life.

Phase 3: Summary

Lead
- CLOUT Team

Duration
- ~1 Month(s)

Key Activities
- Disseminate CLOUT
- Identify Key Partners for Maintenance of CLOUT

Key Outcomes
- CLOUT Dissemination
- CLOUT Maintenance Plan

Appendix: Product Testing Guidance

This appendix provides guidance on the various clinical and technical product testing methods that can be applied to determine limits of use.

A.1 Qualifying Tests

Qualifying tests are commonly used to qualify a product for sale in a certain country. Qualifying tests are often prescribed by national or international bodies as a prerequisite before the product can provided. Examples include ANSI/RESNA and the FDA, in the United States of America. In the context of less-resourced settings, the World Health Organization may have guidelines for testing particular products.

A.2 Performance and Usability Tests

Performance and usability tests are used to elicit failures and performance issues in products. The goal of these tests is to try to subject a product to worst-case scenarios to highlight weak links within the design. The tests include user evaluations, which are used to solicit feedback from users about product design and support verification of other limits of use. All testing should be in compliance with local regulations and good practices.

A.3 Examples of Testing

1. **In-lab qualifying testing:** A first step when evaluating a product is to perform qualifying tests that are relevant to the strength and durability of the product. This is done prior to any user testing to ensure that there are no obvious failure modes or safety concerns with the product.
2. **Controlled environment user testing:** Once the product has passed the relevant qualifying test, a user test can be performed in a controlled environment, such as indoors in a laboratory or office space, and outdoor in a specified space. A single-user test is often performed first, and if the product is safe and reliable, then multiple individuals may be conducted to test the product to gather feedback from a range of potential users.
3. **Single user community-based test:** After controlled-environment testing is complete, the product can be provided to a single user to perform community-based testing. Ideally a 'lead user', who will benefit from the technology and place extreme demands on the product is the best individual to recruit for this stage of testing. This user would need to understand the risks of using the product, and would need to be open to providing detailed feedback.

A.4 Testing Principles

There are several testing principles that are important to keep in mind when designing and performing testing. These best-practices are to help ensure the tests results accurately reflect the performance of the product, and that they are defensible.

1. **Worst-case scenarios:** It is important to know the conditions that are related to the worst-case scenario when designing and carrying out tests. For instance, for the safety of the users, tests are often performed to determine whether a product will fail catastrophically when it is in use. Performing tests under conditions that are average (e.g., average user weight) would predict only whether the product will be safe for approximately ½ of the population of users; any user who weighs above average could be at risk. Instead, testing conditions should be set to reflect the worst-case scenario. Using the same example as above, the user weight condition should be selected to be the max weight of a user who may use the product. In conditions where the parameter is normally distributed, a maximum value is typically considered two standard deviations above the mean (mean + 2*SD).
2. **Repeated trials:** There is variability in all tests that are performed, which leads to a variation in the testing results. The variability could be from many sources, some known and some unknown. For instance, the welds on a frame may not be consistent which could lead to failures during load testing of one frame but not another. Testing methods are also sometimes difficult to reproduce, which can lead to different test results even with all other variables being fixed. To address this variability, it is important to perform multiple trials and investigate the average and standard deviation of the test result (or another applicable statistical test). A general rule of thumb is that as the variability increases, so do the required number of repeated trials. Best-practice is to perform three repeated trials of each product to determine the test results. As variability increases, the number of repeated trials should increase. In-home testing with users is an example where there may be wide variability, and thus at least 10 repeated trials may be necessary.
3. **Documented methods:** It is critical to document all test methods and results. This helps ensure that the test is defensible when questioned, and that it can be repeated by others if necessary. A general rule of thumb is that all tests must be documented with enough detail that the test can be replicated by someone else.

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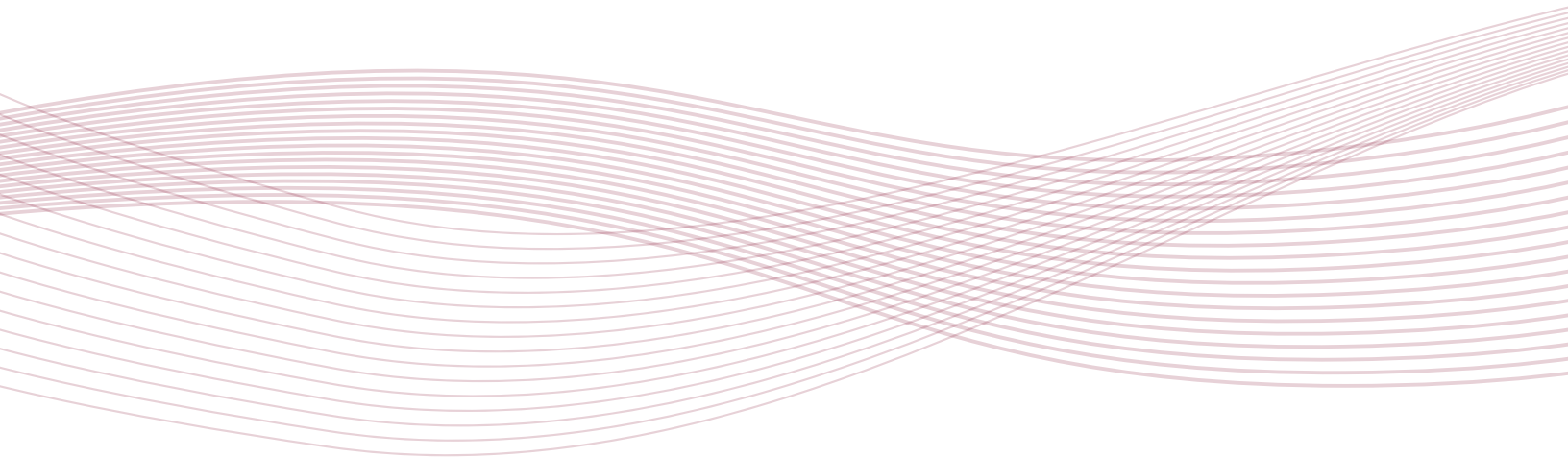


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