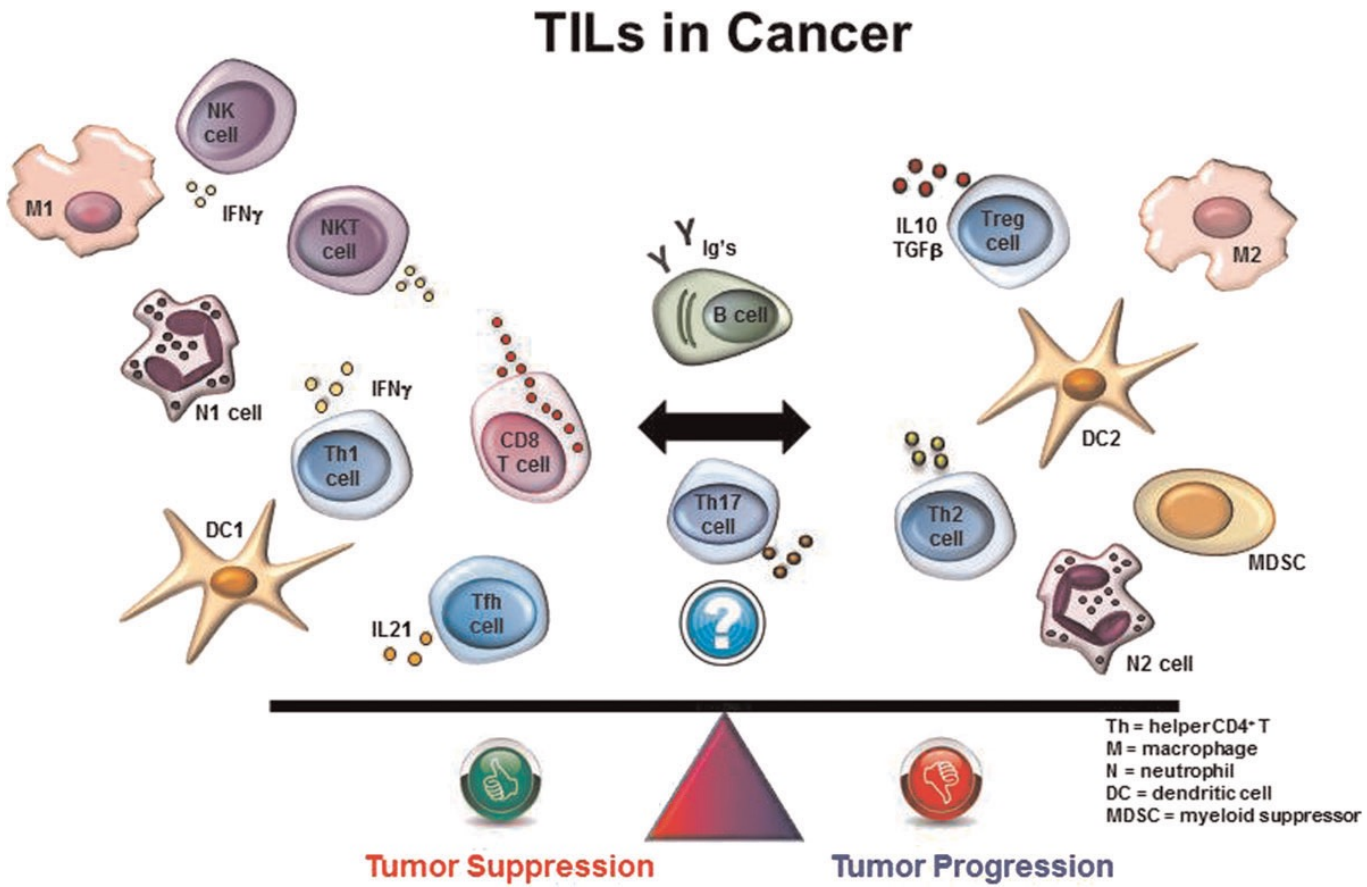
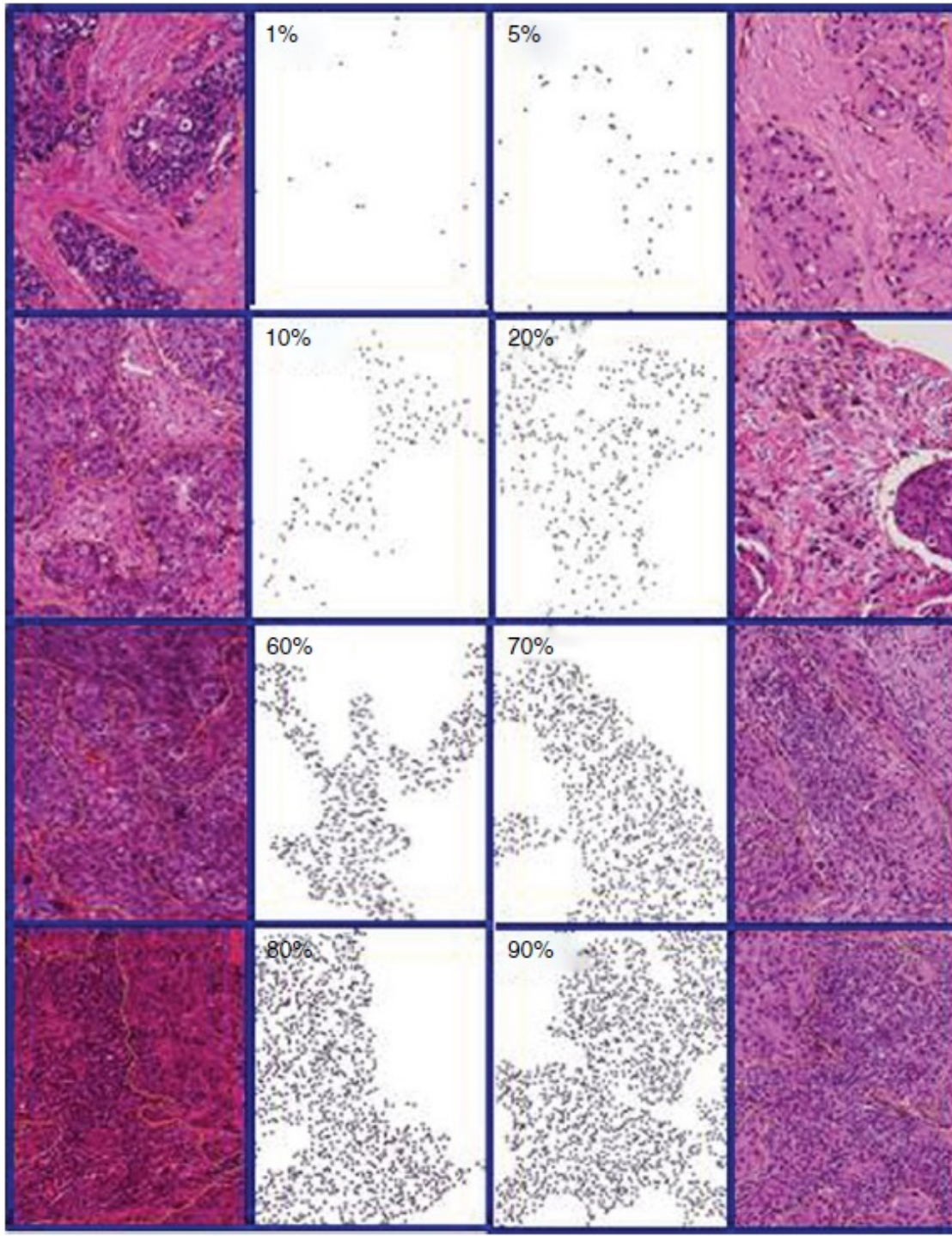
TILs RS Project

A regulatory science approach for morphology-based biomarkers in tissue sections

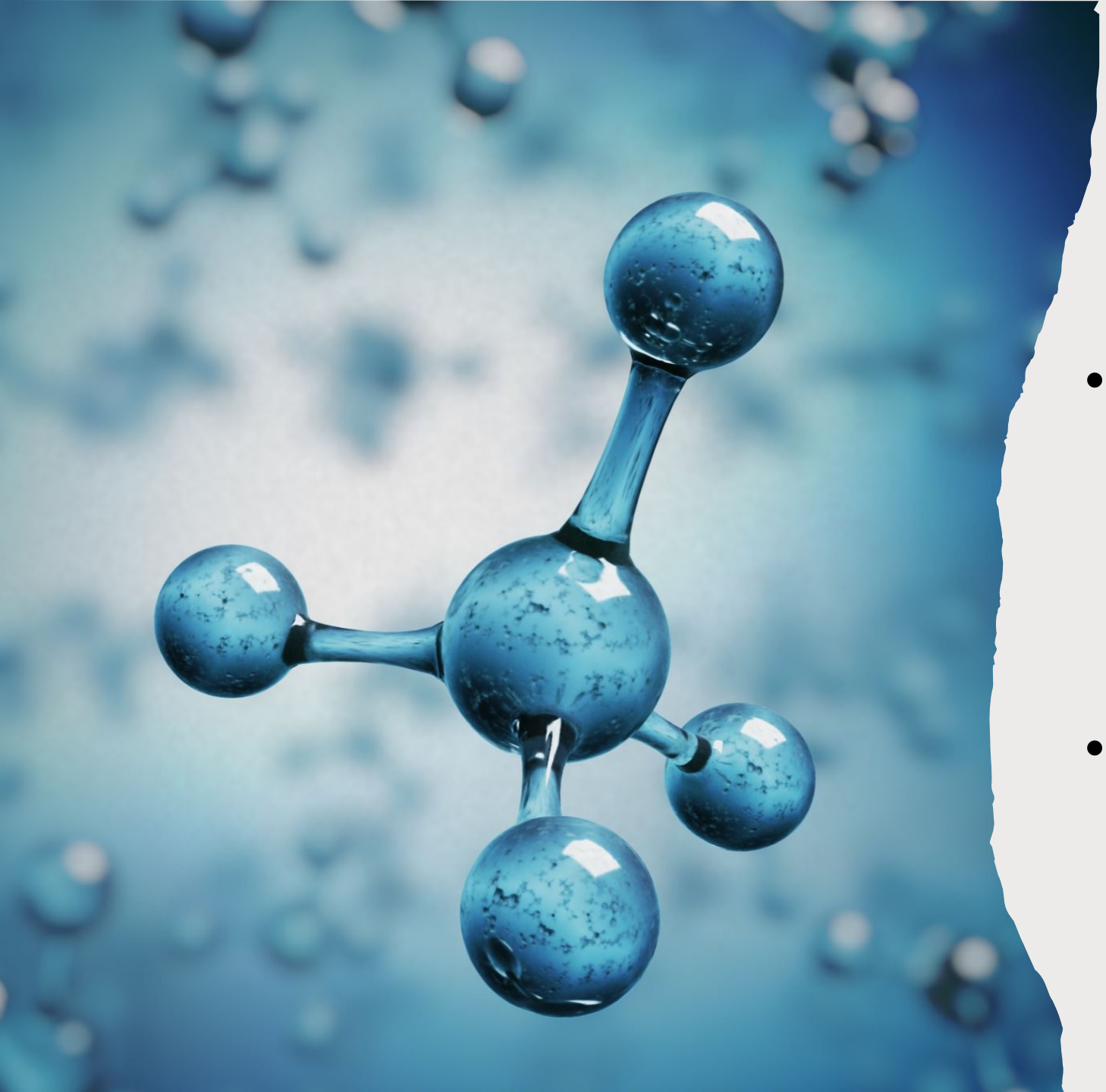
Project Leads

- Kim Blenman
- Roberto Salgado





Salgado, et. al. 2015 Annals of Oncology. doi:10.1093/annonc/mdu450



Background

- There is insufficient understanding regarding regulatory approaches for morphology-based biomarkers (e.g., TILs in H&E or IHC/IF sections)
- It is unclear as to what would be the “best practices for consideration”

Approach & Objectives

- Collaboratively contribute to the creation of regulatory science approaches
  - Objective 1: Write a whitepaper that proposes a regulatory science approach for morphology-based biomarkers
  - Objective 2: Explore options for existing regulatory programs (e.g., MDDT) and pathways (e.g. CoDx) or insufficiencies or propose a new pathway

Deliverables

1. Produce the whitepaper (e.g., as a peer-reviewed manuscript)
2. Share it with the TILs WG and PIcc communities
3. Submit it to the FDA for commenting (e.g., QSub program)

Value proposition

"How will the proposed project be valuable to each of these categories?"

Regulatory: contribute regulatory science approaches to an area in which these approaches currently do not exist

Clinical: (1) benefit to regulators – provide possible "best practices for consideration" and (2) benefit to patients (in particular, low-to-middle income communities/countries) – opportunity to utilize low-cost standard H&E TILs for assessment of the immune microenvironment of tissue

R&D: enable researchers and software developers to develop compliant tools