



2021 PROJECT REPORT

MONITORING THE ADEQUACY OF IMPLEMENTATION AND ADHERENCE TO
INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH) GUIDELINES

Consistent Cohort 2019 vs 2021 ICH Study

Prepared by:

Juan Lara, Research Analyst

Magda Bujar, Manager, Strategic Development

Neil McAuslane, Scientific Director

18 January 2022

v.1.5

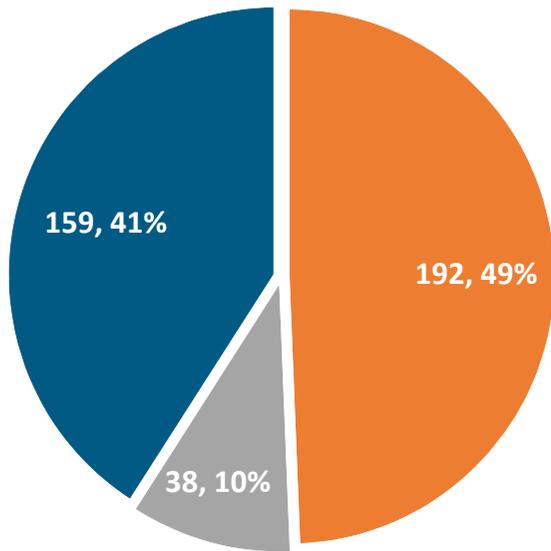
	Guidelines	Authority	Pharmaceutical industries
Tier 2	<ul style="list-style-type: none"> • E2A – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting • E2B(R3) – Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports • E2D – Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting • M1 – Medical Dictionary for Regulatory Activities Terminology • M4 – Common Technical Document 	<ul style="list-style-type: none"> • ANVISA, Brazil • NMPA, China • HSA, Singapore • MFDS, Republic of Korea • TFDA, Chinese Taipei • TITCK, Turkey 	<ul style="list-style-type: none"> • 20 Pharmaceutical companies were surveyed, where • 17 are global pharmaceutical companies • One is a single region pharmaceutical company • Two are local country pharmaceutical companies <hr/> <ul style="list-style-type: none"> • 18 pharmaceutical companies are focused on innovative medicines • The rest are focused on both innovative medicines and generics

Questions of the survey related to this analysis

- **Question 1a** that asks about the companies' experience with ICH Guidelines
- **Question 1** that asks about the companies' view on the implementation status for ICH Guidelines
- **Question 1.2 and 1.2.2** that ask about the adequacy of implementation of the ICH Guidelines
- **Question 1.3** where is asked about the companies' view on the adherence status for ICH Guidelines

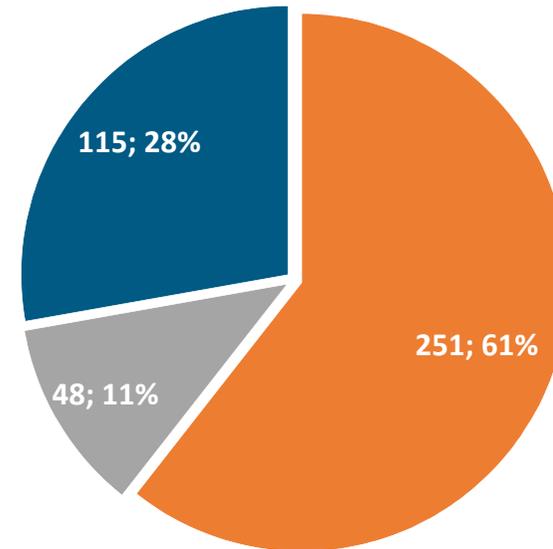
Company responses relating to adequacy of implementation and/or adherence across Tier 2 Guidelines for ICH non-Standing non-Founding Regulatory Members

2019's Report



Total = 389*

2021's Report



Total =414**

- Adequately implemented and full adherence/too early to assess adherence
- Inadequate implementation/ Lack of adherence
- Implementation not started/in process/not applicable

Notes:

n1, n2(%): n1 is the number of responses shared by scoped companies and n2(%) is its proportion; n3 is the total number of responses.

*: In total 389 company responses were analyzed out of 600 possible responses, 211 were excluded due to lack of experience or blank in the relevant questions

** : In total 414 company responses were analyzed out of 600 possible responses, 186 were excluded due to lack of experience or blank in the relevant questions