



BSI Standards Publication

In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

National foreword

This British Standard is the UK implementation of ISO 20916:2019.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

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**In vitro diagnostic medical devices —
Clinical performance studies using
specimens from human subjects —
Good study practice**

*Dispositifs médicaux de diagnostic in vitro — Études des
performances cliniques utilisant des prélèvements de sujets humains
— Bonnes pratiques d'étude*



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