Bold Insight

Market-by-market guide to conducting HFE studies in China, Japan, and Korea

A practical reference for medical device and combination product teams.

Recruiting lead times

Participant type	CHINA	JAPAN	KOREA
Clinicians (general)	4–6 weeks; one-on-one sessions are more feasible than group sessions, as coordinating HCP leave at a specific time is difficult	2–4 weeks; longer if additional requirements apply (e.g., number of patients treated, years of experience)	3-5 weeks
Specialist HCPs (e.g., interventional cardiology)	6–8 weeks; identify named alternates at contracting time	4+ weeks; longer if additional requirements apply (e.g., number of patients treated, years of experience)	4–6 weeks via hospital usability center networks; identify named alternates at contracting time
Patients / caregivers (general)	3–5 weeks; recruitment relies heavily on personal networks and hospital connections, not just third-party recruiting firms; plan caregiver participation into session logistics and consent from the start	4–6 weeks; allow time for consent translation and back-translation	3–4 weeks with strong incidence screening; recruitment relies heavily on passive methods (hospital bulletin boards, posters); finalization can be slower than expected
Rare disease patients	Plan for 6–8+ weeks; Multiple recruiting channels are needed (doctor networks, social media, patient chat groups)	6+ weeks	High difficulty; plan early and consider patient associations as a channel
No-show buffer	10–20%; evening sessions carry highest risk	10–20%; build extra breaks between sessions	10–15%; daytime slots more reliable

Facility lead times

Facility type	CHINA	JAPAN	KOREA
Commercial usability lab	2–3 weeks	4–6 weeks (major hubs)	2–3 weeks
Hospital simulation suite / OR/ICU mock-up	3–6 weeks; gated by department head calendars and equipment availability. Simulated hospital facilities are typically customized per study. Renting space directly from hospitals or teaching hospitals is extremely challenging and can be very expensive	8+ weeks; internal review processes add significant lead time; hospitals typically do not accommodate external research, so conference room settings are common	3–5 weeks via hospital usability center network; centers are hospital-affiliated and well-suited for HCP recruiting
Home-use simulation	Pre-visit safety checks and post-visit device inventories required; validate connectivity on local networks before pilot day	Scripted moderator safety protocols required; post-visit device inventory essential; explicit consent required for any media use beyond the study	Feasible; Korean-language scripts and materials required; high fidelity to actual use environment (lighting, noise, distractions) is more important than facility certification

In-country validation requirements

Participant type	CHINA	JAPAN	KOREA
In-country validation required?	Depends on use-risk level. High use-risk devices require a China-foreign UE difference analysis (covering users, use scenarios, and regulatory requirements). If differences are acceptable, foreign summative data plus a global post-market analysis and difference analysis report may be sufficient without in-China testing. If differences are unacceptable, in-China re-confirmation (targeted or complete) is required. Medium and low use-risk devices do not require in-China summative testing; a use error assessment report plus foreign UE materials is sufficient.	Not mandatory, but additional in-country studies may be required for patient-facing software as a medical device (SaMD), devices where display results directly impact diagnostic or treatment decisions, or cases where Japanese-language UI poses misinterpretation risk	Not mandatory; data compliant with IEC 62366-1 is accepted| for Korean submission, provided it demonstrates representativeness of the Korean intended user profile and use environment
Regulatory anchor	China references IEC 62366-1:2015+A1:2020 as an international standard; YY/T 1474-2016 is the Chinese industry standard equivalent. Not a direct adoption of IEC 62366-1, but a parallel regulatory guidance aligned with its principles. Final national HFE/UE guidance issued March 19, 2024.	JIS T 62366-1:2022; compliance required for device approvals as of April 1, 2024; phased in by class (now fully implemented)	KS IEC 62366-1 (national mirror of ISO/IEC 62366-1); usability engineering mandatory for all device classes since July 1, 2022
Overseas data accepted?	Case-by-case; China-foreign UE difference analysis required for high use-risk devices. Two alternative pathways: (1) equivalent device comparison, where mature products may use a comparison evaluation against an already China-registered equivalent device instead of summative testing; (2) clinical trials can serve as supporting data but generally cannot substitute for summative testing	Yes, with two explicit justifications: (1) equivalence of use context, and (2) localization risk assessment confirming Japanese-language UI elements do not introduce new use errors	Yes; manufacturer must demonstrate representativeness of intended user profile and use environment for the Korean market
Device scope	Applies to Class II and III devices; IVDs are explicitly excluded; Class I may voluntarily follow. Devices are categorized by use-risk level: • High use-risk: use errors may cause serious injury or death; critical tasks present; requires full UE Research Report (10 sections) plus summative testing. • Medium use-risk: use errors may cause minor injury; no critical tasks; requires Use Error Assessment Report (6 sections). • Low use-risk: use errors unlikely to cause injury; requires Use Error Assessment Report (6 sections). Use-risk level is determined through risk analysis or post-market data of similar devices; the companion Application Notes also prescribe a trial catalog of 19 high use-risk device types (all Class III) that require a full UE Research Report	Class I: summative not mandatory except for SaMD and consumer-use products; Classes II, III, IV: summative generally required; PMDA reviews scenario selection rationale and residual risk acceptability for Class III and IV	Generally mandatory for all new devices (Class 1–4) focusing on the severity of harm and probability of occurrence; however, exceptions apply for legacy devices (UOUP) and minor design modifications that do not increase use-related risks.
Regulatory body notes	Guidance is principle-based with no worked examples or product-specific walkthroughs. Early dialogue with CMDE (Center for Medical Device Evaluation) is advisable for first-time submissions.	PMDA offers no published case studies; Japan is strict about publicizing data; no official templates exist	MFDS actively publishes guidance and practice-based materials; policy goal is to enable manufacturers to conduct HFE/UE independently; MFDS considers FDA practice closely, so referencing FDA MAUDE database findings in submissions is advisable

Ethics and documentation

Requirement	CHINA	JAPAN	KOREA
IRB / ethics review	NMPA UE guidance is silent on IRB. Under broader Chinese regulations, IRB is required if the study qualifies as "biomedical research involving humans". Studies limited to product use experience and operational feedback may be classified as market research and not require IRB. Clarify with regulatory counsel case-by-case.	Summative: IRB recommended (data supports regulatory submission); Formative: risk-based; may not be required for low-risk studies not involving vulnerable populations. External ethics review boards are applicable.	IRB is not administratively mandated (treated as non-clinical testing); even in hospital-affiliated centers, IRB approval is commonly advised as not required; confirm approach with facility at contracting time
Minimum sample size	Summative: 15+ per user group (15 = ~90% error detection; 20 = ~95%; 30 = ~97%); Formative: 5–8 per user group; multiple rounds permitted.	No fixed minimum, however, it's recommended to follow the n=15 guideline if the product is expected to be marketed globally; PMDA evaluates representativeness of intended users, coverage of hazard-related use scenarios, and rationale for sample size	Summative: minimum 15 participants per user group recommended; Formative: typically 5–8 participants per user group
Evaluation scope	Summative covers critical tasks only (use errors that could cause serious injury or death). Field testing may omit certain critical tasks for safety; omissions and supplementary plans must be documented.	Scope limited to hazard-related use scenarios; critical tasks must be identified through risk analysis	Covers hazard-related use scenarios and critical tasks directly related to user safety; does not require evaluation of all user tasks
Document localization	Full localization required beyond translation: units, symbols, dosage formats, IFUs. Color and symbol meanings can differ significantly or be opposite in meaning; address during localization risk assessment, not just pilot.	Translation and back-translation of consent and moderator guides required; pilot session essential to confirm clarity before summative	Korean-first documents, not English-with-notes; check symbol comprehension and color conventions during pilot
Traceability	Trace from use-risk management through formative findings, risk controls, and summative critical-task list. The guidance requires a UI traceability analysis report covering relationships between UI requirements, design, verification & confirmation, and risk management.	Same trace required; clause-by-clause traceability to JIS T 62366-1 expected	Same trace; for bridging rationales, explicitly compare user profiles, environments, and labeling differences; confirm alignment with the User Specification submitted for Korean approval

QUICK TIPS

Korea

Recruitment relies heavily on passive methods (bulletin boards, posters) even within hospital settings. Finalization can be slower than expected; build in contingency time.

Japan

Research participation is less culturally normalized in Japan than in Western countries. Physician panels are relatively well established, making HCP recruitment faster than patient recruitment, which relies on personal referrals and typically requires longer lead times.

Cross market

- For rare specialist roles, identify named alternates at contracting time.
- Import logistics for batteries and controlled components can add 1–3 weeks. Ship a fully functional technical setup early and validate connectivity on local networks before pilot day.

China

- Frequent usability study participants should be excluded in principle; if included, document the rationale.
- Design and development staff cannot serve as participants or evaluators; third-party testing excludes manufacturer and affiliated employees; evaluators must have UE experience
- Significant variation exists within China; Tier 1 coastal cities and Tier 3/4 cities differ meaningfully in technology familiarity, health literacy, and communication styles; user group composition should account for this, particularly for devices intended for broad domestic distribution.

Cultural and moderation considerations

Consideration	CHINA	JAPAN	KOREA
Session structure	Private 1:1 required for summative; group formats are unreliable due to collectivism and "save face" dynamics; moderators must normalize error discovery and use neutral probes.	Private 1:1 preferred; build rapport before task-based work; use task-based probes ("walk me through what you expected here"); avoid leading questions; HCPs may hesitate to criticize devices used at their own institutions	Generally candid in 1:1 settings; in mixed-seniority group debriefs, assign speaking turns and use anonymous polling to prevent hierarchy effects
Participant mindset	"Face" (面子) culture is a direct data validity risk: participants may avoid acknowledging errors. NMPA guidance explicitly flags this and requires neutral interview techniques, open-ended questions, and framing errors as design problems, not user failings.	Frame errors as learning opportunities; reassure confidentiality and non-attribution of feedback; research participation is less culturally normalized than in Western countries, which can affect both recruiting and engagement	Korean HCPs self-correct quickly; moderators must capture near-misses in real time before this happens. Lay users may deny use errors; opening framing must establish that the study evaluates the product, not the participant.
Older adult participants (50+)	Participants may share more openly with a caregiver present; gather joint context (history, routines) before private task-based performance to avoid inadvertent coaching	Keep sessions to 90 minutes or less; confirm format accommodates mobility or cognitive needs.	Confirm appropriate language register; older participants may prefer formal Korean in consent forms and scripts
Hard-to-reach populations	Low-prevalence condition patients and required caregiver participants extend timelines most	Rare disease and intractable disease specialists, KOL-level physicians, large hospital directors, Stage 3+ cancer patients, patients with poor prognosis, mental illness	Dental disease participants are difficult to recruit; gender-specific conditions and pediatric populations require a particularly careful and sensitive approach
Interpretation and recording	Simultaneous interpretation is standard; budget for interpreter and observation room tech; pre-align on how to handle real-time translation of task errors	Recording patient faces is sensitive; obscure identifiers during playback and obtain explicit consent for any media use beyond the study; pre-align on interpretation protocol	In-language moderation strongly preferred; Korean-first materials, not translated English
Scheduling norms	HCPs favor weekday evenings and weekends. Emergency physicians' availability depends on shift scheduling.	HCP sessions commonly after clinic hours (evenings) or on weekends	Clinicians favor early evenings; lay users generally available during standard business hours; residents and nurses can be recruited for coordinated daytime slots

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Conduct of Human Factors Evaluations in Asia: Considerations From Local Experts - China, Japan, South Korea

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Trusted, long-term collaboration

Bold Insight brings human factors engineering and medical device research expertise to every study, with a track record supporting regulatory submissions and iterative design validation across the product development lifecycle. For studies in China, Japan, and South Korea, we leverage long-standing local partnerships, including our sister companies, Uism and XplusX, in **ReSight Global** and Hankook Research, through the **UXalliance**, an organization that we helped found 20 years ago. These aren't transactional vendor relationships. They are embedded, quality-aligned partnerships built over years of global fieldwork and mutually beneficial training. The result: consistent data collection, culturally informed moderation, and reliable in-country execution, with no nuance lost in translation.

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