



DAFTAR SINGKATAN YANG ADA DALAM UJI KLINIK

- ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (Dewan Internasional untuk Harmonisasi Persyaratan Teknis Penggunaan Farmasi bagi Manusia)
- FDA: Food and Drug Administration (Badan Pengawas Obat dan Makanan AS)
- EMA: European Medicines Agency (Badan Pengawas Obat Eropa)
- MHLW: Ministry of Health, Labour and Welfare (Kementerian Kesehatan, Tenaga Kerja, dan Sosial Jepang)
- PMDA: Pharmaceuticals and Medical Devices Agency (Badan Farmasi dan Alat Kesehatan Jepang)
- GXP: Good X Practice (Cara Praktik X yang Baik)
- GCP: (Clinical) Cara Uji Klinik yang Baik (CUKB)
- GLP: (Laboratory) Cara Praktik Laboratorium yang Baik
- GMP: (Manufacturing) Cara Pembuatan Obat yang Baik (CPOB)
- GPSP: (Post-marketing Study) Cara Studi Pasca Pemasaran yang Baik
- GVP: (Vigilance) Cara Pengawasan yang Baik
- GQP: (Quality) Cara Praktik Kualitas yang Baik
- GCLP: (Clinical Laboratory) Cara Praktik Laboratorium Klinis yang Baik

- CRO: Contract Research Organization (Organisasi Peneliti Kontrak)
- CRA: Clinical Research Associate (Staf Peneliti Klinis)
- CPL (PL): Clinical Project Leader (Pimpinan Proyek Klinis) (Pimpinan Proyek)
- PM: Project Manager (Manajer Proyek)
- HP: Hospital (Rumah Sakit)
- GP: General Practitioner (Dokter Umum)
- SMO: Site Management Organization (Organisasi Pengelola Uji Klinik)
- PI: Principal investigator (Peneliti Utama)
- SI: Sub-investigator (Peneliti Pembantu)
- CRC: Clinical Research Coordinator (Koordinator Peneliti Klinis)
- ARO: Academic Research Organization (Organisasi Peneliti Akademis)
- CSO: Contract Sales Organization (Organisasi Penjualan Kontrak)
- IRB: Institutional Review Board (Dewan Kaji Institusi - DKI)
- IM: Investigator's Meeting (Pertemuan Peneliti)
- FPI: First patient In (Pasien pertama uji klinik)
- FPFV: First Patient First Visit (Kunjungan pertama pasien pertama uji klinik)
- LPI: Last Patient In (Pasien terakhir uji klinik)
- LPLV: Last Patient Last Visit (Kunjungan terakhir pasien terakhir uji klinik)
- LPO: Last Patient Out (Pasien terakhir uji klinik keluar)

- PRT: Protocol
(Protokol Uji Klinik)
- CRFz: Case Report Form
(Formulir Laporan Kasus - FLK)
- ICF: Informed Consent Form
(Formulir Persetujuan Setelah Penjelasan)
- EDC: Electronic Data Capture
(Pengambilan Data Elektronik)
- IB: Investigator's Brochure
(Brosur Peneliti)
- SOP: Standard Operating Procedure
(Prosedur Operasional Baku - POB)
- SAP: Statistical analysis plan
(Rencana Analisis Statistik)
- CSR: Clinical Study Report
(Laporan Studi Klinis)
- RBM: Risk Based Monitoring
(Pemantauan Berbasis Risiko)
- SDV: Source Data Verification
(Verifikasi Data Sumber)
- CTN: Clinical Trial Notification
(Pemberitahuan Uji Klinik)
- QA: Quality Assurance
(Jaminan Mutu)
- QC: Quality Control
(Pengawasan Mutu)
- AE: Adverse Event
(Kejadian Tidak Diinginkan - KTD)
- SAE: Serious Adverse Event
(Kejadian Tidak Diinginkan Serius - KTDS)
- CTD: Common Technical Document
(Dokumen Teknis Umum)

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Contact: Remedy & Company Corporation

Address: TOKYO TORCH Tokiwabashi Tower 23F 2-6-4, Otemachi, Chiyoda-ku, Tokyo, 100-0004 Japan

T: +81 3-5299-7011 F: +81 3-5299-7021

E: info@intellim.co.jp