

Contents

● Jpn J Pharmacoepidemiol
vol.24 no.2 July 2019

● **Announcement**

ISPE's 12th Asian Conference of Pharmacoepidemiology •
The 25th Annual Meeting of JSPE 5E

● **Original Article**

Relationship of Concomitant Medications on Infusion Related Reactions to
Infliximab: A Case-Control Study Using Individual Case Safety
Reports Database Tetsu KOBAYASHI, et al. 43

Validation and Recalibration of Charlson and Elixhauser Comorbidity
Indices Based on Data From a Japanese Insurance Claims Database
..... Tomomi KIMURA, et al. 53

● **Special Issue on "What the Diovan Case Brought to Japanese
Clinical Trial ?"**

Preface Tatsuo KAGIMURA 65

1. An Appropriate Implementation of Clinical Trials and Morality of
Investigators Iwao KUWAJIMA 67

2. About the Meaning of "Describe a False or Exaggerated Article" in
the Pharmaceutical Affairs Law Hiroshi YASUHARA 75

3. Roles and Responsibilities of Trial Statisticians
..... Satoshi TERAMUKAI 79

4. History and Future Direction of Academia Clinical Trial Regulation:
Lessons of Diovan Affairs and Concerns on Clinical Trials Act
..... Yoji NAGAI 87