

The Development and Validation of a Roadmap for Traceability

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Abstract. Organisations who operate in the safety critical domains such as the medical device, aviation, and automotive domains must ensure their software is safe and provide objective evidence to this effect. One way of achieving this is by adhering to domain specific regulations and guidelines which specify a comprehensive implementation of traceability. However there is a gap between regulatory traceability requirements and what is implemented in practice. This lack of compliance means that organisations find it difficult to assess the safety of their software and thus ensure its safety. One reason for non-compliance with regards to traceability is a lack of guidance on what traceability to implement or how to implement it. In this paper we present the development and validation of a roadmap for the implementation of traceability in the medical device domain. The roadmap will provide medical device organisations with a pathway for effective traceability implementation.

Keywords : software traceability, medical device, roadmap, compliance, safety critical software, standard, guideline

1 Introduction

Developing software in the safety critical domain is a difficult task as manufacturers must comply with numerous regulations and guidelines. Additionally, it is incumbent on the manufacturers of such software to prove that their software is safe. This involves submission of a safety case which is a reasoned argument supported with objective evidence proving that the software is safe for its intended use [1]. Establishing effective software development processes that are based on recognised engineering principles appropriate for safety critical systems will greatly contribute towards the safety of the software. At the heart of such processes they must incorporate traceability.

Traceability is the ability to establish links (or traces) between source artefacts and target artefacts [2]. Tracing, which is the process of developing traces, is an important technique that can help to ensure that the right system is being designed and implemented. It is important to implement "just the right amount" of traceability in "just the right way" so that the risk-to-reward ratio benefits a project's circumstances. Otherwise, you may find that:

1. A project suffers from excessive overhead without commensurate quality improvement.

2. The project fails to deliver the requisite quality

Neither of these outcomes is desirable therefore it is beneficial to define and implement the right traceability strategy from the beginning. In the medical device domain, the “right amount” of traceability is determined by the medical device standards and guidelines. These standards require traceability between each phase of the Software Development Lifecycle (SDLC), Risk Management and Change Management processes, e.g. traceability between software requirements and software architectural design. These standards’ traceability requirements ensure verification of inputs to outputs. Additionally, the “right way” is influenced by traceability best practices.

However despite the regulatory requirements for traceability and the many benefits it has to offer, most existing software systems lack explicit traceability links between artefacts [3] and required phases. This leads to difficulties in verifying and validating the software. Numerous reasons have been identified for reluctance in implementing traceability, including a lack of guidance in terms of what traces to implement and how to implement them. As a result practitioners are ill informed as to how best to accomplish this task [4, 5]. To assist medical device organisations in addressing the lack of guidance on how to implement effective traceability, this paper presents the development and validation of a traceability roadmap.

While there is no standard definition of a roadmap, many definitions do exist, for example a roadmap is *‘the view of a group of stakeholders as to how to get where they want to go to achieve their desired objective’*[6], or a roadmap is *‘a series of milestones, comprised of goals, that will guide an organisation, through the use of specific activities, towards compliance with regulatory standards’*[7]. In effect a roadmap is a plan that allows organisations put solutions in place in order to achieve specific goals.

The remainder of this paper is structured as follows: Section 2 outlines various types of roadmaps and roadmap development methodologies while Section 3 outlines the development methodology used to develop the roadmap presented in this paper.

Section 4 details the structure of the developed roadmap while Section 5 presents the findings of an expert evaluation of the roadmap and a discussion of those findings, while Section 6 concludes the paper.

2 Related Work

Robert Phaal et al., [8] leading authorities in the world of roadmapping (the process of developing a roadmap), examined approximately 40 roadmaps and categorised them into 8 types of roadmap (in terms of purpose) and 8 formats of roadmap (in terms of graphical format). Based on the purpose that they serve, the following 8 types of roadmap have been identified: Product planning; Service/capability planning; Strategic planning; Long range planning; Knowledge asset planning; Program planning; Process planning; and Integration planning. Based on the graphical format, the following 8 formats of roadmap have been identified: Multiple layers; Single layer; Bars; Tables; Graphs; Pictorial representations; Flow Charts; and Text.

Phaal et al. note that a range of roadmaps observed may be partially due to a lack of an accepted standard for roadmap development, or may be due to the fact that organisations need to adapt their approach to suit their particular situation i.e. business purpose, available resources etc. The authors also note that roadmaps can contain elements of more than one type of roadmap resulting in many hybrid forms of roadmap, which can result in organisations finding them difficult to use.

As a result of challenges organisations encountered when developing roadmaps Phaal et al. developed a fast start approach called T-Plan to support the rapid initiation of roadmapping [9]. These challenges included: keeping the roadmapping process "alive" on an ongoing basis; starting up the process; and developing a robust method. The T-Plan approach is based on four facilitated workshops. The first workshop ("Market") aims to establish a set of prioritized market and business drivers for the future, reflecting external and internal factors. The second workshop ("Product") aims to establish a set of "product feature concepts" that could satisfy the drivers identified in Workshop 1. The third workshop ("Technology") aims to identify possible technological solutions that could deliver the desired product features. The fourth workshop ("Charting") draws the marketing and technology strands together to produce the first roadmap. Its format is defined in terms of time scales, levels and product strategy.

The Software Engineering Institute in collaboration with Carnegie Mellon University and the Hewlett-Packard Company have developed a Software Process Improvement (SPI) Roadmap [10]. This roadmap is a generic long range integrated plan for initiating and managing a SPI program. Its purpose is to provide a generic description of the steps involved in implementing a SPI program, at both a strategic level and an operational level. The roadmap describes a process improvement program that occurs in three phases, made up of six major activities within these phases. The three phases are analogous to the SEI's IDEAL model (Initiating, Diagnosing, Establishing, Acting and Learning) for software process improvement. The phases are:

- Initiate process improvement;
- Baseline the current processes and opportunities;
- Implement process improvement by developing and sustaining improvements within the organization.

Flood et al., [11] have developed a SPI roadmap for the implementation of medical device standards. The goal of this roadmap is to implement the processes necessary to meet the requirements of specific medical device standards, and not to improve existing processes as in traditional SPI models. The methodology used to develop the roadmap is similar to the methodology used by Barafort et al., [12] for the construction of ISO/IEC 15504-2 [13]compliant process assessment and process reference models. The methodology contains seven steps as follows:

1. Identify requirements of the standards;
2. Logically group all goals;
3. Separate grouped goals in line with ISO/IEC 15504 capability levels. These grouped goals form milestones;
4. Order the milestones based on capability levels and logical groupings;
5. Validate the generated roadmap;
6. Identify activities that can meet the identified goals;

7. Validate activities in host organisation.

While there are numerous publications on roadmap development methodologies [14-17], the most common methodology is a three phase approach: an initiation phase which includes defining the scope and boundaries of the technology roadmap, a development phase, and a follow up phase which includes roadmap validation and implementation plan.

3 Methodology

To develop a roadmap it is necessary to answer the following three questions: Where are we now? Where are we going? and How do we get there?

The objective of this roadmap is to provide a pathway for the implementation of traceability in a manner which is compliant with the medical device standards requirements for traceability, and also to provide a pathway that adopts the best practices for traceability implementation. These requirements and best practices provide an answer to the question ‘Where are we going?’ An analysis of the medical device standards (which included ISO/IEC 62304 [18], ISO/IEC 14971[19], ISO/IEC 13485 [20], and the FDA guidance documents [21-23]) yielded 26 requirements for traceability. These requirements were then transformed into a ISO/IEC 15504-2 [13] compliant process assessment and process reference model using the TIPA transformation process [12]. The application of this process assessment model (PAM), developed prior to this roadmap [24], provides a baseline of an organisation’s current state with regards to traceability and answers the question ‘Where are we now?’. To determine the best practices for implementing traceability a literature review was conducted which yielded 23 best practices [25]. These 23 best practices were categorised under the 6 headings of: Traceability Policy; Traceability Information Model; Resources; Appropriate Techniques; Standard Operating Procedure and Communication Method.

Now that the requirements and best practices for traceability implementation were identified a decision as to the type and format of the roadmap was required. In contemplating the taxonomy of roadmap types and formats identified by [8] it was considered that the traceability roadmap aligned with the ‘Process planning’ type of roadmap. This type supports the management of knowledge, focusing on knowledge flows that are needed to facilitate effective traceability implementation. In addition to, and perhaps more important than roadmap type, the format of the roadmap was then considered. It was decided that the roadmap should be a hybrid version entailing both the ‘single layer’ and ‘text’ formats. This hybrid version was chosen for the following reasons:

- Combinations of pictorial information with text-only information facilitate significant improvements in understanding [26];
- The single layer roadmap is a graphical format and can present a lot of information in a readily understandable format;
- The traceability roadmap needed to present a lot of information such as base practices and the benefits that an organisation could leverage through each phase of the implementation. In addition, it was felt that an implementation case study would be of great benefit to organisations that do not have exper-

tise in the area of traceability. Therefore it was decided that the best way to present this information would be in text format.

4 Roadmap Overview

The roadmap contains three separate sections. Section 1 contains an overview (see Figure 1) of the steps an organization should take when implementing an effective traceability process. During the **pre-production stage** 'Plan for Traceability', an organisation should decide at an organisation level, or the project manager should decide at the project level which of the traceability best practices to implement. The best practices are numbered from 2.4.1 to 2.4.6 and this is the suggested order of implementation as there are certain dependencies between them, for example the Traceability Information model details the traces to be implemented and this information should be known before deciding on required resources.

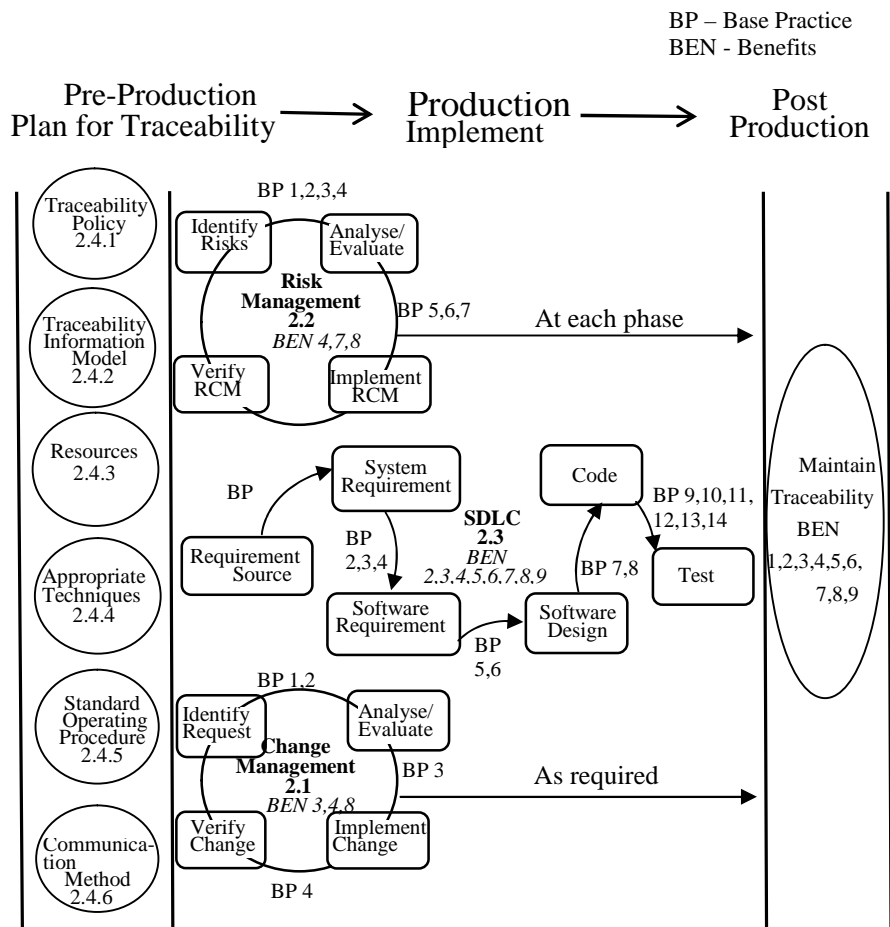


Fig. 1. Traceability Roadmap Overview

The **Production stage** in Figure 1 indicates implementation of traceability through the Software Development Lifecycle (SDLC) and the supporting processes of Risk Management and Change Management. The SDLC, Risk Management and Change Management processes respectively contain 14, 7 and 4 base practices (as distinct from best practices identified in Pre-Production). Figure 1, indicates at what stage during these processes the base practices should be exercised. These base practices have been extracted from the traceability PAM developed in conjunction with this roadmap [24]. Risk Management and thus risk management traceability should be implemented at each stage of the SDLC and through the maintenance lifecycle whereas Change Management and thus change management traceability should be implemented whenever a change is required through the SDLC and maintenance lifecycle.

Traceability needs to be maintained throughout Production and **Post-Production** or it will degrade and become untrustworthy. Maintaining traceability through Post-Production requires exercising the same development processes (i.e. SDLC, Risk Management and Change Management) and same base practices exercised during the production stage.

Section 2 of the roadmap contains details of the base practices for implementing traceability through the SDLC, Change Management, and Risk Management processes in addition to the best practices for implementing traceability. These base practices, are the activities that contribute to achieving the effective implementation of traceability through the SDLC, Risk Management and Change Management processes. For example Base Practice 1 (BP1) of the SDLC is: Establish bi-directional traceability between System requirement and their source.

Section 3 of the roadmap contains an implementation case study which guides the reader through the implementation of traceability in a fictional organization and is thought to be of particular benefit to organisations with little experience in software process improvement or implementation of traceability.

Figure 1 also indicates the benefits that can be leveraged during the SDLC and supporting processes of risk management and change management e.g. benefits 4, 7 and 8 can be leveraged through Risk Management traceability. The benefits are:

Benefit 1: Maintenance. Accurate traceability information facilitates making changes correctly and completely during maintenance, thus improving productivity.

Benefit 2: Reuse of components. The traceability matrices facilitate reusing product components from past projects and thus increasing productivity.

Benefit 3: Impact Analysis. Traceability information can be used to quickly and accurately identify the impact of any proposed change to the system.

Benefit 4: Project Management. Traceability information allows project managers to have current data on the progress of the project. By analysing the traceability matrices, the project manager can quickly determine which artefacts have been implemented and thus determine if schedule is on target.

Benefit 5: Customer confidence. The traceability matrices can be presented to the customer as reassurance that the customer is getting the product that they requested.

Benefit 6: Verification and Validation. The SDLC traceability matrix can be used to prove that a requirement has been designed into the system and implemented in the code. This validates the requirement. Similarly the trace matrix can be used to prove that the requirement, design and code have been tested which verifies the requirement, design and code.

Benefit 7: Certification. Regulation normally requires critical systems are certified before entering service. This involves submission of a safety case. A good safety case encompasses an effective risk mitigation process which is highly dependent on requirements traceability.

Benefit 8: Key personnel leaving. Documenting the links between artefacts through the traceability matrices reduces the risks of information being lost if key personnel leave the project/organisation.

Benefit 9: Test failures. If tests fail, the SDLC traceability matrix can be used to identify the artefacts that potentially cause the failures, as requirements, design and code are linked to software requirements test.

5 Validation of the Roadmap

5.1 Research Method

An initial validation of the traceability roadmap has been conducted by expert review. Eight experts agreed to participate and were chosen based on their expertise in one or more of the following: a) roadmap development, b) medical device standards, c) requirements traceability, d) medical device software development and e) software process improvement. A brief overview of the experts credentials include:

Expert 1 has seven years in industry and seven years in academia researching traceability;

Expert 2 has more than thirty years' experience in software development, is a consultant of a major medical device manufacturer, is a member of the ISO/IEC JTC1 WG10 (Process assessment), and is the author of the addendum of IEC 62304:2006 showing the mapping between 62304 and 12207;

Expert 3 has worked in the software industry for about 12 years as programmer, analyst, project manager and database administrator and is Chief Scientist with a major software research centre;

Expert 4 has forty years' experience in software development, the last ten of which have been in medical device software specialising in integration of traceability;

Expert 5 has twenty years' experience in software development in roles such as Quality manager, and Lean and Agile coach. He has established a UML modelling concept to support 100% traceability;

Expert 6 has managed software design and development processes for a medical device manufacturer. This role included oversight of software quality assurance;

Expert 7 develops software for laboratory testing in a medical device company and has experience with tests and requirements traceability according to IEC 62304;

Expert 8 has experience in industry software development, open source software development and roadmap development.

Each reviewer was sent a copy of the roadmap along with a questionnaire which focused on the roadmaps ‘fit for purpose’. Some of the questions asked for an opinion based on the 5 level Likert scale [27] including a rationale for their response, while some of the questions asked for an opinion (without the Likert scale) and a rationale for their opinion. The questions requiring a Likert scale response are listed in Table 1. An example of a question without the Likert scale asked in the questionnaire is: Do you agree with the order of implementation depicted in Figure 1? Please give a short rationale for your opinion.

After all responses were received they were tabulated and a focus group consisting of four members from the Regulated Software Research Centre based in Dundalk Institute of Technology, Ireland was then convened to discuss the responses and arrive at a general consensus as to what changes should be made to the roadmap.

5.2 Findings

The eight experts were asked three questions which required a response rated on a five point Likert scale where 1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree or Disagree, 4 = Agree and 5 = Strongly Agree. The questions and responses are shown in Table 1.

Table 1. Reviewers responses rated on Likert scale

Questions	Rating				
	1	2	3	4	5
To what extent do you agree that the traceability implementation roadmap is usable in practice?		2	1	3	2
To what extent do you agree that the traceability roadmap is adaptable and customisable to different company settings (size, culture, resources etc.)?	1		2	5	
To what extent do you agree that the traceability roadmap is useful in practice?		1	2	4	1

The table indicates for example that in response to the question, ‘To what extent do you agree that the traceability implementation roadmap is usable in practice?’, two reviewers *strongly agreed* that it did while three reviewers *agreed* that it did etc. So while the table indicates an overall positive response, a series of further questions in the questionnaire elicited a total of 42 comments/suggestions for improvement. These comments were categorized under three main headings of Structure, Content, and Rationale as shown in Table 2.

Table 2 Categorisation of Reviewer Comments

EXPERT	STRUCTURE			CONTENT							RATIONALE			
	Figure 1 Structure	Regulatory Reference Location	Traceability Benefits Location	Less Content/ Complexity	Tools/ Automation	Implementation Detail	Adaptability/ Flexibility	Additional Benefits	Content Applicability	Additional Content	Signposting	Overview Explanation	Base Practice v Best Practice	Tracing Rationale
1			1								1		1	
2	2	1	1	3	1			1	1			1		
3	1													1
4	1				2		1		2	4				
5				1	1	1				1				
6				1	2		1		2	1		1		
7								1						
8				1				1				1		
Total Comments	4	1	2	6	6	1	2	3	5	6	1	3	1	1

The Structure category contained 7 comments about the structure of the roadmap. These comments related to:

- the order of the best practices under Pre-Production in Figure 1;
- a comment stating that references to medical device standards should be in an Appendix;
- 2 comments stating that the benefits of traceability should be in the introduction.

The majority of received comments were categorized under the Content category. This category contains 29 comments which were generally focused on the substance of the roadmap. These comments related to:

- Six comments stated that they thought the roadmap had too much content and was too complex e.g. *“I would have like to make it much shorter with better visualizations”*.
- Six comments were also made with regard to tools and automation, suggesting that while the roadmap offers both automated and manual options, the roadmap would be better served if it *‘encourages automation more’*.
- One comment on implementation detail suggests that a better explanation of how to complete matrices is required;
- Three comments suggested that a number of additional benefits of traceability could be added to the roadmap;

- Two reviewers thought that the roadmap could be improved if it was more flexible and that the methods suggested for implementing traceability should be marked as exemplar;
- Five comments were made with regard to the applicability of some of the content in the roadmap. These comments questioned the best practice of not using traceability in performance reviews, and if there is a need for a Standard Operating Procedure;
- Six comments were made with regard to adding additional content to the roadmap. These comments included adding additional columns to the trace matrix, adding a section stating how the roadmap is applicable to different SDLC types e.g. Agile, Spiral, Iterative, and finally one reviewer thought that *'in order to be persuasive it is important to sell traceability'* .

The Rationale column contained 6 comments relating to the reviewers understanding of the roadmap and are summarised as:

- One reviewer thought that the roadmap could be improved with better 'sign-posting' to direct the reader through the document;
- Three reviewers thought that the Overview section was not self-explanatory and needed more detail;
- One reviewer was confused with the terms best practice and base practice;
- One reviewer considers that the rationale for traceability in the Introduction section could be improved.

5.3 Discussion

As a result of the comments/suggestions for improvement the focus group, which was convened after all the comments were received, came to a decision regarding changes to be made to the roadmap. The changes are listed under the Structure, Content and Rationale categories.

Structure Category: One comment thought that references to the standards which were in Section 2 of the roadmap should be put in an Appendix. This comment is related to six other comments categorised under the Content column which refer to the roadmap having too much content. The focus group agreed that the references to the regulations were not necessary for the implementation of the roadmap and were for informative purposes only and so agreed that they should be put in an appendix.

Two comments thought that the Introduction to the roadmap should contain the benefits of traceability. These comments relate to a comment under the Content category which states that it is important to sell traceability, and also relates to a comment under the Rationale column which states that the rationale for traceability in the Introduction could be improved. The focus group considered that putting the benefits of traceability in the Introduction would inappropriately extend the Introduction. It was agreed that the benefits and barriers section should be moved to an Appendix and referenced in the Introduction.

Content Category: Six comments under the Content section stated that the use of automatic tools should be encouraged more (as against manual methods which were described in Section 2 of the roadmap). These comments are related to two other comments under the Content section which state that the manual methods should be marked as exemplar. The focused group agreed with these comments and so the man-

ual methods are marked as exemplar and moved to an appendix, which has the additional benefit of making the roadmap less complex. Additionally the use of automated trace tools will be highlighted in the roadmap overview along with a tool decision flowchart in Appendix D.

Three comments stated that a number of additional benefits of traceability could be added to Figure 1 e.g. benefits 5, 6 and 7 should be added to Change Management. The focus group considered that these three benefits were generic across the three processes and so it was agreed to add them to the three processes.

A number of comments were made with regard to adding additional content to the roadmap. The focus group considered these comments and agreed to add a paragraph in the Introduction to address how the roadmap is applicable to different SDLC types e.g. Iterative, Spiral, Agile etc.

Rationale Category: The focus group agreed that adding hyperlinks to the roadmap would improve the readability of the document. This was in response to one reviewer's comment about improving the 'signposting' throughout the roadmap.

One reviewer stated that using the two terms 'best practice' and 'base practice' was confusing. The focus group agreed not to change these terms as 'base practice' is the term used in ISO/IEC 15504 and this is the standard on which the PAM related to this roadmap complies with. Additionally the term 'best practice' is a term used throughout the literature and is generally known. It was however agreed that a distinction between the terms should be made in the Introduction of the roadmap.

5.4 Complete Roadmap

A table of contents of the completed roadmap is shown in Table 3. The main body of the roadmap now contains four relatively short sections with a lot of informative material referenced in the Appendix.

Table 3 Completed Roadmap Table of Contents

Introduction	Section 4 Barriers and possible solutions Leveraging traceability benefits
Scope	Appendix A Difference between IEC 62304 and ISO 12207
Section 1 Roadmap Overview	Appendix B Traceability links and references to Standards
Section 2 Traceability Milestones, Outcomes and Base Practices for each of the processes: Change management Risk management SDLC	Appendix C Exemplar traceability methods and tasks
Section 3 Implementation Case Study	Appendix D Traceability Best Practices in detail

6 Conclusion

To assist medical device organisations improve their traceability, a roadmap for the implementation of traceability has been developed. This roadmap is based on a ISO/IEC 15504 compliant Process Assessment Model (PAM) developed by the authors prior to this roadmap. The PAM will assist medical device organisations understand their actual traceability performance and management of activities, and the potential for improvement. The roadmap will then provide the pathway to that improvement and ensure compliance with the medical device standards and traceability best practices.

Eight experts reviewed the roadmap. While the response was mostly positive they made a total of forty two comments suggesting fourteen areas for change. A focus group reviewed these comments and through consensus agreed to make two changes to the structure of the roadmap, four changes to the content of the roadmap, and two changes to aid understanding (rationale) of the roadmap. Based on the review feedback and resulting amendments which have resulted in its enhancement, the roadmap is now ready for pilot assessment within two medical device organisations.

Acknowledgement

This research is supported by the Science Foundation Ireland Principal Investigator Programme, grant number 08/IN.1/I2030 and by Lero - the Irish Software Research Centre (<http://www.lero.ie>) grant 10/CE/I1855.

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