Building Relationships with your Investigators

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Southeast Clinical Oncology Research (SCOR) NCORP
with Southeastern Medical Oncology Center
in Goldsboro, NC

CRP Education Meeting, Friday, May 15, 2015

Objectives

- Learn how communication within the research team leads to better understanding of research protocols
- Learn how communication with cancer patients can increase trust
- Learn the importance of nurses/CRPs in the clinical trial process

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What does it mean to be a professional?

Why does your physician want to do clinical trials?

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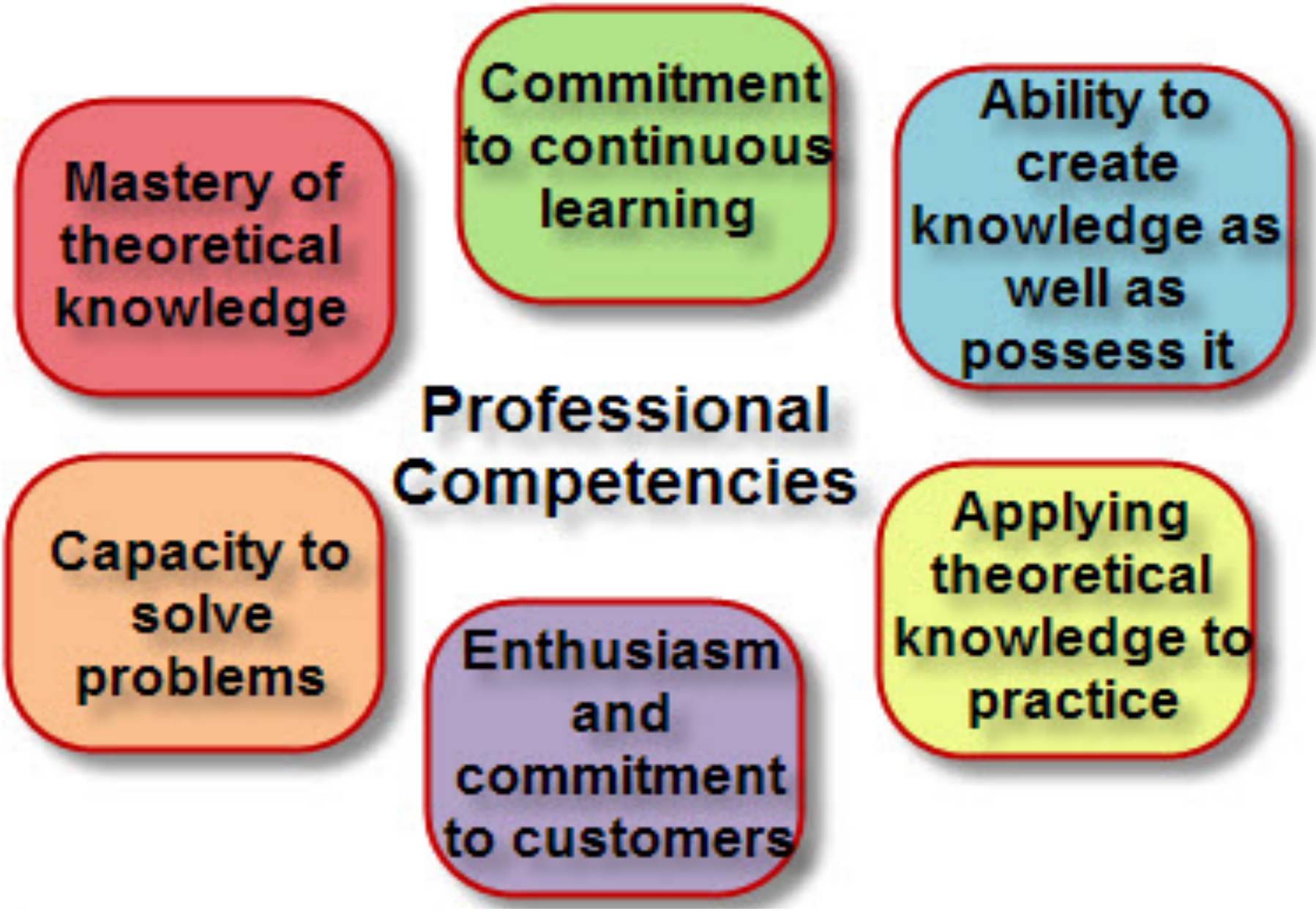

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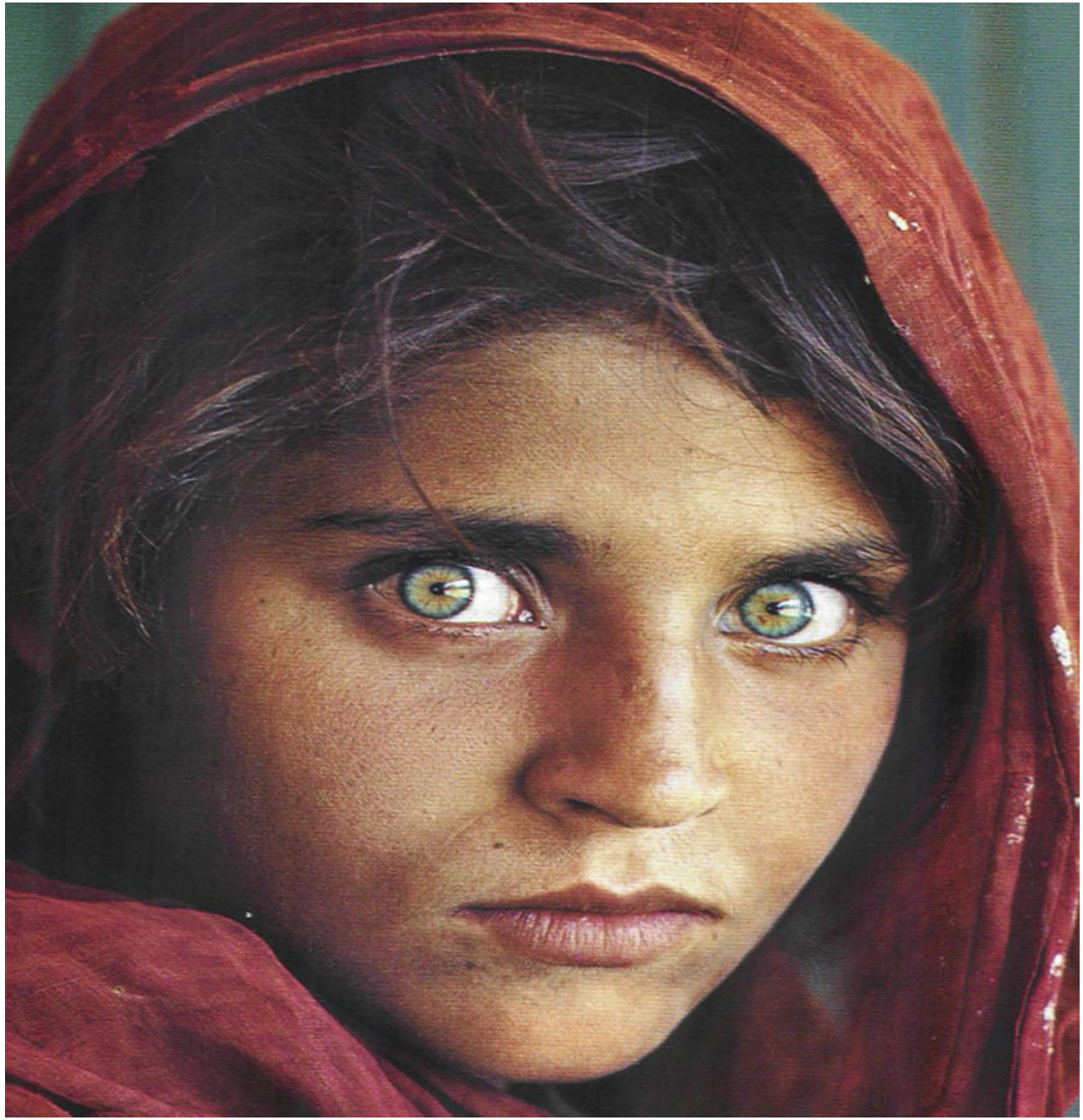
Why do we do clinical trials or research?

For our patients and for all the patients of the world.



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Commitment to Continuous Learning: New Chemotherapy Drugs

Sir William Osler said “it is important to use a drug early while it is still effective.”

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Your Investigator

- Will want to use drugs early to try to help his patients
- They may look at cancer as a “Chess game” with the doctor and patient playing against the cancer
- This can affect their judgment as they push the envelope to get them on study

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The ability to create knowledge

- Every patient who does not get offered a clinical trial slows the fight to cure cancer and ultimately increases the death rate from cancer
- The knowledge that we have today is inadequate → we must learn more

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Accruing to clinical trials can be difficult

- Accruing to clinical trials is a skill and there is a learning curve
- Building the relationships with investigators can be challenging
- Hopefully, you will learn things that may help you and your team accrue to clinical trials

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Why is it important to be a "Clinical Trialist"?

Applying theoretical knowledge to practice:

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5 Yr. Survival Myeloma

- 1970s 26%
- 1996-2002 33%
- Pts on clinical trials - approx 50%

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Research

- Represents medicine’s new frontier and greatest hope
- Leads doctors to new and improved treatments
- Helps save lives and reduces the cost of medicine

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Clinical Trialist

- Believes in the scientific process
- Is curious about how we can improve the treatment of an illness
- Believes we do not have all the answers and the treatment of illnesses will change with time

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Clinical Trialist

- Willing to spend the time and energy needed to advance medical knowledge
- Not willing to accept the “status quo” as “the-state-of-the-art” when it comes to treatment
- Is altruistic

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Protocol Barriers

- Presentation of the protocol:
  - Body language of physician and staff
  - Tone of voice and eye contact
  - Enthusiasm
  - Conviction that the protocol is the “state-of-the-art” treatment
  - Don’t talk “over” the patient and not listen to patient
  - “I would not put my family on that trial”

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Enthusiasm and Commitment to Customers:

- Some physicians indicate they don't find the trial interesting. So they don't put the trial through their IRB or open the study; therefore, their patients don't have the option of participation in the trial.
- The patients should have the choice. The physician should not be so paternalistic.
- These are your low accruing doctors

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Patient Perspectives

- Receive medical benefits from the clinical trials
- Benefit from increased monitoring and care
- Peace of mind
- Motivated by a desire to help others or a desire to help the investigators

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As oncologists, we owe society our best effort to cure cancer.

This means placing all eligible patients on clinical trials.

We can make errors in judgment as to who should go on study.

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Personal Satisfaction

There is a lot of satisfaction in putting patients on studies which, in turn, changes the way we treat our patients.

It is humbling when the studies we are using change our biases.

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What are the Issues?

- Discussing the protocol
  - Audio taping the discussion → this is critical in my opinion.
- Developing the **trust**
- Explaining it in a way the patient and family can understand
- Ethical issues
- Not putting patients on study who are not eligible

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Capacity to Solve Problems: Discussing the Protocol

- Audio tape the discussion
  - Most pts. will not hear what you say
  - Give them a copy of the audio tape
  - “Information block” mode
  - Their mind is thinking about all sorts of things when you say certain key words
  - One patient remembered only 2 items

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Commitment to Customers: Developing Trust

- Give them the time they deserve
- Don’t look rushed even if you are
- Act as if they are the only patient you have that day
- Remember, non-verbal language is real

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Professionals

- Prevent fabrication of data
- Generate quality data
- Keep data current
- Take pride in your work
- Take pride in helping the patients on clinical trials

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Professionals

- Work as a “team”
- Value the input of team members
- Value the time and effort of the patients and recognize their contribution and altruism

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Ineligible patients

- How to deal with a physician who is trying to enroll an ineligible patient
  - Go over the eligibility list with the doctor
  - Point out your area of concern
  - Send the executive officer an email with the specific question
  - Document what the executive officer has said

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Ineligible patients

If the executive officer says the patient is or is not eligible, that is the final answer.

You cannot put a patient on a study if they are ineligible. It is a protocol violation. If it is intentional, it is fraud.

Exceptions to eligibility **cannot** be granted

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Ineligible patients

You are there to protect the patients from going on studies to which they are not eligible

You have to work as a team which means you have to speak up

When you work as a team magic happens and when you don’t . . . .

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Flying a 777

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Too low on approach

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Ineligible patients

- What happened?
- Why did the co-pilot not work with the pilot?
- Why did they not see the problem ahead?
- You have to break the chain of mistakes

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Errors

- How do deal with a physician who is making errors with protocol tests and data
  - Put the orders into the computer yourself before the patient comes to the office (make it easier for the doctor)
  - Have a policy stating after the pt. sees the doctor, the chart goes to the research staff for review

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Errors

- Research staff reviews every patient before treatment to make sure dose adjustments are made correctly due to toxicity
- If there is required documentation not being created, give the physician a note reminding them to make comments about specific toxicities.

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The Team

- Alone we cannot change the treatment of cancer.

We must work together!!

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The Team

- Nurses are critical in:
  - Dealing with drug logs and dose modifications
  - Double checking with the physician when toxicities are discovered and the patient forgets to mention to the physician.

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The Team

- Nurses are critical in:
  - Helping explain the treatment to patients
  - Helping to monitor side effects
  - You must have nurses understand the importance and value of clinical trials in order for them to be on board

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The Team

- CRP (Clinical Research Professional)
  - Makes sure data is submitted in a timely fashion according to protocol guidelines
  - Makes sure no fabrication of data occurs
  - Makes sure forms are filled out in timely fashion

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The Team

- CRP
  - Evaluates patients for eligibility
  - Makes sure tests are ordered on time
  - Makes sure toxicities are recorded
  - Makes sure physicians follow the protocol
  - Makes sure . . . .

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The Team

- Lab Personnel
- Front desk/receptionist
- Research/Chemotherapy/Staff nurses
- Pharmacy/research pharmacist

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The Team

- The team is not only the physician
- The team is a group of individuals working together
- In accruing to clinical trials, the team is what works. No one person is more important than another.

Example: The brain is not more important than the heart, lungs or blood. All have to work together for the body to function.

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Ethics

- A fine balance exists between scientific advances and the protection of patients.

The first step in the evolution of ethics is a sense of solidarity with other human beings.

Albert Schweitzer

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Ethics

- The public's perception of research, its benefits, and its risks are shaped by the way research is conducted.
- It is essential the research community comes to value the ethics of research as central to the scientific process.

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Ethics

- The research community as a whole suffers when even a few investigators ignore basic principles of ethics.
- Scientific misconduct and fraud should never occur.

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“… Any deterioration in the protective foundation we have laid can cause direct harm to human subjects of research and indirect harm to the reputation of the investigators, their academic institutions, and the entire research community...

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"…Moreover, if we are to keep testing *new medicines and new approaches* to curing disease, we cannot compromise the trust and willingness of patients to participate in clinical trials".

Donna Shalala, Ph.D.

NEJM 9/14/2000

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Why do we conduct clinical trials?

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For our patients

and for all

the patients

of the world

Professionals

Imagine the impossible . . .

. . .find a way to do it!

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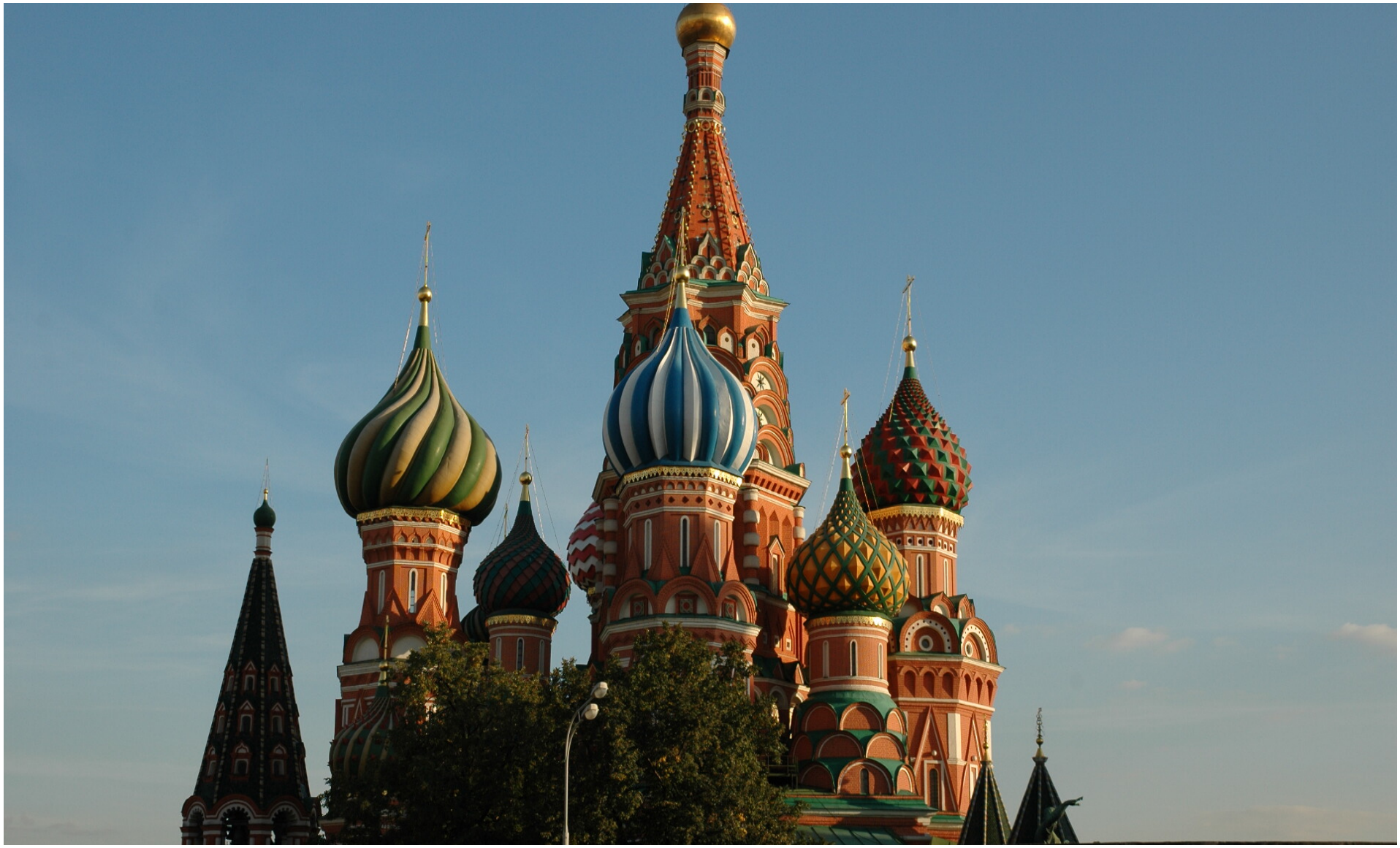

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“There is nothing impossible to him who will try.”

Alexander the Great

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Team

- We have to work together
- You have to develop a team
- You must communicate
- You must protect your patients' rights
- You must ensure the right tests are done at the right time and the right drugs are given to the right patient

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This is unacceptable

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Conclusion

- Questions

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