

# DIN EN ISO 20916:2024-07 (E)

## In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)

---

<b>Contents</b>		<b>Page</b>
<b>European foreword</b> .....		<b>4</b>
<b>Annex ZA (informative) Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered</b> .....		<b>5</b>
<b>Foreword</b> .....		<b>9</b>
<b>Introduction</b> .....		<b>10</b>
<b>1</b>	<b>Scope</b> .....	<b>12</b>
<b>2</b>	<b>Normative references</b> .....	<b>12</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>13</b>
<b>4</b>	<b>Ethical considerations</b> .....	<b>22</b>
4.1	General.....	22
4.2	Improper influence or inducement.....	22
4.3	Responsibilities.....	22
4.4	Ethics committee involvement.....	22
4.5	Informed consent.....	23
<b>5</b>	<b>Clinical performance study planning</b> .....	<b>23</b>
5.1	General.....	23
5.2	Risk evaluation.....	24
5.3	Design of the clinical performance study.....	25
5.4	Investigator brochure.....	25
5.5	Clinical Performance Study Protocol (CPSP).....	26
5.5.1	General.....	26
5.5.2	Principal investigator responsibilities.....	26
5.5.3	Contents of the CPSP.....	27
5.6	Case report forms.....	30
5.7	Recording of specimen information.....	31
5.8	Specimen accountability and integrity.....	31
5.9	Study site selection.....	31
5.9.1	Site qualification.....	31
5.9.2	Site assessment.....	31
5.9.3	Site selection.....	31
5.10	Monitoring plan.....	32
5.11	Agreements.....	32
5.12	Labelling.....	32
<b>6</b>	<b>Study site initiation</b> .....	<b>32</b>
6.1	General.....	32
6.2	Prerequisites.....	33
6.3	Training.....	33
6.4	Initiation of the study site.....	33
<b>7</b>	<b>Clinical performance study conduct</b> .....	<b>34</b>
7.1	General.....	34
7.2	Responsibilities of the sponsor.....	34
7.3	Study site monitoring.....	34
7.3.1	General.....	34
7.3.2	Routine monitoring.....	34

7.3.3	Monitoring reports.....	35
7.4	Security and confidentiality of data.....	36
<b>8</b>	<b>Close-out of the clinical performance study.....</b>	<b>36</b>
8.1	Close-out activities.....	36
8.2	Clinical performance study report.....	36
8.3	Document retention.....	38
8.4	Suspension or premature termination of the clinical performance study.....	38
<b>9</b>	<b>Auditing.....</b>	<b>39</b>
<b>Annex A</b>	<b>(normative) Additional general requirements for certain studies.....</b>	<b>40</b>
<b>Annex B</b>	<b>(normative) Clinical performance study protocol (CPSP).....</b>	<b>43</b>
<b>Annex C</b>	<b>(normative) Investigator brochure.....</b>	<b>47</b>
<b>Annex D</b>	<b>(normative) Clinical performance study report.....</b>	<b>49</b>
<b>Annex E</b>	<b>(normative) Communication with the ethics committee.....</b>	<b>52</b>
<b>Annex F</b>	<b>(normative) Informed consent.....</b>	<b>54</b>
<b>Annex G</b>	<b>(normative) Adverse event categorization.....</b>	<b>58</b>
<b>Annex H</b>	<b>(informative) Good clinical performance study documentation.....</b>	<b>62</b>
<b>Annex I</b>	<b>(informative) Auditing.....</b>	<b>67</b>
<b>Bibliography</b>	<b>.....</b>	<b>68</b>