**Supplementary file**

**Supplementary file 1: Interview guide for the retrospective phone interview**

**Company**

1. **Company type and size**
   * Small- and medium- size enterprise (<250 persons)
   * Large enterprise (≥250 persons)
   * Globalized company
2. **Location**
   * France only
   * Europe
   * Worldwide
3. **Product portfolio**
   * Medical devices only
   * Medical devices and pharmaceuticals
4. **Within your company, is there a person or a department dedicated to the management of clinical studies?** 
   * Yes
   * No
5. **Within your company, is there a person or a department dedicated to market access issues?** 
   * Yes
   * No

**Medical device features**

Please give details on the medical device submitted to CODIMS:

1. **Name of the medical device:**
2. **Indication of use:**
3. **Classification:**

|  |  |
| --- | --- |
| Class I |  |
| Class IIa |  |
| Class IIb |  |
| Class III |  |

1. **Year of CE marking:**
2. **Outside France, is the medical device marketed in another European country?**
   * Yes
   * No

**Market access strategy**

1. **Was CODIMS submission targeted as a priority compared to submission at the national level?** 
   * Yes
   * No

**1-a) Why?**

1. **Prior to CODIMS submission, has the medical device been adopted by other hospitals in France?** 
   * Yes
   * No
2. **How did you reach the clinician who requested CODIMS assessment of your medical device (information, formation, involvement in clinical trials, *etc.*)?**
3. **Did you encourage the clinician(s) to try the medical device by providing free units?** 
   * Yes
   * No
4. **Did you provide the clinician(s) with some specific training on the use of your medical device?** 
   * Yes
   * No

**Assessment process**

1. **What type(s) of study(ies) has/have been developed for your medical device?**

|  |  |
| --- | --- |
| Randomized controlled trial |  |
| Prospective controlled trial |  |
| Prospective study |  |
| Retrospective study |  |
| Case study |  |

1. **Have specific studies been developed for CODIMS assessment?**
   * Yes
   * No

**2-a) If yes:**

**2-a-1) What type(s) of study(ies)?**

* + Technical specification study
  + Clinical and/or controlled trial
  + Observational study
  + Economic evaluation or budget impact analysis
  + Other

**2-a-2) What types of problems have you faced in the development of this/these study(ies)?**

* + No problem
  + Some methodological issues in the design of the study
  + Lack of qualified personnel resources within your company to manage the study
  + Lack of financial resources
  + Challenges with recruitment of clinicians
  + Time constraint
  + Other

**2-b) If no, why?**

* + Sufficient data
  + Lack of financial resources
  + Lack of time
  + Other

1. **When requesting CODIMS assessment, did the clinician contact you to fill in the form?** 
   * Yes
   * No
2. **Did you request some advice from a clinician or a consultant to write the value proposition summary you submitted to CODIMS?**
   * Yes
   * No
3. **When CODIMS requested your value proposition summary, had you anticipated its preparation?**
   * Yes
   * No
4. **What was CODIMS’ recommendation after the assessment of your medical device?**
5. **How have you been informed of CODIMS’ recommendations regarding your medical device?**
6. **Were you satisfied with the transparency of the overall process? If no, why?**
7. **Were you satisfied with the timeline of the process? If no, why?**
8. **What is your level of awareness regarding the CODIMS assessment process?**
9. **Overall, how do you feel about the CODIMS assessment process?**