PERSPECTIVES

Integrating ICH Good Clinical Practice (GCP) Principles and Essential Documentation into Dermatology Residency Education in China

Xiaoxia Ding[1], Peijiao Wang[2], Xiaohua Tao[1], Yi Tang [ID][1]

[1]Center for Plastic & Reconstructive Surgery, Department of Dermatology, Zhejiang Provincial People's Hospital (Affiliated People's Hospital), Hangzhou Medical College, Hangzhou, Zhejiang, People's Republic of China; [2]Chinese Medicine Hospital of Tiantai County, Taizhou, People's Republic of China

Correspondence: Yi Tang; Xiaohua Tao, Center for Plastic & Reconstructive Surgery, Department of Dermatology, Zhejiang Provincial People's Hospital, Hangzhou, Zhejiang, People's Republic of China, Email tangyi@hmc.edu.cn; taoxiaohua@hmc.edu.cn

Abstract: Integrating International Council for Harmonisation Good Clinical Practice (ICH GCP) principles, including essential documentation and ethical standards, into medical education is crucial for building clinical trial capabilities and advancing research literacy. However, dermatology residency programs in China currently lack a formal framework for incorporating these principles. This perspective article proposes a three-module curriculum tailored to address this gap and align Chinese dermatology residency education with international standards. The first module, Foundational Clinical Research Knowledge, introduced in the second year of residency, covers key GCP principles, such as the roles and responsibilities of IRB/IEC, investigators, and sponsors, as well as the significance of essential documents like clinical protocols and investigator brochures. The second module, Dermatology Subspecialty Training with GCP Principles, conducted in the third year, emphasizes advanced trial design, protocol amendments, and investigator responsibilities. The third module, Communication and Ethics Training, spans both years, focusing on interdisciplinary collaboration, IRB/IEC responsibilities, and ethical decision-making. The curriculum incorporates stepwise learning, hands-on exercises, and regular assessments while addressing practical barriers such as resource and cost limitations through faculty-supported programs. By fostering critical thinking and interdisciplinary communication, this model aims to equip residents with the skills to lead ethically sound, patient-centered clinical trials, ultimately advancing evidence-based dermatology education and practice in China.

Keywords: good clinical practice (gcp) training, dermatology residency, medical education reform, ethics in clinical training, research literacy

Introduction

The residency training system in China, standardized in 2014, has played a pivotal role in unifying medical education and ensuring a consistent level of competence among physicians nationwide.[1,2] The dermatology residency pathway in China typically consists of three main stages: a 5-year undergraduate medical education (equivalent to MBBS), a 3-year standardized residency training program, and subsequent certification exams. During the standardized residency program, trainees are first exposed to general clinical practice through rotations across various departments, with dermatology-focused training often commencing in the latter half of the program. After completing the residency and passing a national certification exam, physicians may practice as certified dermatologists. However, further development of advanced clinical techniques and research competencies beyond initial certification is left largely to individual effort.[3,4]

While this centralized system has brought much-needed uniformity, several limitations uniquely impact dermatology training. First, specialized dermatology training in China starts relatively late compared to international systems, delaying the development of advanced subspecialty skills. Second, resource disparities between urban and rural training institutions exacerbate inequalities, as facilities in rural areas often lack experienced mentors, advanced equipment, and opportunities for research collaborations.[5] Third, the lack of structured integration of research and ethics training

Table I Comparison of Dermatology Residency Training Stages in China, the United States, and Europe (Germany Example)

Training Stage	China	United States	Europe (Germany Example)
Undergraduate Education	5 years undergraduate medical program (MBBS equivalent).	4 years undergraduate + 4 years medical school (MD).	6 years combined undergraduate and medical education.
Basic Clinical Rotations	3 years standardized residency program, includes general and some dermatology rotations.	1-year general clinical internship (preliminary year).	1-year general clinical rotations (PJ year).
Specialty Training	Begins during the later years (2–3 years) of residency, followed by certification.	3 years focused dermatology residency (clinical practice and research).	5 years dermatology residency (clinical + subspecialty training).
Research and Clinical Trial Training	Rarely integrated during residency; typically developed post-residency.	Integrated into residency, especially in academic institutions.	Varies by country; research often integrated into residency.
Certification and Career Development	Board certification achieved after national examination; continuing education not mandatory.	Certification through American Board of Dermatology (ABD); recertification required.	Certification through national exams; ongoing education encouraged.

poses a significant barrier to advancing evidence-based practice and participation in clinical trials. As shown in Table 1, the training stages differ significantly among countries, highlighting critical gaps in the Chinese residency system in terms of delayed specialization and limited research integration.[6,7]

Research literacy—the ability to understand, design, conduct, and critically evaluate clinical studies[8]—is a fundamental skill in modern dermatology. It enables dermatologists to engage in evidence-based decision-making, participate in therapeutic advancements, and contribute to clinical trials testing cutting-edge treatments. However, existing training systems in China lack a structured framework to develop research competency during residency, leaving many dermatologists inadequately prepared for such roles.

To address this deficiency, adopting internationally recognized guidelines such as Good Clinical Practice (GCP) can provide a robust foundation for research training in residency programs. GCP, established by the International Council for Harmonisation (ICH), outlines the ethical and scientific standards for clinical research. Its core principles include ensuring patient safety through IRB/IEC oversight, maintaining trial integrity through investigator and sponsor responsibilities, and establishing transparency with essential documents such as informed consent forms, clinical protocols, and investigator brochures.[9–11] Aligning residency training with these principles not only enhances research literacy but also prepares residents to contribute to the growing field of dermatology research, where clinical trials play a pivotal role in evaluating novel therapies and treatments.

The limitations of China's dermatology residency training system, as analyzed above, highlight an urgent need for systematic reform. Addressing these gaps is essential to align the curriculum with international standards and to equip future dermatologists with the skills necessary to meet the comprehensive needs of their patients. In the following sections, a proposed curriculum framework will be introduced, incorporating GCP principles to bolster research literacy and improve the overall quality of dermatology residency training in China.

Curriculum Framework and Implementation Strategy
Overall Objectives

The current dermatology residency training system in China lacks a structured framework for integrating Good Clinical Practice (GCP) principles and ethics education, leading to limited research participation and ethical awareness among residents.[12] To address this gap, the proposed curriculum systematically incorporates GCP standards and ethics training, equipping residents with the skills necessary to conduct high-quality clinical research and uphold ethical standards in

medical practice. By aligning with international best practices while addressing the unique challenges of the Chinese healthcare system, such as clinical trial quality issues and gaps in research training frameworks,[13] this curriculum aims to bridge gaps in research literacy and ethical training within dermatology residency programs. It ultimately fosters a new generation of dermatologists capable of contributing to global clinical research.[14]

Theoretical Basis for Curriculum Design

The curriculum integrates international best practices with the practical needs of China, establishing its theoretical foundation through three key aspects. First, it draws on internationally recognized models, including the ACGME residency training framework in the United States, which emphasizes competency-based education and continuous assessment, the United Kingdom's NHS training modules that prioritize interprofessional collaboration and patient-centered care,[15] and the ICH-GCP guidelines, which provide ethical and quality standards for clinical trials.[16] Second, it addresses critical challenges within the Chinese context, such as urban-rural resource disparities, limited access to experienced mentors in rural areas, and the lack of structured research training programs.[17] These challenges underscore the urgent need for a standardized curriculum that can be adapted to diverse healthcare settings across the country. Finally, the curriculum is supported by existing evidence, with international studies demonstrating the benefits of integrating GCP principles into medical education[18] and showing statistically significant improvements in knowledge and awareness of clinical research.[19] Such evidence highlights the necessity and feasibility of this curriculum within the Chinese dermatology residency context, ensuring its relevance and potential impact on improving clinical research practices and ethical standards.

Module Design

The curriculum is divided into three interconnected modules, each building upon the previous one to ensure a progressive development of skills and knowledge. The phased implementation schedule is illustrated in Figure 1. The design also integrates the principles of Good Clinical Practice (GCP) by focusing on the roles and responsibilities of key stakeholders (IRB/IEC, sponsors, and investigators) and providing hands-on training with practical tools and examples.
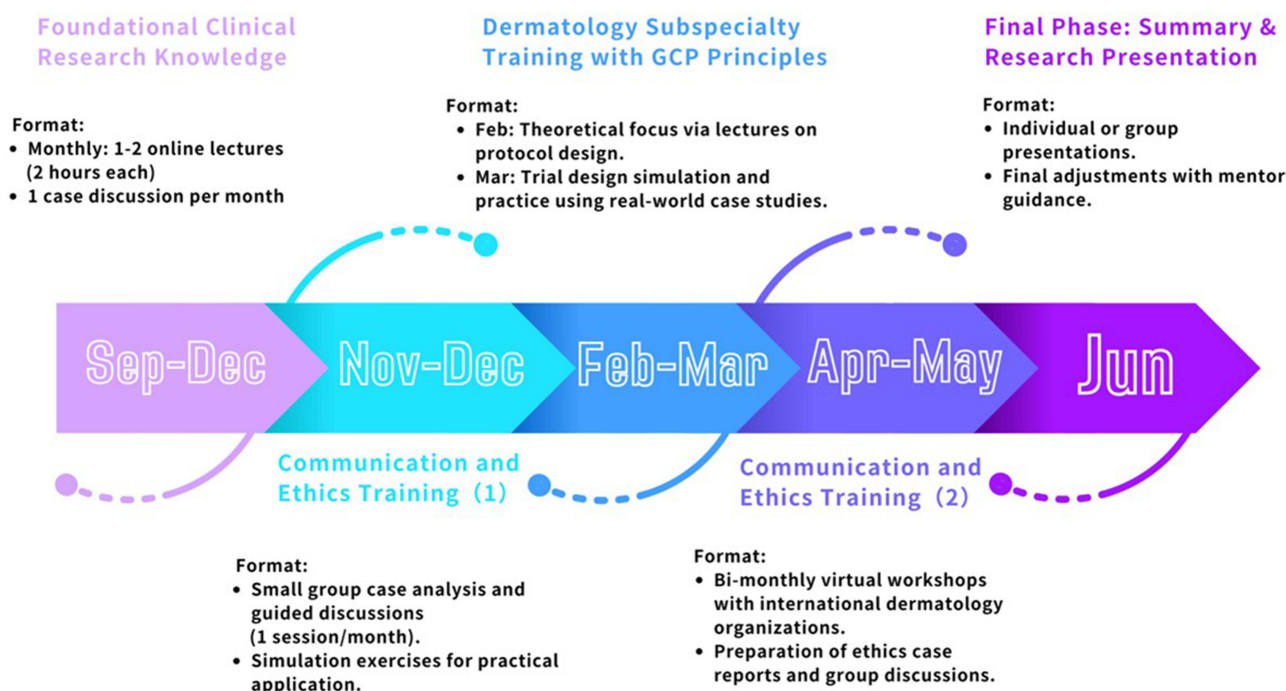
Figure 1 Scheduled Timeline of Training Modules for Dermatology Residents in the GCP Program.

Module 1: Foundational Clinical Research Knowledge (Second Year)

This module is designed to introduce residents in their second year of dermatology specialization to the core principles of GCP and essential clinical research skills. The focus is on understanding the roles and responsibilities of IRB/IEC, investigators, and sponsors, as well as the importance of essential documents like clinical protocols and investigator brochures. Key topics include the fundamental principles of ICH-GCP, covering informed consent, patient privacy protection, and accurate data recording. Training also explores the development and management of essential documents, using real-world ethical conflict cases from dermatology clinical trials to encourage practical application of learned concepts. Delivered between September and December, the module combines lectures, case studies, and interactive workshops. To enhance accessibility, especially for residents in rural or resource-constrained regions, online resources such as IRB application templates and video tutorials are provided.

Module 2: Dermatology Subspecialty Training with GCP Principles (Third Year)

Conducted in the third year during advanced dermatology training and subspecialty focus, this module builds on foundational knowledge by emphasizing advanced trial design, protocol amendments, and investigator responsibilities. Residents engage with topics like innovative approaches to dermatology-specific trials, the ethical and regulatory implications of protocol amendments, and the role of investigators in multicenter studies, particularly concerning data integrity and subject safety. Practical sessions include drafting mock clinical trial protocols, using electronic data capture (EDC) systems, and participating in simulated trial scenarios. To make the learning experience dermatology-specific, residents are tasked with designing a clinical trial protocol for a new treatment for psoriasis under GCP guidelines, with peer review and faculty feedback provided to reinforce technical and collaborative research skills.

Module 3: Communication and Ethics Training (Second and Third Year)

Spanning both the second and third years of residency, this module aims to strengthen communication skills, ethical decision-making, and interdisciplinary collaboration, particularly within the context of international research projects. Residents explore topics such as effective communication with patients, research teams, and ethics committees; ethical decision-making in complex clinical scenarios (eg, obtaining informed consent from vulnerable populations); and interdisciplinary collaboration through virtual seminars and multicenter research projects. To incorporate international exposure, residents participate in virtual seminars hosted by the International Society of Dermatology (ISD) and collaborate on mock multicenter trials. The module also includes mentorship opportunities with experienced researchers, participation in ongoing clinical studies, and guidance on preparing research manuscripts for submission to peer-reviewed journals. Interactive workshops and virtual collaboration tools simulate real-world interdisciplinary interactions, providing further practical preparation for career advancements.

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Justification for Module Distribution

The distribution of modules across the residency program is carefully designed to align with the residents' clinical responsibilities and academic calendar, ensuring optimal learning outcomes without disrupting their clinical training.

First Year: Residents primarily rotate in other departments (eg, internal medicine, surgery), providing limited exposure to dermatology-specific training. As such, GCP and research modules are deferred to the second and third years when residents are more focused on dermatology.

Second Year: Residents typically begin their dermatology rotations in September, making it an appropriate starting point for foundational GCP and ethics training. This ensures residents develop a solid understanding of the principles and guidelines necessary for conducting clinical research before engaging in advanced activities. Module 1 is introduced during this year to establish a strong foundation in clinical research.

Third Year: During the final year, residents focus on advanced training and subspecialties, providing an ideal opportunity to integrate skills in clinical trial design, implementation, and research competency development. Considering that some clinical master's students complete their residency training by the end of June, the curriculum's final phase, including the summary and presentation of research projects, is scheduled to conclude by June. This adjustment ensures that all participants complete the program in alignment with their residency timelines while gaining practical experience in clinical trial management.

Implementation Strategy

The implementation strategy for this curriculum focuses on addressing urban-rural disparities, enhancing mentorship, and ensuring continuous evaluation and improvement. To ensure accessibility in resource-constrained areas, the curriculum will leverage online platforms for content delivery, allowing dermatology residents in rural settings to access high-quality training materials. Additionally, mentorship networks will be established by connecting experienced dermatologists from urban centers with rural residents through virtual sessions and periodic on-site visits. Residents' progress will be assessed through a combination of written exams, practical exercises, and participation in clinical research projects, ensuring comprehensive evaluation of their skills and knowledge. Feedback from both residents and faculty will be collected annually to refine the curriculum and address emerging needs, fostering a process of continuous improvement.

Implementation Barriers and Solutions

Potential Barriers

Resource and Cost Constraints

Implementing a structured GCP curriculum requires significant institutional resources, including trained faculty, access to clinical research materials, and technological infrastructure for online learning. These requirements pose challenges, particularly in rural areas where research infrastructure and funding are limited.[20,21]

Time Allocation in Residency Schedules

Dermatology residents in China face demanding clinical schedules, leaving limited time to engage in structured educational activities beyond their primary responsibilities. The integration of additional training modules into their already packed schedules may lead to resistance or reduced participation, especially if the perceived workload is too high.

Variability Across Institutions

Significant variability exists across institutions, with urban teaching hospitals often equipped with advanced research capabilities, while rural hospitals lack basic infrastructure and faculty expertise. This disparity creates unequal opportunities for hands-on research training.

Proposed Solutions

To address these challenges, the curriculum will adopt flexible, hybrid learning models. **Foundational topics**, such as GCP principles and research ethics, will be delivered via asynchronous online modules, allowing residents to learn at their own pace without disrupting their clinical duties. **Practical components**, including trial simulations and ethical dilemma scenarios, will be conducted during designated research rotations or weekend workshops to maximize participation. To mitigate resource disparities, a **national online platform** supported by government and academic institutions will be established, offering standardized GCP training content accessible to all residency programs regardless of location.

Faculty development programs will also be prioritized to ensure high-quality instruction. **Train-the-trainer workshops** will be conducted by certified GCP educators to prepare local faculty for delivering the curriculum. Additionally, **international partnerships**, such as collaborations with the International Society of Dermatology (ISD), will provide global best practices and mentorship opportunities, further enhancing the quality of instruction.

Pilot Testing and Iterative Refinement

Finally, a pilot program will be launched at select teaching hospitals to assess the curriculum's feasibility and effectiveness. Key metrics, such as resident participation rates, research output, and faculty feedback, will be collected to guide iterative improvements before scaling the program for nationwide implementation. This iterative approach ensures that the curriculum remains adaptable and responsive to the diverse needs of dermatology residency programs across China.

Discussion

The proposed structured GCP curriculum addresses critical gaps in China's dermatology residency training, particularly in the areas of research literacy, ethics, and clinical trial competencies.[22] By introducing a modular, phase-based framework, the curriculum ensures that residents are gradually immersed in Good Clinical Practice (GCP) principles, from foundational knowledge in Year 2 to hands-on application in Year 3.[16] This progressive approach respects the intense clinical demands of residency while equipping trainees with the competencies needed to participate in and manage ethical and high-quality clinical trials. As China continues to expand its contributions to global medical research, integrating GCP training into its residency programs is both timely and essential for aligning residents' competencies with international standards. One of the main challenges in implementing this curriculum relates to the diversity of institutional capacities across China. Resource disparities between hospitals, particularly between urban academic centers and regional medical institutions, present difficulties in standardizing access to research training. Many regional hospitals face limited clinical research infrastructure and lack faculty trained in GCP principles.[23] Additionally, the immersive nature of clinical duties in residency programs poses a significant obstacle to dedicating time specifically for structured GCP training. Residents may perceive such training modules as extraneous unless they are seamlessly integrated into their career development pathways and are explicitly aligned with the requirements of institutional and national certification systems.

To address these barriers, the hybrid delivery model proposed in the curriculum offers a practical solution. By leveraging online platforms for knowledge-based components, such as ethics and research processes, the model ensures that foundational training is accessible to all residents, regardless of institutional resources.[24] Practical components, such as trial simulations and essential document management, can then be conducted during specialized workshops or research rotations.[25] This approach not only minimizes the burden on residents' schedules but also allows smaller institutions to

collaborate with larger, resource-rich hospitals for practical training opportunities. Furthermore, partnerships with international organizations and Contract Research Organizations (CROs) can provide additional avenues for resource-sharing and hands-on learning experiences, thereby bridging the gap for under-resourced districts.[26]

Globally, GCP training has been successfully implemented in residency programs through similar strategies. In the United States, online modules developed by the National Institutes of Health (NIH) have allowed for the standardized delivery of key GCP content, alleviating time constraints on busy medical trainees (https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/good-clinical-practice-training). Meanwhile, Europe's centralized digital platforms ensure uniform access to high-quality materials, promoting consistency across member states.[27] India, which faces resource disparities similar to China, has partnered with CROs to provide practical training opportunities at no additional institutional cost.[28] These examples highlight the feasibility of implementing scalable and adaptable GCP frameworks, even in resource-constrained settings, and provide valuable models for China's dermatology residency programs.

While these international examples offer insights, this curriculum strongly emphasizes alignment with China's unique healthcare system and institutional realities. Specific mechanisms, such as integrating GCP training into nationally mandated residency standards and providing faculty development programs, ensure that the framework is tailored to local needs.[29] Pilot testing in tertiary academic institutions, followed by expansion to regional hospitals, would also provide an opportunity to refine the curriculum based on implementation feedback.[30] Ultimately, these strategies would help ensure scalability and long-term sustainability, which are critical for maintaining program integrity and widespread adoption.[31]

Despite its numerous advantages, the proposed curriculum is not without limitations. Institutional readiness to adopt and adapt to new training requirements remains a concern, particularly in smaller hospitals with limited budgets.[32,33] Furthermore, achieving widespread acceptance among residents and faculty may require a cultural shift in how medical education prioritizes research training.[34,35] Overcoming initial resistance will necessitate raising awareness of the practical and professional benefits of GCP training, including enhanced career prospects and improved competency in clinical research. Longitudinal evaluations of program outcomes could further build trust and demonstrate the curriculum's value to stakeholders.

In conclusion, this curriculum represents a progressive step toward addressing the pressing need for research competency within dermatology residency programs in China. By integrating international best practices with a tailored, modular approach, it aligns with the unique realities of China's healthcare system. While challenges such as resource allocation, institutional variability, and gaining program acceptance remain, these barriers can be overcome through targeted strategies like hybrid delivery models, resource-sharing partnerships, and phased implementation. If effectively adopted, this framework has the potential to enhance the ethical and professional competencies of dermatology residents, fostering their ability to contribute to biomedical research and strengthening China's role in global clinical trials.

Conclusion

The proposed GCP curriculum bridges critical gaps in China's dermatology residency programs by integrating global research ethics and practices within a structured, locally adaptable framework. With hybrid learning methods and phased implementation strategies, it effectively addresses variability in resources while promoting scalability. By fostering a new generation of clinician-researchers equipped with both ethical rigor and technical competence, this initiative supports not only the individual professional growth of residents but also China's capacity to produce high-quality, globally aligned clinical research. Ultimately, this program sets the stage for China to enhance its leadership in the international biomedical research community.

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Disclosure

The authors report no conflicts of interest in this work.

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