

Appendix 1: CLEO® scale

1. Clinical impact

Score	Impact	Definition: The clinical impact is evaluated according to <u>the most likely case expected, not the worst / best case</u>
-1C	Negative	The PI can lead to adverse outcomes on clinical status, knowledge, satisfaction, patient adherence and/or quality of life of the patient.
0C	Null	The PI can have no influence on the patient regarding the clinical status, knowledge, satisfaction, patient adherence and or quality of life of the patient.
1C	Minor	The PI can improve knowledge, satisfaction, medication adherence and/or quality of life OR the PI can prevent harm that does not require monitoring/treatment.
2C	Moderate	The PI can prevent harm that requires further monitoring/treatment, but does not lead to or does not extend a hospital stay.
3C	Major	The PI can prevent harm which causes or lengthens a hospital stay OR causes permanent disability or handicap.
4C	Avoids Fatality	The PI can prevent an accident that potentially causes the need for intensive care or death of the patient.
UND	Undetermined	The available information does not allow to evaluate clinical impact.
<ul style="list-style-type: none"> The clinical impact is evaluated in terms of the benefit to the patient. Harm: alteration of physical and mental capacities arising from an accident or illness. Quality of life: physical function (autonomy, physical abilities, capacity to perform the tasks of daily life etc.), psychological (anxiety, depression, emotions etc.), social (relative to family environment, friends or professional contacts, engaging in personal relationships, participation in social and leisure activities etc.) and somatic (symptoms related to the disease). Monitoring: monitoring clinically relevant (physiological or psychological) variables, and/or biological parameters. Treatment: changing therapy or adding an additional medical / surgical treatment. 		

2. Economic impact

Score	Impact	Definition
-1E	Increase in cost	The PI increases the cost of the drug treatment.
0E	No change	The PI does not change the cost of drug treatment.
1E	Decrease in cost	The PI cuts the cost of drug treatment.
UND	Undetermined	The available information does not allow to evaluate economic impact.
<ul style="list-style-type: none"> The cost of drug therapy contains two main elements: <ul style="list-style-type: none"> The cost of the drugs The cost of monitoring drug therapy (e.g., clinical monitoring, kinetics, biological monitoring etc.). The cost of drug therapy is based on the financial cost for the hospital. 		

3. Organizational impact

Score	Impact	Definition
-1O	Negative	The PI reduces the quality of care.
0O	Null	The PI does not change the quality of care.
1O	Positive	The PI increases the quality of care.
UND	Undetermined	The available information does not allow to evaluate organizational impact.
<ul style="list-style-type: none"> The organizational impact is coded in terms of the overall impact on the quality of the care process from the perspective of the health care providers (e.g., time saving; improved security, knowledge or job satisfaction for nursing staff; facilitating tasks or teamwork, continuity of care etc.) 		