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DATABASE OF CASES OF PRODUCTS AND SOFTWARES DEVELOPMENT IN THE HEALTHCARE AREA

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ABSTRACT

In the development of products it is important to know the best practices and techniques employed as a way to be able to adapt them to better results. The healthcare area benefits from such knowledge, since there are many challenges in identifying users and engaging them in the project in order to meet their needs. This study presents a database of cases of products and softwares development in the healthcare area. A systematic bibliographic review was carried out on the Scopus and Web of Science databases and articles that contained cases of product and/or software development in the healthcare area and presented details of the users' involvement throughout the development process were selected. The database is made up of 203 articles, 160 of which relate to software development, 26 are product development cases (hardware) and 18 describe product development with software. This database serves as a reference for researchers and practitioners who want to seek evidence of best practice and ways to engage users in the development of healthcare products/software.

Key-words: *user involvement; participatory design; health; systematic review, bibliometric analysis.*

1. INTRODUCTION

Several norms are imposed in the medical area to avoid problems in the use of products and services and among them the need to involve users in the development process (MONEY et al., 2011; SHAH; ROBINSON, 2006). Money et al. (2011) have found that, even so, many product and service development processes still face difficulties. The authors emphasize the way to involve the user, which method to use and who are the users to be involved.

Shah and Robinson (2006) highlight the importance of involving the user in different stages of the product life cycle to capture different perspectives. Despite the large number of methods available, developers choose to use a limited range, according to an interview conducted by Shah and Robinson (2006). The authors identified that focus group methods and questionnaires are the most used when engaging users.

During a product/service development process, all user groups should be considered and participate in the engagement process (VON HIPPEL, 2005). However, in the medical field, identifying which users involve may be a problem. Money et al. (2011) they found that often only physicians are involved in the project. There are others that can be considered as users of healthcare products: general healthcare professionals, such as nurses and physiotherapists (MARTIN et al., 2010); patients with disabilities or with special needs (SHAH; ROBINSON; ALSHAWI, 2009); elderly patients (SHAH; ROBINSON; ALSHAWI, 2009); general patients (MARTIN et al., 2010); technician (PIETZSCH et al., 2009); and anyone who has contact with the product, such as product maintenance, cleaning, transportation and training (MARTIN et al., 2010), patients relatives and caregivers responsible for the surgery department (MARTIN et al., 2010), and researchers, students and trainees (SHAH; ROBINSON; ALSHAWI, 2009). Some user groups may be overlooked in development and this can lead to usability issues (CARRUTHERS; PHILIP, 2006).

Data from the studies of Shah, Robinson and Alshaw (2009) and Money (2011) on methods used and who are the users involved in product development were identified through interviews with medical product manufacturers and no literature research was done on a sample of able to discuss the state of the art. In order to explain a phenomenon and discuss a theory, Tranfield et al. (2003) indicate the use of the systematic review. This study presents a literature database with information on product development processes (hardware) or software in the medical area where there were application of methods to involve the user. Data on quantity and incidence of

methods used in user engagement, the types of users involved and the number of products and software were identified. The bibliometric analysis detected an increase number of publications on this topic, which countries are involved in the research, and also the journals.

2. METHODOLOGY

The combination of a systematic review and bibliometric analysis was used as methodology, proposed by Conforto, Amaral and Silva (2011). The objective of the SR is to generalize knowledge through theoretical synthesis in fields and subfields of research. This type of methodology has been frequent in the medical field in management research, probably because it can explain a phenomenon and at the same time ensure consistency in the analyzes of the theory (TRANFIELD; DENYER; SMART, 2003).

Conforto, Amaral & Silva (2011) recommend a 3-step-roadmap to develop SR researches in the area of operations management, focusing on product development and project management. This research is organized into 3 phases: entry, processing and exit (Figure 1).

On the first phase, the research objective, sources (Scopus and Web of Science), search string and inclusion/exclusion criteria were defined.

On processing phase, the quantity of articles identified before and after the inclusion/exclusion criteria is presented. In total, 538 articles were retrieved in the search string, 63 were duplicates, so 475 articles were considered for the first filter in the processing phase. After reading the abstract of these articles, 332 were considered for the second filter and the entire article was read. On the last phase, bibliometric analysis from 203 papers were shown and discussed as a result.

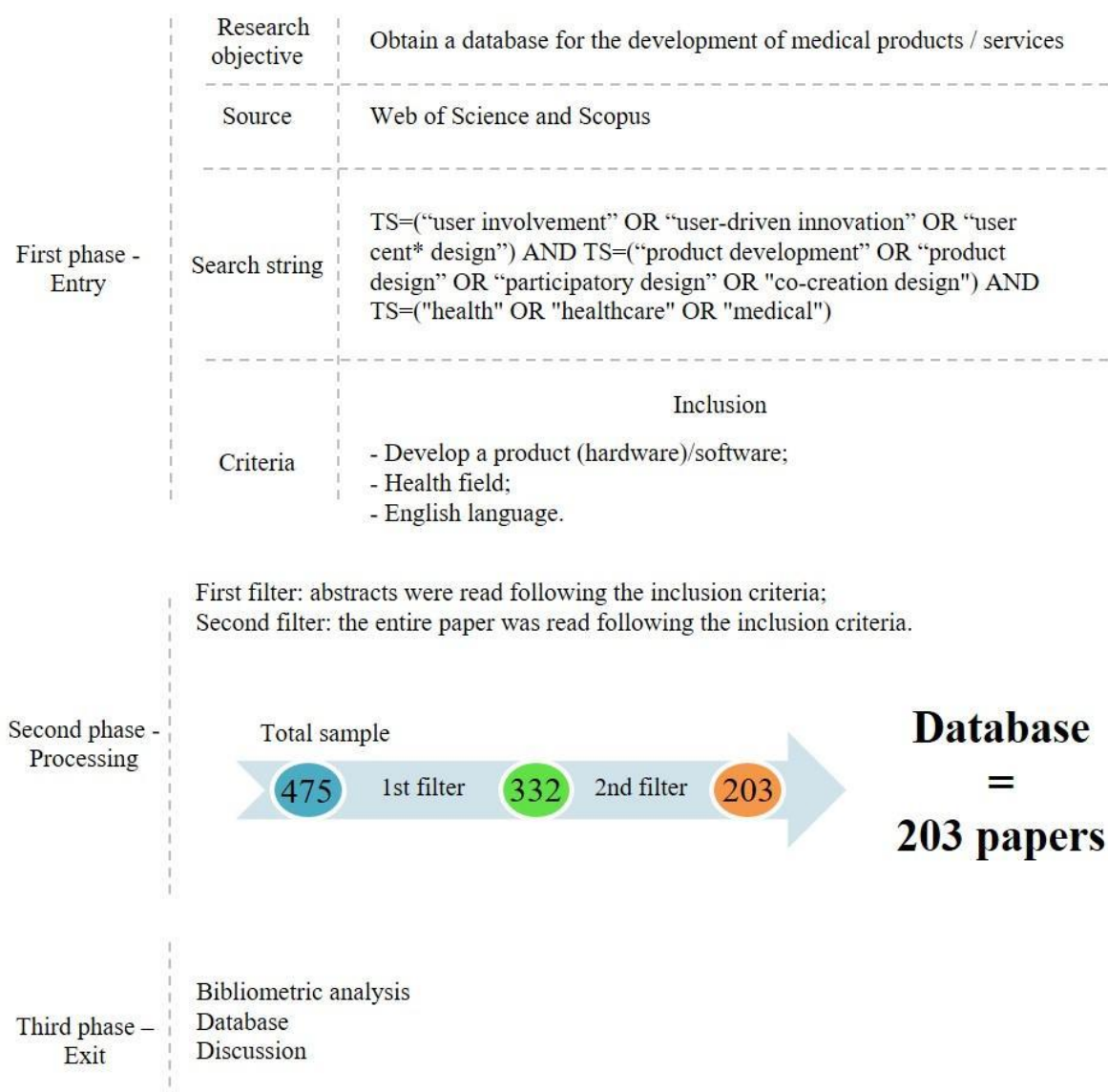


FIGURE 1 - Methodology process. Source: authors

3. RESULTS AND DISCUSSION

After the processing phase, 203 articles were cataloged (Appendix A). These studies present product (hardware) and/or software development in the medical field, all of them involve users throughout development.

3.1 PRODUCT AND SOFTWARE

Among the 203 papers, there is a great focus for the development of software (160 papers, ID 45 - 203). Programs are developed in 102 articles (ID 45 - 145); mobile application in 47 (ID 146 - 192); and websites in 11 papers (ID 193 - 203).

The product development corresponds to approximately 12% of the analyzed articles (26 papers, ID 1 - 26), while the combination of software and product development in articles was the least identified. Only 18 articles (ID 27 - 44) products are developed related to a program or application.

3.2 METHODS USED FOR USER INVOLVEMENT

In the database were identified 24 different methods used to involve users in different stages of development, such as concept, design, testing and trials (SHAH; ROBINSON, 2006).

The most used method is "prototyping" (190 articles; ~ 94%). Only 10 of the software articles (159) do not use prototypes to test the generated concepts. However, in article ID 133 a usability test and a heuristic evaluation are applied, in this way, it is believed that a prototype of the developed software has been made, even if it is a low fidelity one. Otherwise, these tests could not be applied. Among product articles (with or without a combination with software - total of 44), only 3 of them do not use prototypes for testing. It should be noted that a minority of the articles develops more than one prototype throughout the development, being one of low fidelity (CHIOU et al., 2014) and at least one of high fidelity (RUDD; STERN; ISENSEE, 1996). This practice indicates that the interactivity of the development phases was performed (AITCHISON et al., 2009), a good development practice focused on the user.

The second most applied method is "interview" (149 articles, ~ 73%). Among these articles, only one (ID 92) makes exclusive use of this method, being a development for software. A good practice in health products / services development is the application of more than one method, having a combination of them, better extracting the usability aspects (SHAH; ROBINSON, 2006).

"Questionnaire" is the third most applied method (65 articles, ~ 32%). It is noted that the articles ID 6 (product development) and ID 39 (product development + software) only apply this method. This practice is also in agreement with the combination of methods by Shah and Robinson (2006).

Still with a significant percentage, the following methods are applied: observation (~ 29%) and focus group (~ 28%). The methods that obtained a lower index of application were: user cases

(3 articles), contextual inquiry (3 articles) and storytelling (1 article). The latter 7 methods cited were applied for software development.

All the methods have greater application in the software area and none of them has a significant number of applications in the product developments in the articles analyzed. For example: 190 articles applying prototyping, only 24 are product development; of the 58 that apply focus group, only 5 are for product; of the 14 that apply personas, only 1 is for product.

Although some methods are quite common in the areas of product and software, they are still poorly applied in health care. For example, "heuristic assessment" is a method initially developed for software analysis (NIELSEN, 1993); however, it is poorly applied in healthcare technologies (5% of articles with software or product development + software). The same happens with the "personas" method, common in information technology projects / softwares (GRUDIN; PRUITT, 2002; HJALMARSSON; GUSTAFSSON; CRONHOLM, 2015; RAMOS, 2013) and Web development (GARRETH, 2011), but only 8% of analyzed articles that develop software apply persona.

Figure 2 gives an overview of how many times the identified methods have been applied, and the relation of which methods are applied by which articles analyzed is in Appendix B.

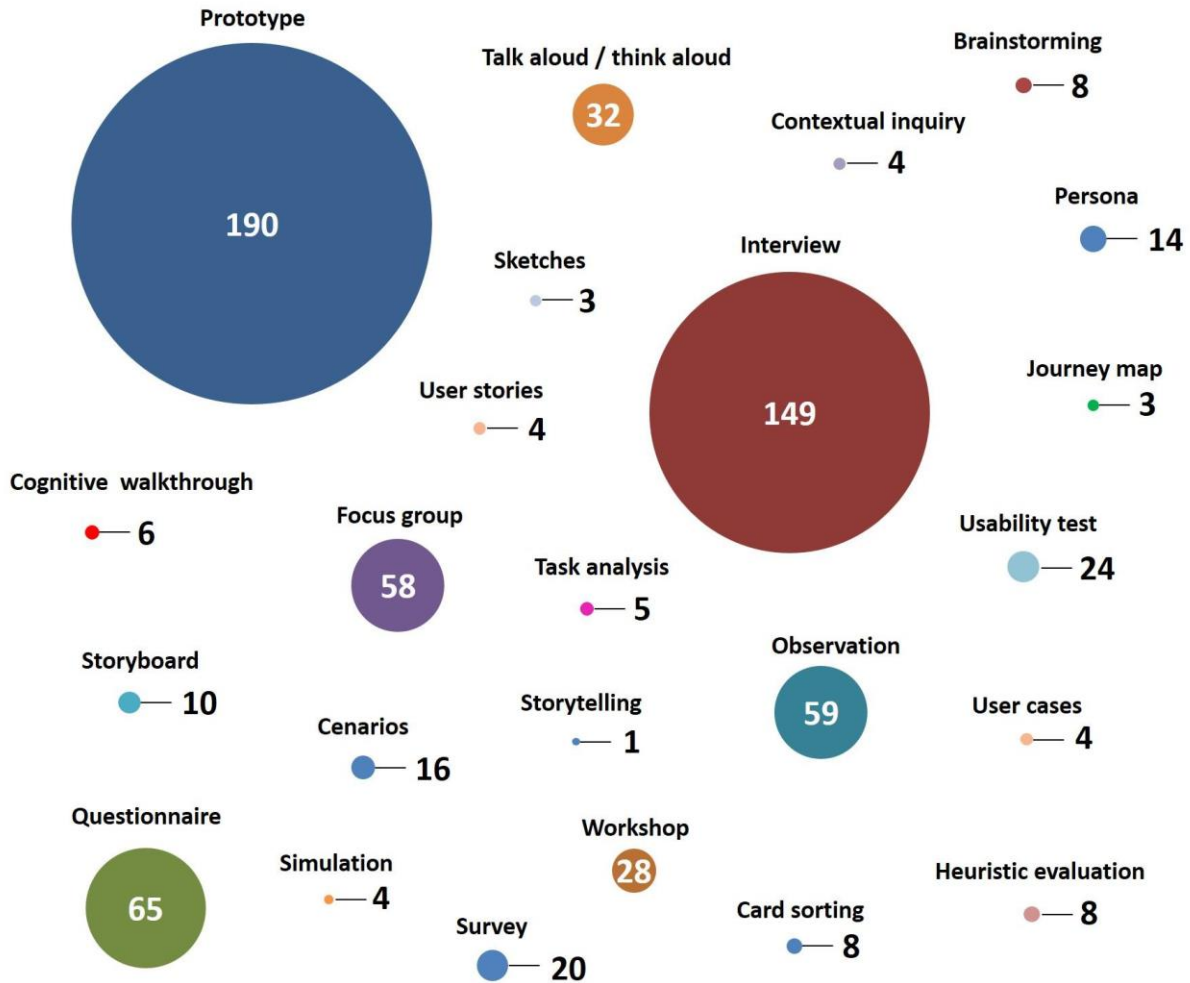


FIGURE 2 - Number of times a method was applied. Source: authors

3.3 Users

In the articles collected in the database, it was evident the importance of product development to be user focused and all types of users being considered (STACCINI et al., 2001). Most cases involved more than one type of user, such as patients (children, elderly and adults), family members, physicians, nurses, psychologists, and caregivers. In 48 articles (~ 24%), only one type of user was involved (ID 1, 5, 14, 17, 29, 30, 32, 44, 45, 49, 53, 54, 60, 64-66, 68, 69, 71, 75-77, 81, 86, 91, 102, 104, 125, 135, 139, 148, 149, 156, 157, 168, 171, 175, 183, 185, 194-200 and 204). Nine cases (~ 4%) did not involve the users that the developers considered as end-users (ID 20, 27, 53, 65, 84, 86, 92, 102 and 191), while 4 cases (IDs 20, 27, 84 and 191)

focused on patients but only involved health professionals. On the other hand, cases 53, 65, 86, 92 and 102 aimed to assist health professionals but only involved patients.

Among the analyzed articles, most focus on the involvement of patients and their families and/or caregivers, physicians and nurses (MARTIN et al., 2010; SHAH; ROBINSON; ALSHAWI, 2009). However, those database articles that develop products, none of them involves or mentions users who have indirect contact with the products, as responsible for maintenance, cleaning, transportation and training (MARTIN et al., 2010).

3.4 Bibliometric analysis

The case database is composed of articles published in journals (60% - total of 122) and articles published in conferences (40% - total of 81) (Figure 3). There is a greater number of publications concentrated in 7 journals, only one of which is not focused on healthcare, but rather has a scope of ergonomics and usability (Applied Ergonomics). These main journals are presented in Table 1.

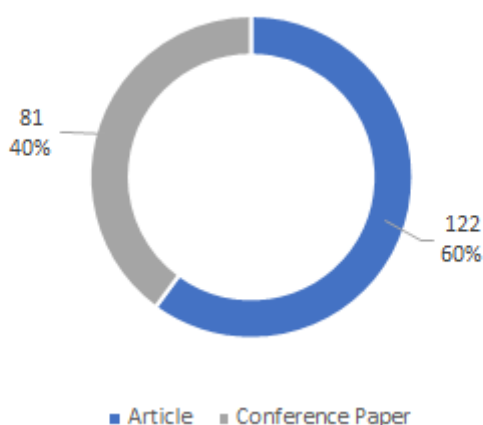


FIGURE 3 - Document type distribution. Source: authors

TABLE 1 - Main journals

| Journals |
|--|
| Journal Of Biomedical Informatics |
| Journal of Medical Internet Research |
| International Journal of Medical Informatics |
| Applied Ergonomics |
| BMC Health Services Research |
| BMC Medical Informatics And Decision Making |
| Health Informatics Journal |

Source: authors

The articles in the database come from 27 countries/territories (accounting carried out according to the country of the corresponding author of each article) (Figure 4). The highest number of cases was reported by authors from the USA (66), UK (25) and Canada (12). After them comes a great majority of European countries (Norway, Denmark, Sweden, the Netherlands and Germany). In Latin America, only 3 countries were identified (Brazil, Colombia and Argentina), Brazil being the largest number of cases (4).

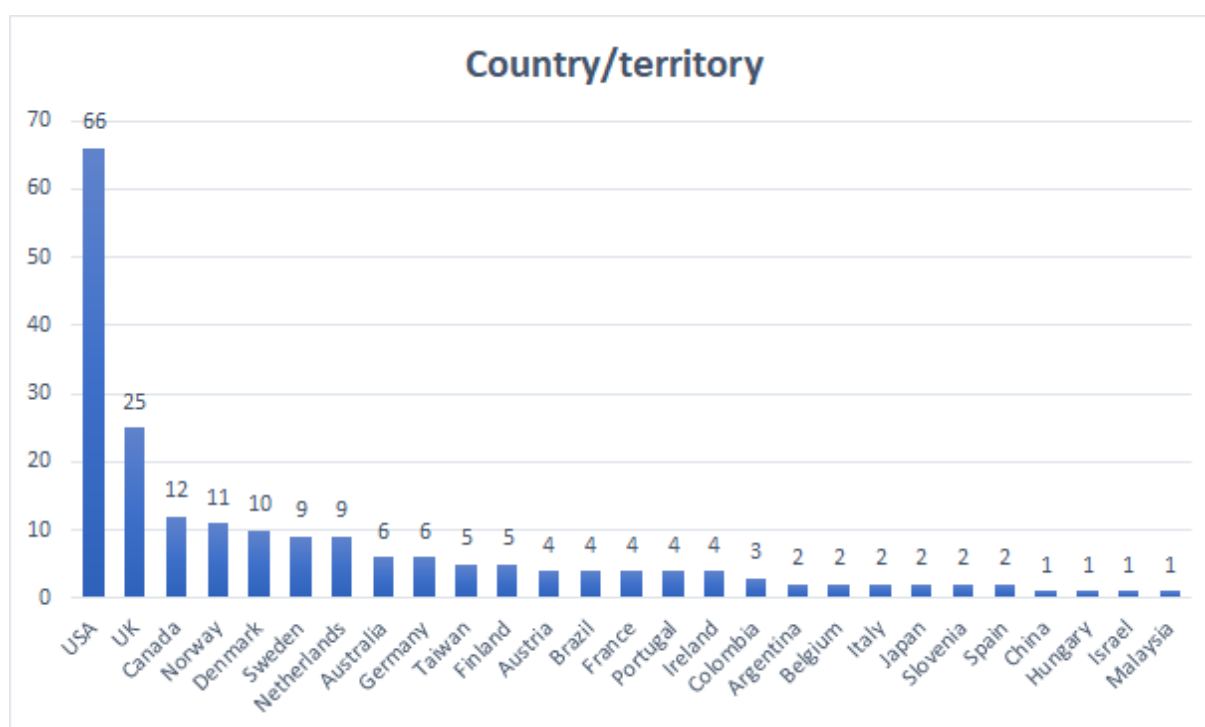


FIGURE 4 - Publication origin. Source: authors

The database comprises a period from 1986 to 2019, as can be seen in figure 5. Until 2004, there was a consistency of one article per year. Since then, there has been a growth in the publications of cases of products and/or software development in the healthcare area, such

growth was accentuated from 2009. The peak of articles presented in the case database was in 2018 with 32 cases cataloged. The database has cases published in the year 2019, accounting for 15 cases so far.

The publication of the usability standards ISO 62366 in 2007 and ISO 60601-1-6 in 2010 may have influenced the increase of user involvement in the development of healthcare products and/or software. These standards guide that development must be done with the active participation of users. They have an international application, but they were published in the USA, which may be related to the large number of published cases in the country.

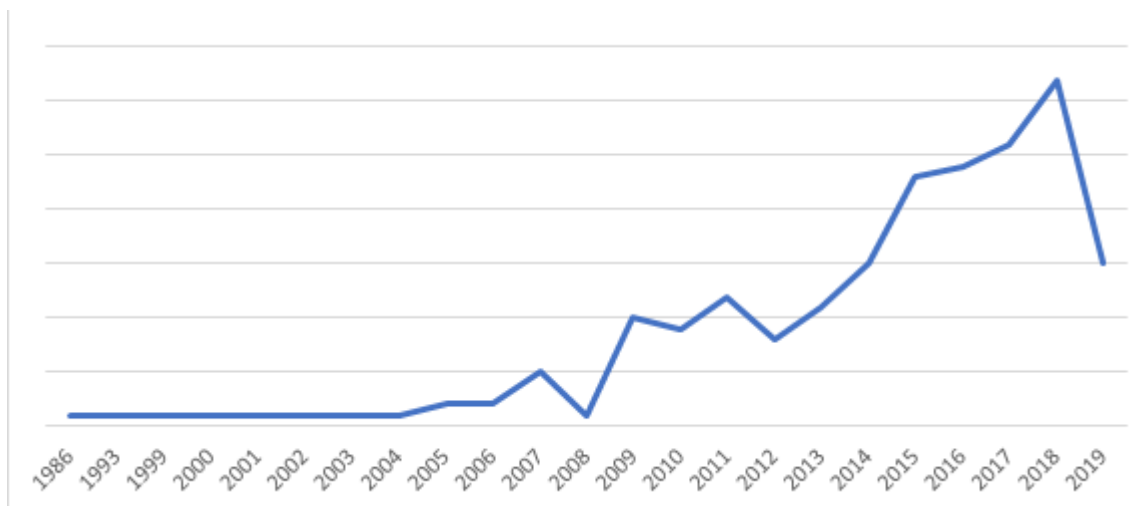


FIGURE 5 - Year of publication of the database articles. Source: authors

4. CONCLUSION

The database presents 203 cases of development of health products and softwares that have involved users throughout development, 160 articles developed software (software, websites and mobile applications), 26 developed products (hardware) and 18 developed products combination and software. Health product development faces the difficulty of managing the needs of different types of users, but despite this, most articles involve more than one type of user in their development cases.

All the cases from our database describe the user involvement through methods. In total 24 methods were applied as a form of user involvement, in which the use of prototypes for the

development of products and softwares in the health area is highlighted. Interviews and questionnaires are also very applied.

Our database presents an extensive review period, articles from several countries and serves as a reference for developers and researchers wishing to rely on cases described in the healthcare product development literature.

5. ACKNOWLEDGMENT

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APPENDIX A

| ID | Product Reference |
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APPENDIX B

| Method | Papers ID |
|--------------------------|--|
| Prototype | 2 – 5, 7 – 38, 40 – 63, 65, 66, 69 – 91, 93 – 103, 105, 106, 108 – 123, 126 – 132, 134 – 203 |
| Observation | 5, 12, 16, 20, 26, 27, 36, 38, 42, 43, 45, 49, 51, 52, 54, 56, 58, 59, 66, 72, 73, 77, 79, 81, 95, 96, 98, 99, 107 – 110, 112 – 114, 118, 123 – 128, 130, 138, 143, 150, 154, 160, 163, 166 – 168, 176 – 178, 182, 184, 190, 199 |
| Interview | 1 – 5, 7, 8, 11 – 13, 16 – 22, 25, 27 – 30, 32 – 37, 41, 43 – 48, 50 – 59, 61 – 63, 65, 67 – 74, 76, 79 – 83, 85, 87 – 89, 92, 94, 95, 97 – 103, 105, 108 – 110, 112 – 114, 116, 118, 119, 124, 126, 128, 129, 131 – 134, 136, 137, 139, 140, 143 – 145, 147 – 162, 164, 165, 168 – 170, 172 – 174, 176 – 182, 184, 187 – 191, 193 – 200, 202, 203 |
| Cenários | 23, 27, 30 – 33, 45, 47, 57, 63, 66, 69, 117, 120, 126, 153 |
| Brainstorming | 37, 45, 67, 68, 158, 167, 179, 180 |
| Questionnaire | 1, 3 – 6, 10, 11, 14, 24 – 26, 32, 39, 41, 43, 45 – 47, 51, 54, 57, 60, 64, 66, 67, 70, 72, 78 – 81, 83, 85, 88, 91, 97, 101, 103, 111, 114, 117, 120, 121, 125, 128, 138, 145, 149, 152, 154, 156, 163, 168 – 171, 174 – 176, 180, 181, 183, 197, 199, 201 |
| Focus group | 11, 17, 21, 23, 24, 28, 29, 31, 37, 42, 52, 54, 55, 57, 59, 61, 65, 71, 74, 79, 80, 91, 100, 102, 106, 113, 114, 117 – 119, 121, 122, 124, 127, 129 – 131, 133, 134, 139, 142, 145, 147, 148, 150, 160, 166, 176, 177, 180, 182, 186, 193, 194, 196, 198, 200, 202 |
| User stories | 27, 47, 158, 197 |
| Persona | 15, 27, 37, 44, 104, 106, 122, 139 – 141, 154, 159, 179, 191 |
| Usability test | 20, 32, 42, 44, 51, 59, 60, 62, 65, 110, 114, 123, 127, 128, 133, 148, 182, 186, 188 – 190, 194, 197, 200 |
| User cases | 46, 104, 154, 197 |
| Heuristic evaluation | 28, 44, 110, 117, 133, 135, 142, 191 |
| Contextual inquiry | 42, 56, 62, 182 |
| Journey map | 106, 141, 159 |
| Cognitive walkthrough | 28, 51, 57, 114, 126, 142 |
| Workshop | 9, 18, 23, 58, 68, 71, 87, 103, 106, 107, 123, 126, 139 – 141, 150, 158 – 160, 162, 166, 178, 183, 185, 190, 192, 195, 202 |
| Survey | 17, 64, 77, 84, 93 – 95, 103, 106, 125, 136, 138, 151, 161, 167, 172, 180, 182, 186, 187 |
| Talk aloud / think aloud | 11, 32, 51, 60, 62, 65, 72, 75, 76, 79, 86, 90, 95, 96, 101, 102, 105, 108, 110, 126 – 128, 134, 135, 145, 148, 154, 165, 168, 181, 197, 200 |
| Task analysis | 4, 61, 63, 70, 129 |
| Simulation | 26, 58, 160, 197 |
| Storytelling | 139 |
| Card sorting | 19, 44, 76, 89, 90, 135, 136, 190 |
| Storyboard | 18, 23, 81, 119, 126, 139, 140, 166, 169, 178, 192 |
| Sketches | 18, 123, 192 |