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active substance: non-clinical and clinical issues (EMA/CHMP/BMWP/42832/05 Rev.1) lays down the non-clinical and clinical requirements for a similar biological medicinal product (“biosimilar”). The non-clinical section addresses the pharmacotoxicological assessment. The clinical section

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Statistical Principles of Clinical Trials Lecture Notes (Modified from Dr. A. Tsiatis' Lecture Notes) Daowen Zhang Department of Statistics North Carolina State University c 2009 by Anastasios A. Tsiatis and Daowen Zhang. TABLE OF CONTENTS ST 520, A. Tsiatis and D. Zhang Contents

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GUIDANCE DOCUMENT. Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories October 2014

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