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NOTE FOR GUIDANCE ON COORDINATING INVESTIGATOR SIGNATURE OF CLINICAL STUDY REPORTS

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COORDINATING INVESTIGATOR SIGNATURE OF CLINICAL STUDY REPORTS

These notes are intended to provide guidance on the designation of the co-ordinating investigator who will sign clinical study reports for multicentre studies.

They should be read in conjunction with the Directive 75/318/EEC as amended, by Directive 91/507/EEC.

They are intended to assist applicants in meeting the requirements of that Directive.

I. INTRODUCTION

Directive 75/318/EEC, as amended, by Directive 91/507/EEC, requires that clinical study reports, which form part of marketing authorisation applications, be signed by the investigator. For multicentre studies the signature of all investigators, or the coordinating (principal) investigator is required (reference Directive 75/318 (as amended) Annex Part 4 C 1).

Each Clinical Study Report submitted as part of a Marketing Authorisation Application, or any variation, extension, specific obligation or follow-up measure to one, should be signed by the investigator or in the case of multicentre studies the co-ordinating investigator.

The Directive does not describe how the co-ordinating investigator in multicentre studies should be designated. The following guidance has been formulated in order to provide an objective, but flexible method for doing this, in the context of each clinical study.

This guidance is to be applied for studies commencing as of the date of coming into effect of this Note for Guidance.

The guidance reflects that in place, in the first Note for Guidance on Good Clinical Practice, at the time the Directive 91/507 was developed and issued.

2. GUIDANCE

The co-ordinating investigator or the process of designating the signatory co-ordinating investigator should be defined in the protocol agreed for the study.