（病院様式1）　　　　　　　　　　　治験実施計画の概要

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 承認№ |  | | | | | | | | | | | | | | |
| 治験課題名 |  | | | | | | | | | | | | | | |
| 治験区分 |  | | | | | | | 相 | | | | 症例数 | | 例 | |
| 依頼者名 |  | | | | | | | | | | | | | | |
| 診療科 |  | | | | | | | | | | | | | | |
| 責任医師名 |  | | | | | | | 職名 | | |  | | | | |
| 目的 |  | | | | | | | | | | | | | | |
| 治験薬品名 | コード番号 | | |  | | | 一般名 | | |  | | | | | |
| 含量 | |  | | | 剤形 | | |  | | | | 貯法 | |  |
| 薬効分類 |  | | | | | | | | | | | | | | |
| 医薬品の  紹介 |  | | | | | | | | | | | | | | |
| 作用機序 |  | | | | | | | | | | | | | | |
| 臨床試験成績 | 国内  海外 | | | | | | | | | | | | | | |
| 副作用 |  | | | | | | | | | | | | | | |
| 試験方法 | 試験デザイン | | | |  | | | | | | | | | | |
| 対　象 |  | | | | | | | | | | | | | |
| 方　法 |  | | | | | | | | | | | | | |
| 併用禁止薬・療法 |  | | | | | | | | | | | | | | |
| 評価項目 |  | | | | | | | | | | | | | | |
| 治験期間 |  | | | | | | | | | | | | | | |