



Faculty of Pharmaceutical Medicine

*Advancing the science and practice of pharmaceutical medicine
for the benefit of the public*

Who's Ready? Making Entrustment Decisions in PMST



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We will start shortly

Please ...

- Mute yourself when not speaking
- Put questions in the chat
- Or raise a hand if you'd like to speak

Polling

- Polling is optional and anonymous
- Scan the QR code or use website details



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**What are
your
instincts
about trust?**



Meet Rich, he's doing PMST

PMST Capabilities in Practice (CiPs)

Specialty CiPs

CiP 1	Enables and supports patients' timely access to medicines appropriate for their clinical needs
CiP 2	Operates within ethical, regulatory and good practice frameworks
CiP 3	Participates in data generation, analysis and communication
CiP 4	Employs pharmacological and clinical data in the design, conduct, analysis and reporting of exploratory clinical trials for new medicines and devices
CiP 5	Conducts clinical research for the development of medical products
CiP 6	Engages in pharmacovigilance and risk-management systems to ensure patient safety and risk-minimisation
CiP 7	Provides up to date evaluations of the benefits and risks of medical products
CiP 8	Supports business decision-making and progression in medical product innovation and development

Generic CiPs

CiP 9	Upholds professional standards and the duties of the GMC's 'Good Medical Practice' and the Faculty of Pharmaceutical Medicine's 'Good Pharmaceutical Medicine Practice'
CiP 10	Works competently within pharmaceutical organisational and management systems
CiP 11	Remains up to date with research and best practices in pharmaceutical medicine, employs reflective practice and undertakes continuing professional development
CiP 12	Applies the principles and practices of leadership and multi-disciplinary teamworking, teaching and developing others
CiP 13	Engages in quality improvement activities , ensuring that ethical, regulatory, and professional business standards are maintained
CiP 14	Keeps the safety of patients and the reliability of evidence at the forefront of decision-making in the design of development programmes for new and marketed medicines

Developing capability in the specialty CiPs

1

Entrusted to observe only

2

Entrusted to act with direct supervision:

Has applied knowledge and understanding of skills required for capabilities and is able to act with them in practice under continuing supervision.

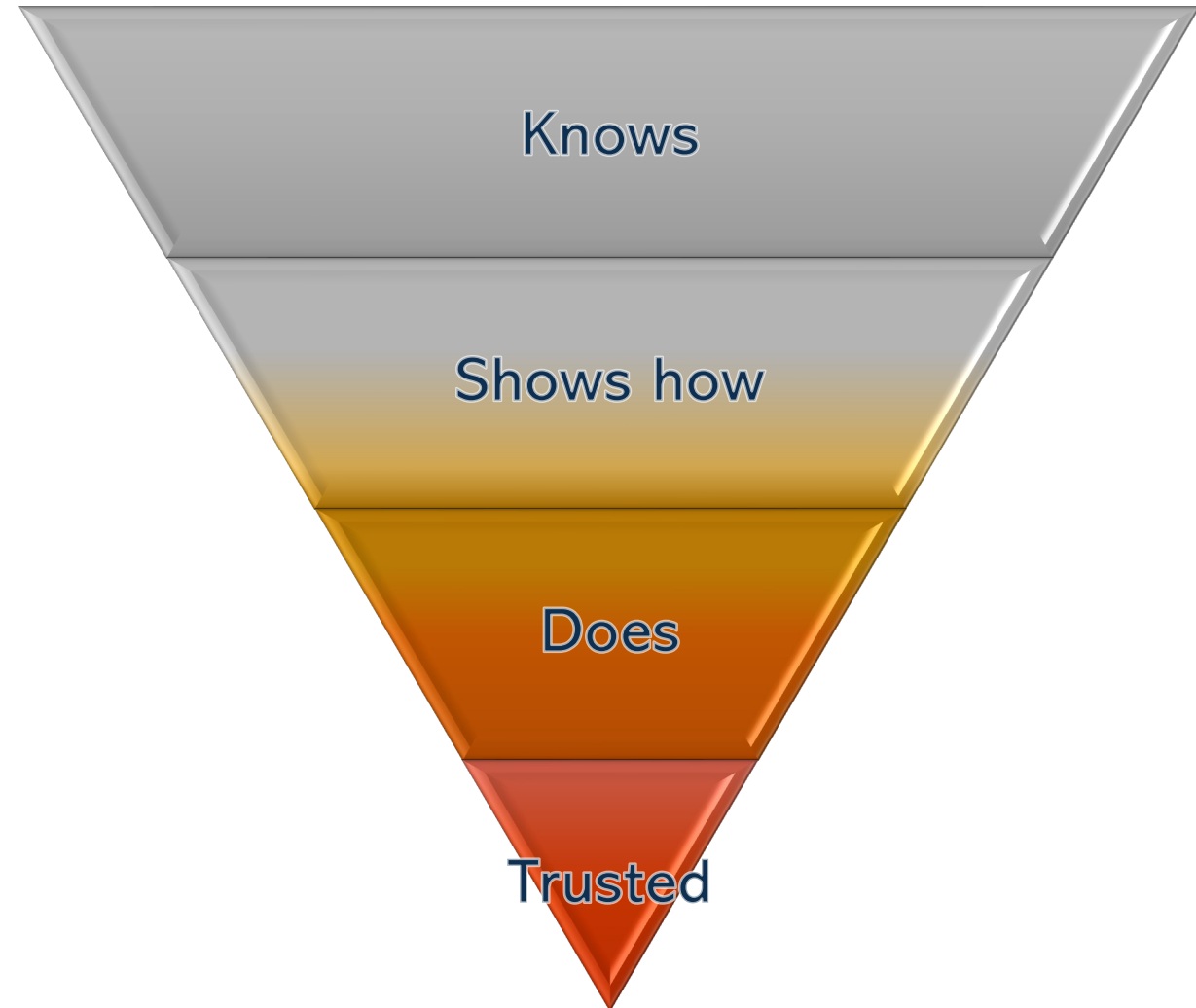
3

Entrusted to act with indirect supervision:

Applies knowledge and skills capably to undertake tasks and activities whilst remaining under continual supervision.

4

Entrusted to act unsupervised



Entrustment decisions

- Entrustment focused assessment is critically different from assessing performance
- Requires thinking ahead to what might happen in the near future, when there is no-one to observe, help or intervene
- Depends on
 - Trainee qualities
 - Trust propensity of supervisor
 - Activity to be completed
 - Contextual variables (case complexity, availability of help)
 - Acquaintance and relationship of supervisor and trainee

Trust





Rich works in clinical
development

CiP 5 Conducts clinical research for the development of medical products

Descriptors

- Contributes to the authorship/review of a Clinical Development Plan (CDP).
- Applies the principles of Good Clinical Practice (GCP), other relevant GxPs and regulatory requirements.
- Identifies, manages and mitigates risk in special populations.
- Contributes to the review and adaptation of study specific documents.
- Contributes to project management strategies.
- Utilises quality management systems for the conduct of clinical studies.
- Able to oversee the conduct of clinical studies.
- Able to interpret the results of clinical studies and contribute to authorship/review of Clinical Study Reports (CSR).



Rich is working on CiP 5

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Rich has been working on an ICF

How far does Rich's information support the entrustability assessment?

- Rich's portfolio contains
- Redacted ICF, with Rich's amends referring to the protocol, IB, readability scores and regulatory requirements
- Evidence of ethics approval
- PMAT conducted with the study director including
 - Ratings of behavioural characteristics, all 'meets expectations'
 - Rich's reflective commentary explaining his learning: how the activity has developed his understanding of the regulations, knowledge of the requirements for study documents, and need to ensure that participants are adequately informed
 - Director's confirmation that the ICF met requirements, the activity meets the relevant requirements of the CiPs and summary of what Rich had learned



Rich has been working on an ICF

Could we make a richer entrustment decision?

Trainee qualities identified from thematic analysis of 10 studies of clinical entrustment decisions

Five key features that clinicians find relevant when deciding to entrust learners

- Capability
- Integrity
- Reliability
- Humility
- Agency



- Ten Cate O, Chen HC. The ingredients of a rich entrustment decision. Medical teacher. 2020 Dec 1;42(12):1413-20.

Capability – relevant trainee features

Relevant knowledge and skill

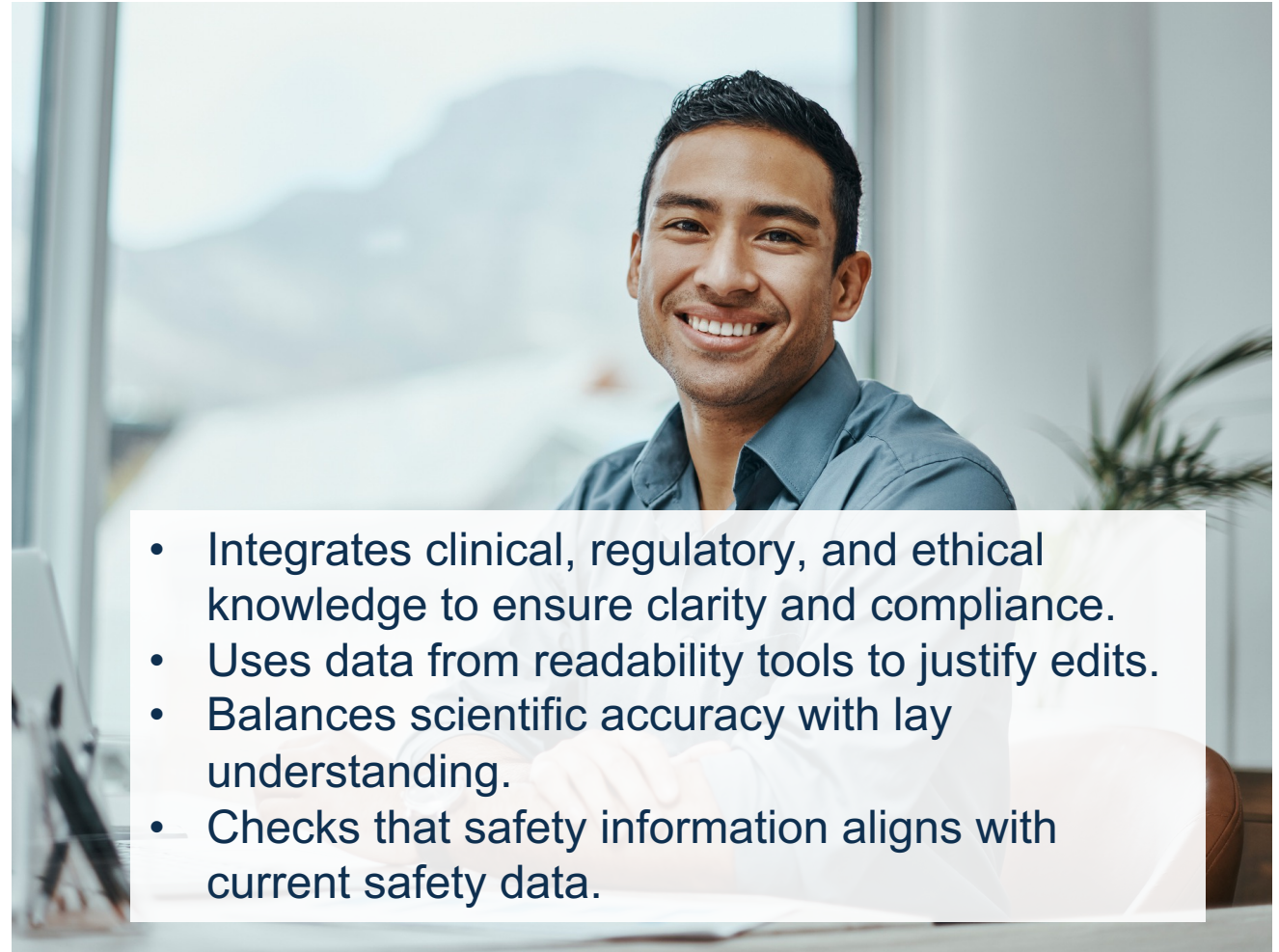
Demonstration of evidence based knowledge

Sound judgement / decision making

Situational awareness – insights into risks, adjusts to evolving circumstances

Organising / prioritizing

Interpersonal skills, collaboration, communication



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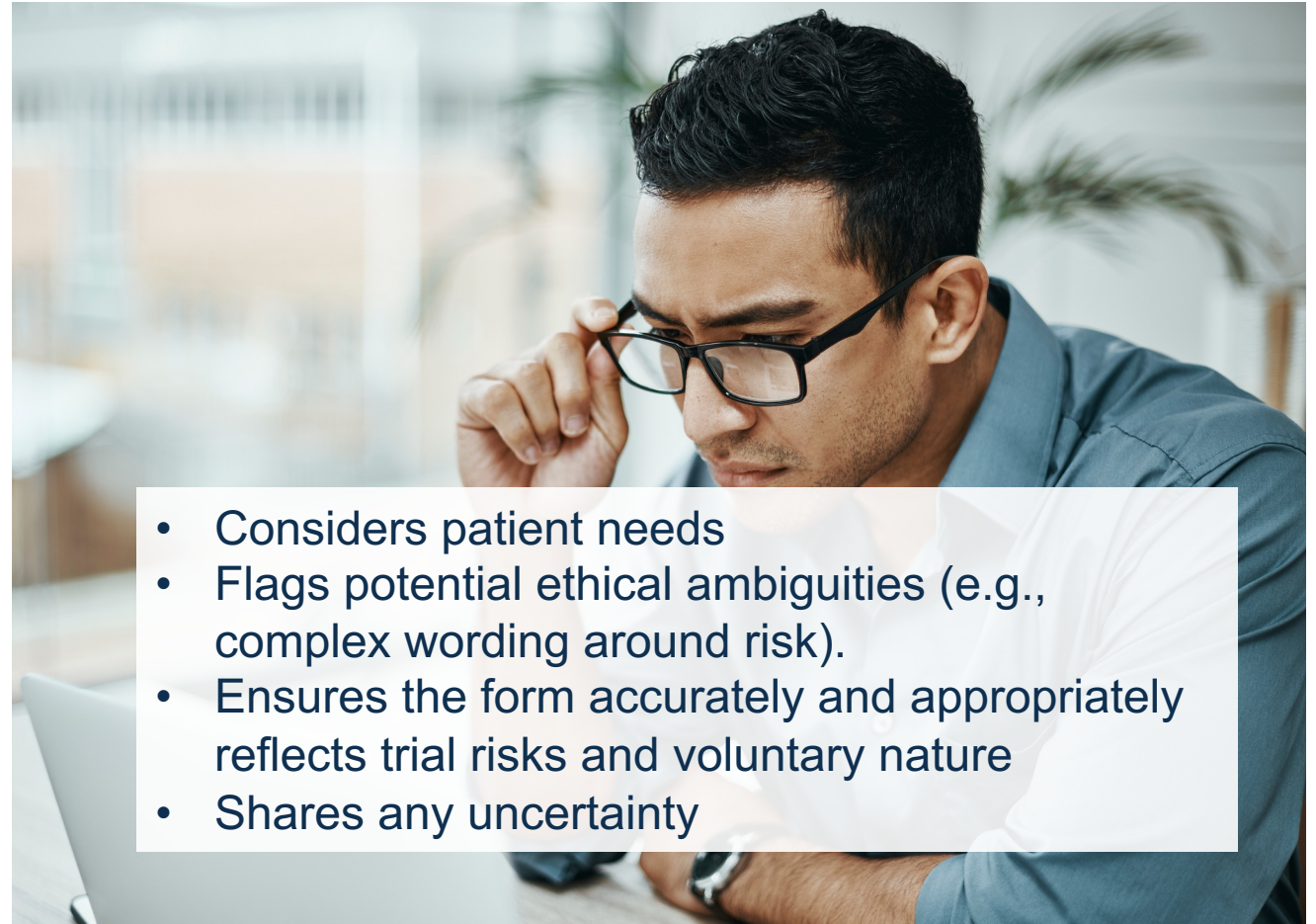
Integrity - relevant trainee features

Not withholding information, admitting errors and oversights

Prioritising patient needs

Being open and empathetic, attending to patient well-being

Holding oneself and colleagues accountable for patient welfare



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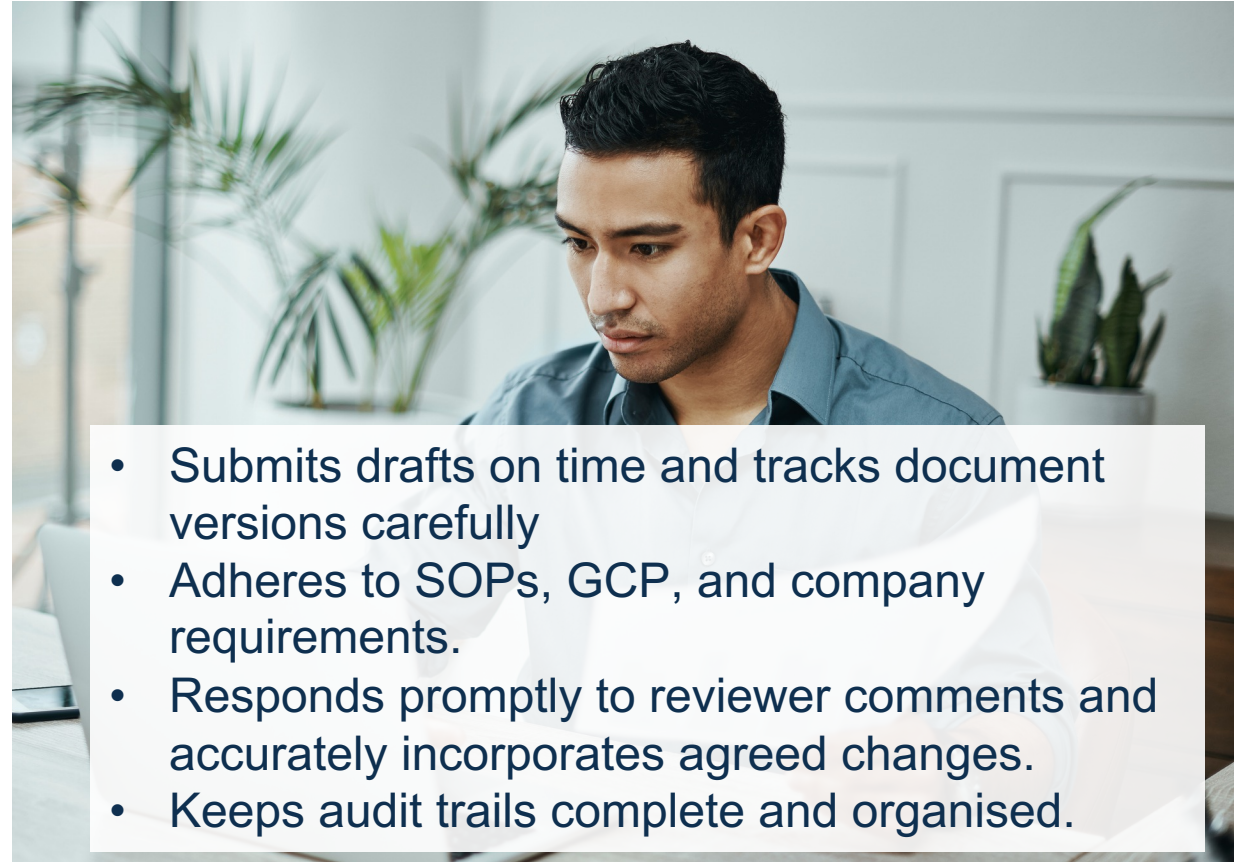
Reliability - relevant trainee features

Taking responsibility, accountable for tasks, doing fair share of team work

Following through on assigned tasks

Conscientious, thorough, attentive to detail, producing accurate information

Consistent, stable performance



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Humility - relevant trainee features

Knowing the limits of own knowledge and skill

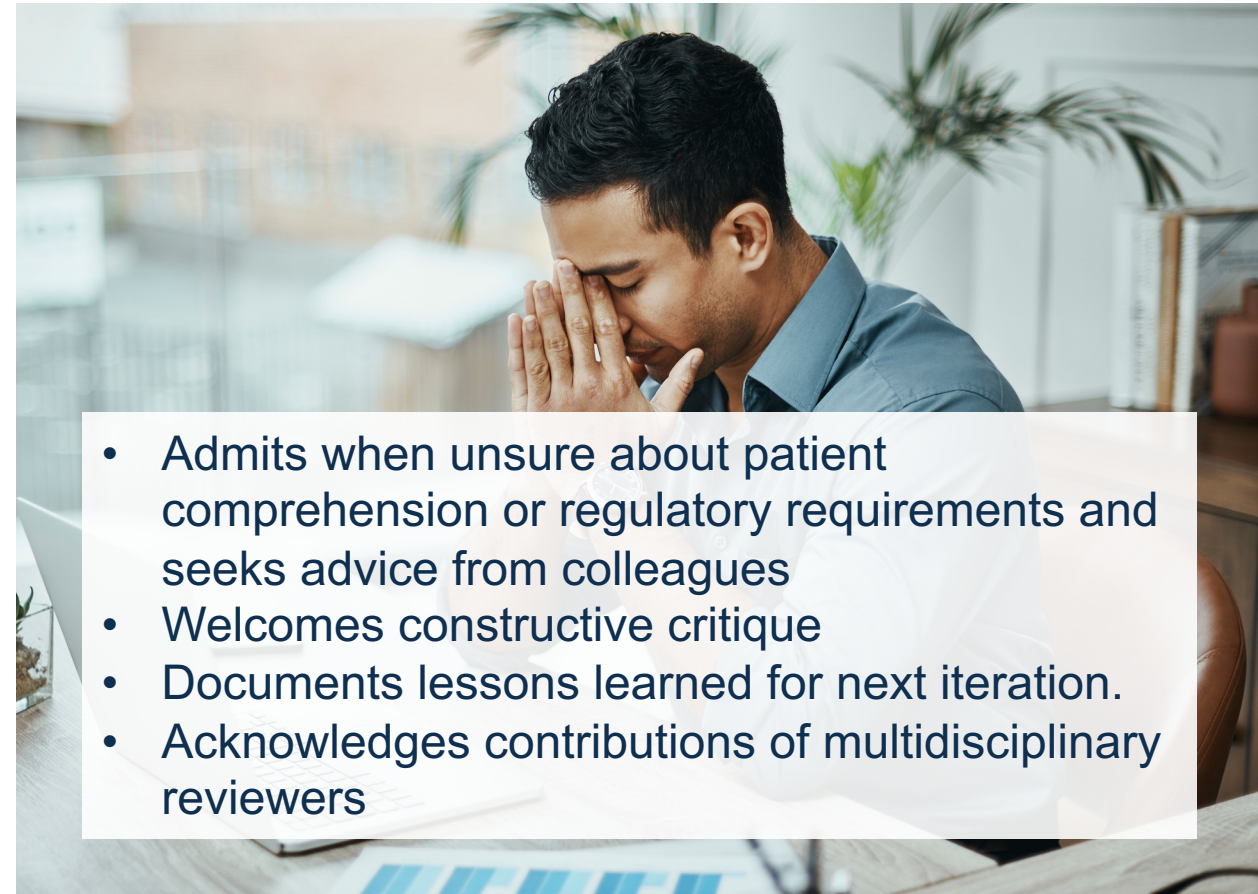
Knowing when to ask for help and being willing to do so

Self-awareness and self-assessment

Being receptive to feedback and learning from it

Accepting that uncertainty exists and one is fallible

Acknowledging that others including non-physicians may have expertise to impart



- Admits when unsure about patient comprehension or regulatory requirements and seeks advice from colleagues
- Welcomes constructive critique
- Documents lessons learned for next iteration.
- Acknowledges contributions of multidisciplinary reviewers

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Agency - relevant trainee features

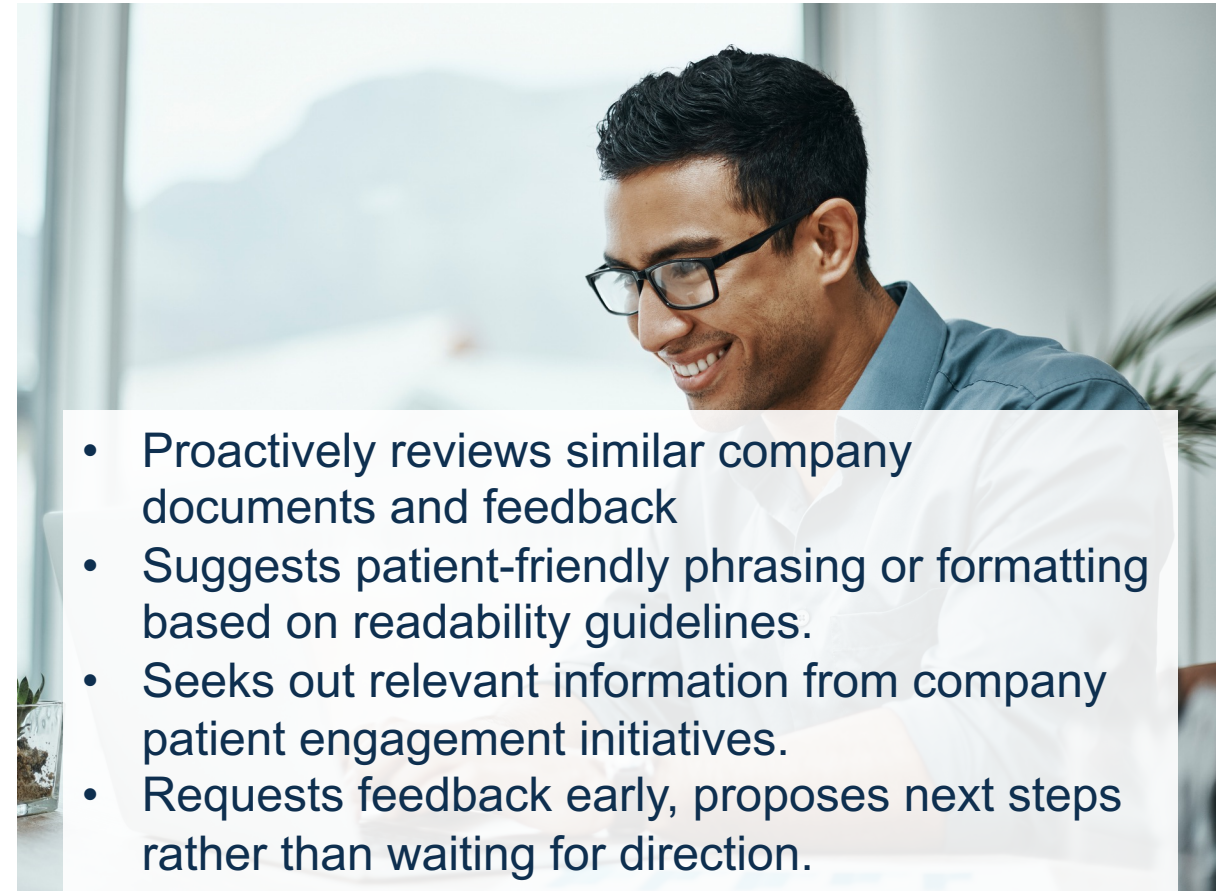
Proactivity and engagement

Invested in patient care and own development

Curiosity, passion, energy and enthusiasm

Offering plans, anticipating problems

Actively seeking opportunities for learning/growth



- Proactively reviews similar company documents and feedback
- Suggests patient-friendly phrasing or formatting based on readability guidelines.
- Seeks out relevant information from company patient engagement initiatives.
- Requests feedback early, proposes next steps rather than waiting for direction.

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Trainee qualities supporting entrustment

A

Agency: Proactive attitude towards work, team, safety and personal development that includes awareness of and acting upon the need for action even when outside of the strict definition of one's responsibilities and practice of adaptive expertise. Agency can manifest within the context of one or more of the other four factors

R

Reliability: Consistent, predictable, and conscientious behavior driven by a sense of accountability and responsibility

I

Integrity: Truthfulness, benevolence, and patient-centeredness, where expertise is employed to benefit patients and decisions are motivated by concern for and made in the best interest of patients.

C

Capability: The ability to perform a specific task in a variety of contexts and within an appropriate time frame, requiring a reasonable understanding and overall view of the clinical situation and ability to communicate and work effectively with others within a system.

H

Humility: Discernment of one's limitations; willingness and ability to ask for help and feedback; receptivity to insights of patients and co-workers; and ability to learn and develop from mistakes, feedback, and the expertise of others.

Using A RICH model in PMST?

Strengths

- Evidence based
- Moves beyond 'what' to 'how'
- Provides a framework for discussion
- Addresses professionalism

Challenges

- 'Motherhood and apple pie'
- Requires explanation
- How to evidence

Could Rich help you to make A RICH entrustment decision?



A decision regarding the increase of autonomy of a trainee in medical education that takes into account their:

Agency (proactive toward work, team, safety, personal development)

Reliability (conscientious, predictable, accountable, responsible)

Integrity (truthful, benevolent, patient-centered)

Capability (specific knowledge, skills, experience, situational awareness)

Humility (recognizes limits, asks for help, receptive to feedback).

Credits

O Ten Cate & H C Chen

ChatGPT

Laura and FPM office

And all of you for taking part

thank you 😊

<https://www.tandfonline.com/doi/10.1080/0142159X.2020.1817348>