

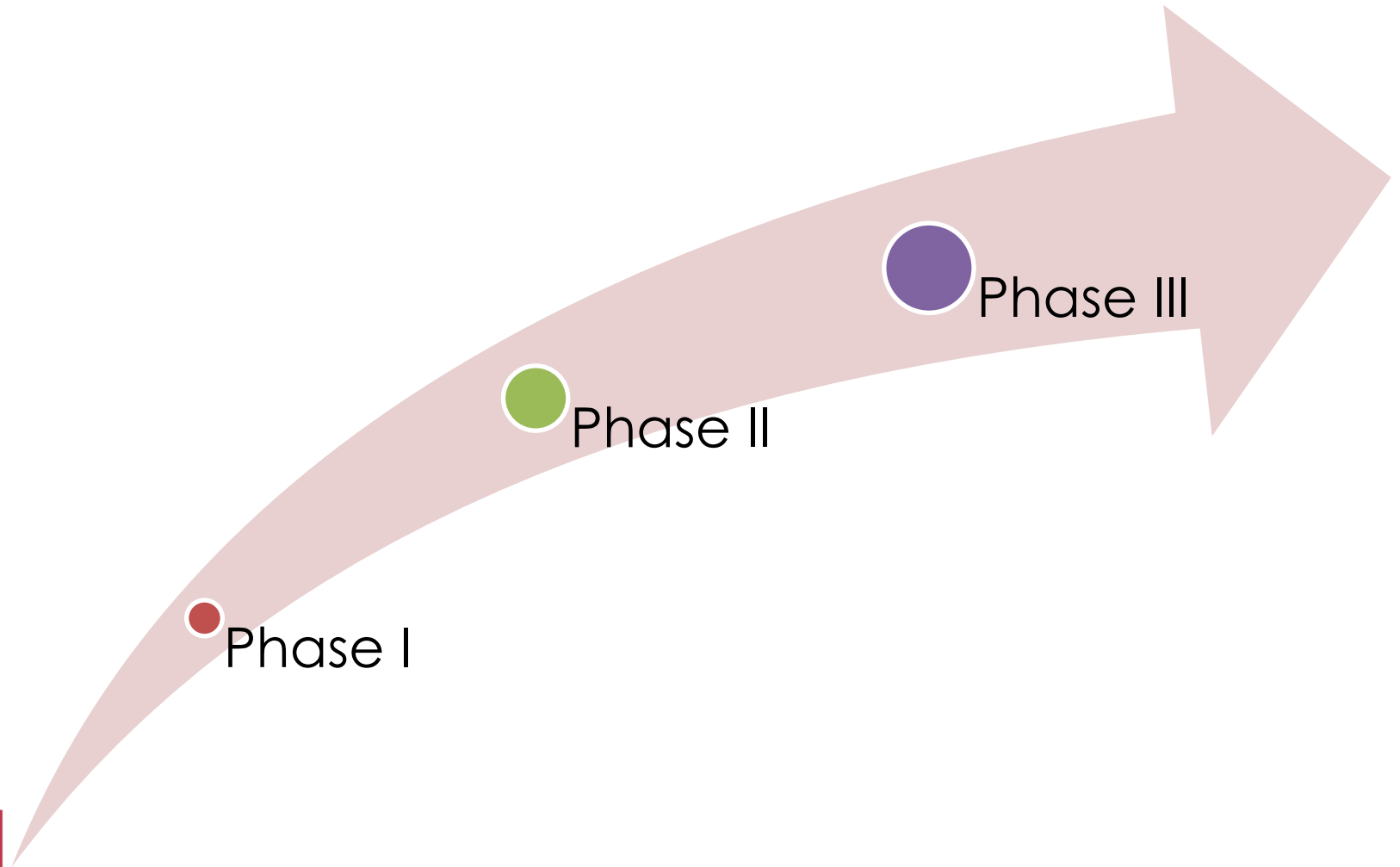
# Application of technological advances to clinical trials

Willem Hanekom

1. Technology for what?
2. Correlates of risk of TB disease as a model

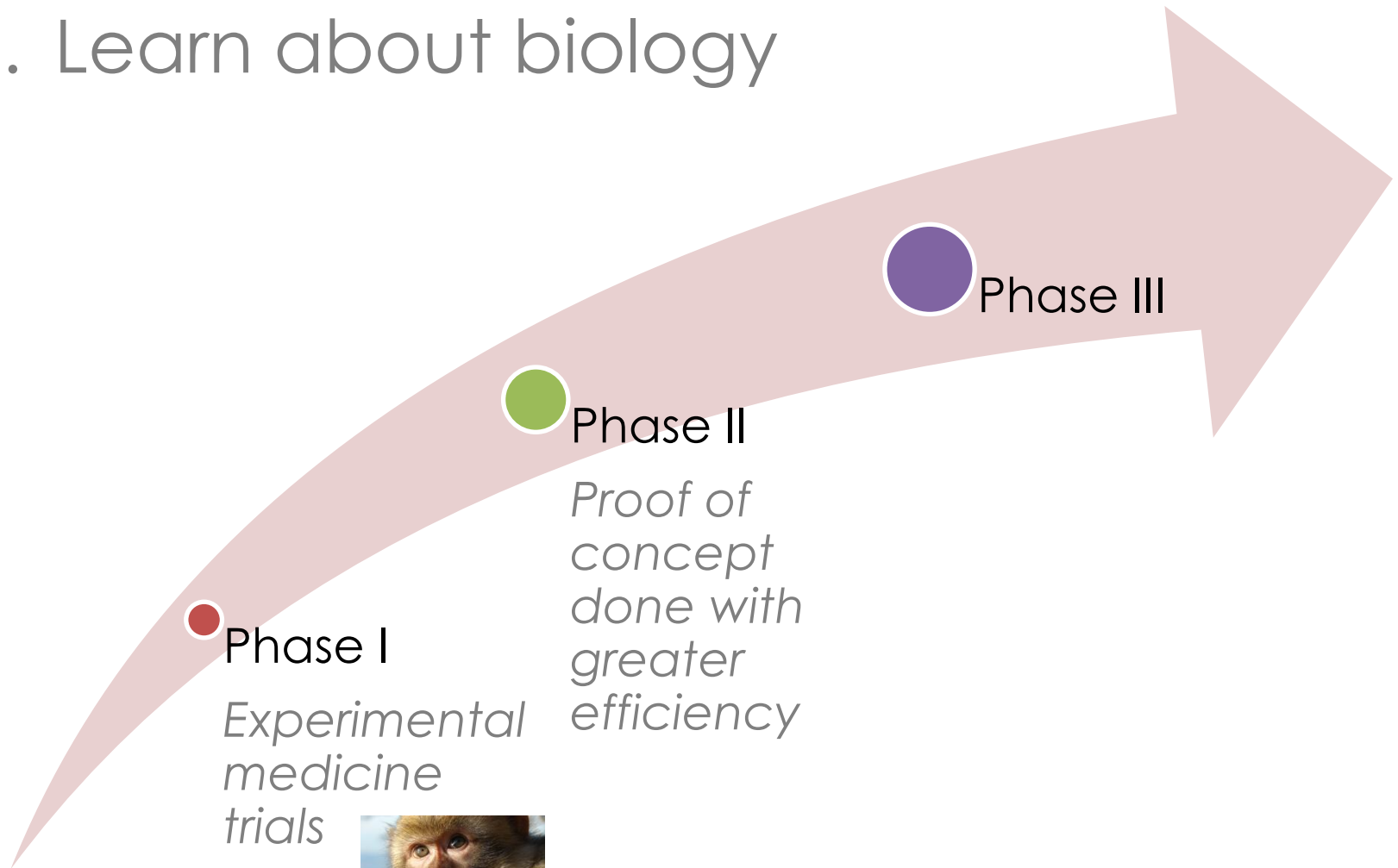
# Old-school clinical trials:

Product development-driven



# Aims of new-school clinical trials:

1. Earlier candidate up selection
2. Learn about biology



# Early phase experimental medicine trials



Test various vaccine **concepts** in similar experiments, e.g.,

- Antigen classes
- Vehicles, adjuvants
- Character of immune response



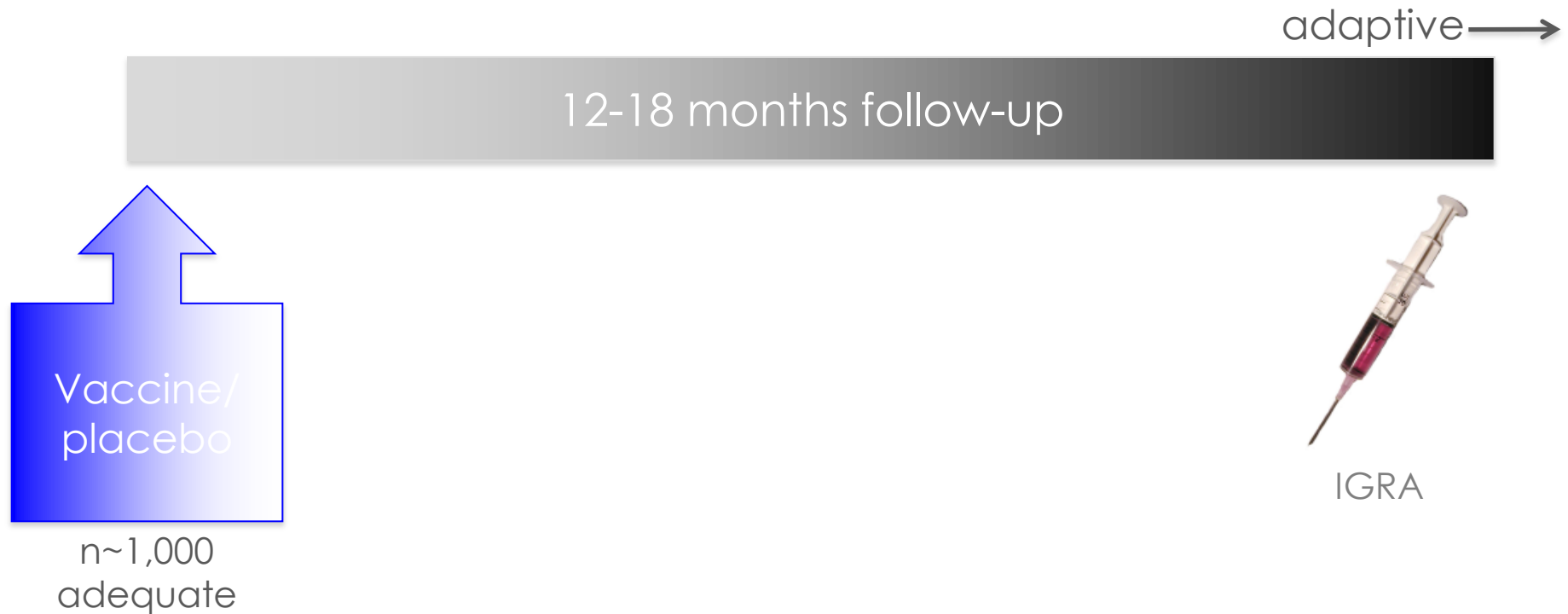
Up select approaches  
Learn about protective immunity



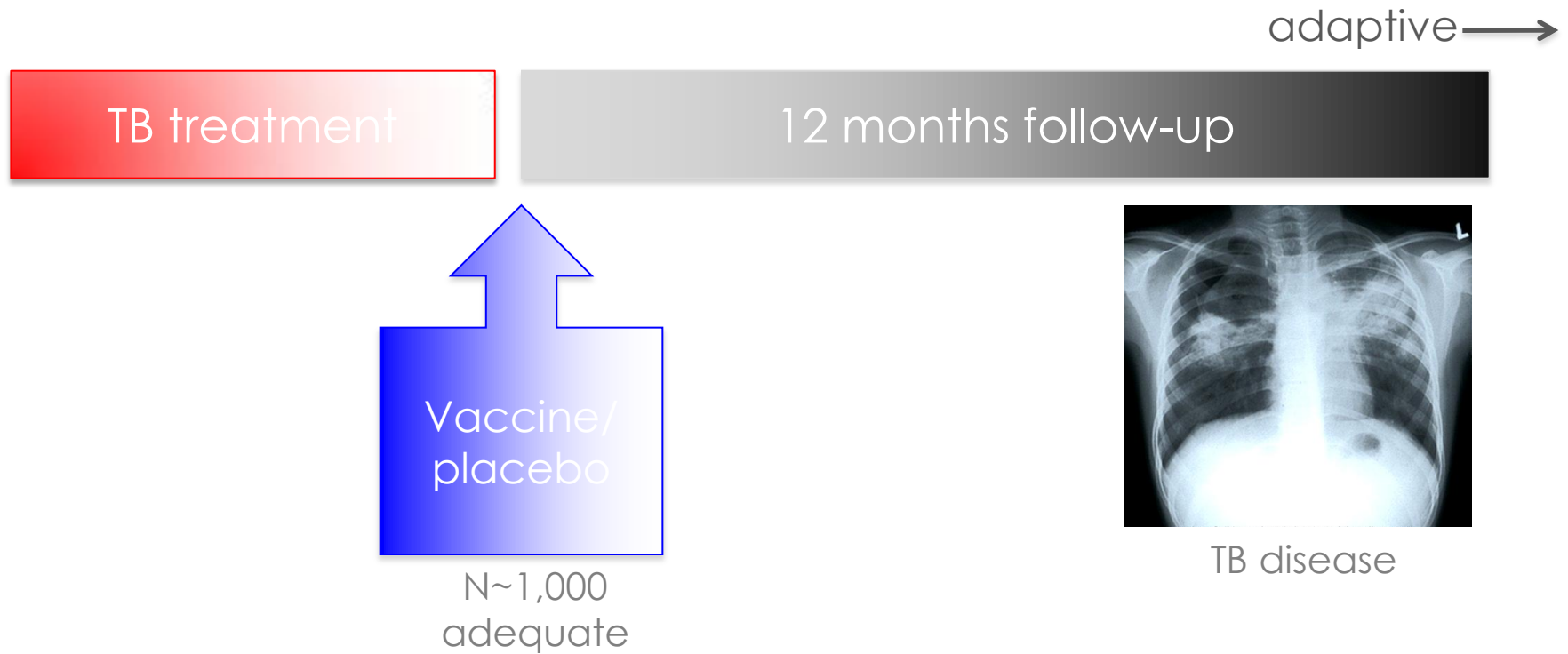
Challenge with Mtb



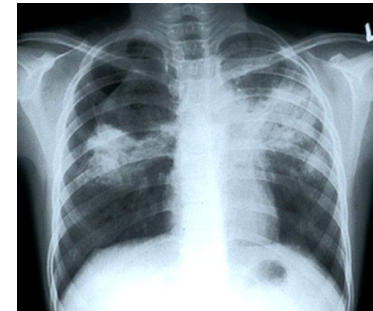
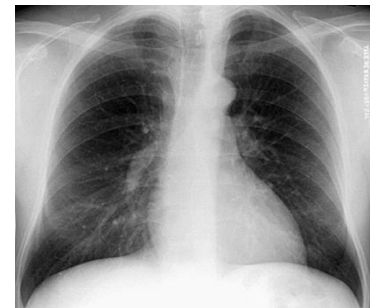
# Efficient test of concept trials: Comparison of efficacy in preventing TB infection



# Efficient test of concept trials: Comparison of efficacy in preventing recurrent TB disease



# Newly identified correlates of risk of TB for reducing sample sizes of efficacy trials



6-0 mo  
3.5x

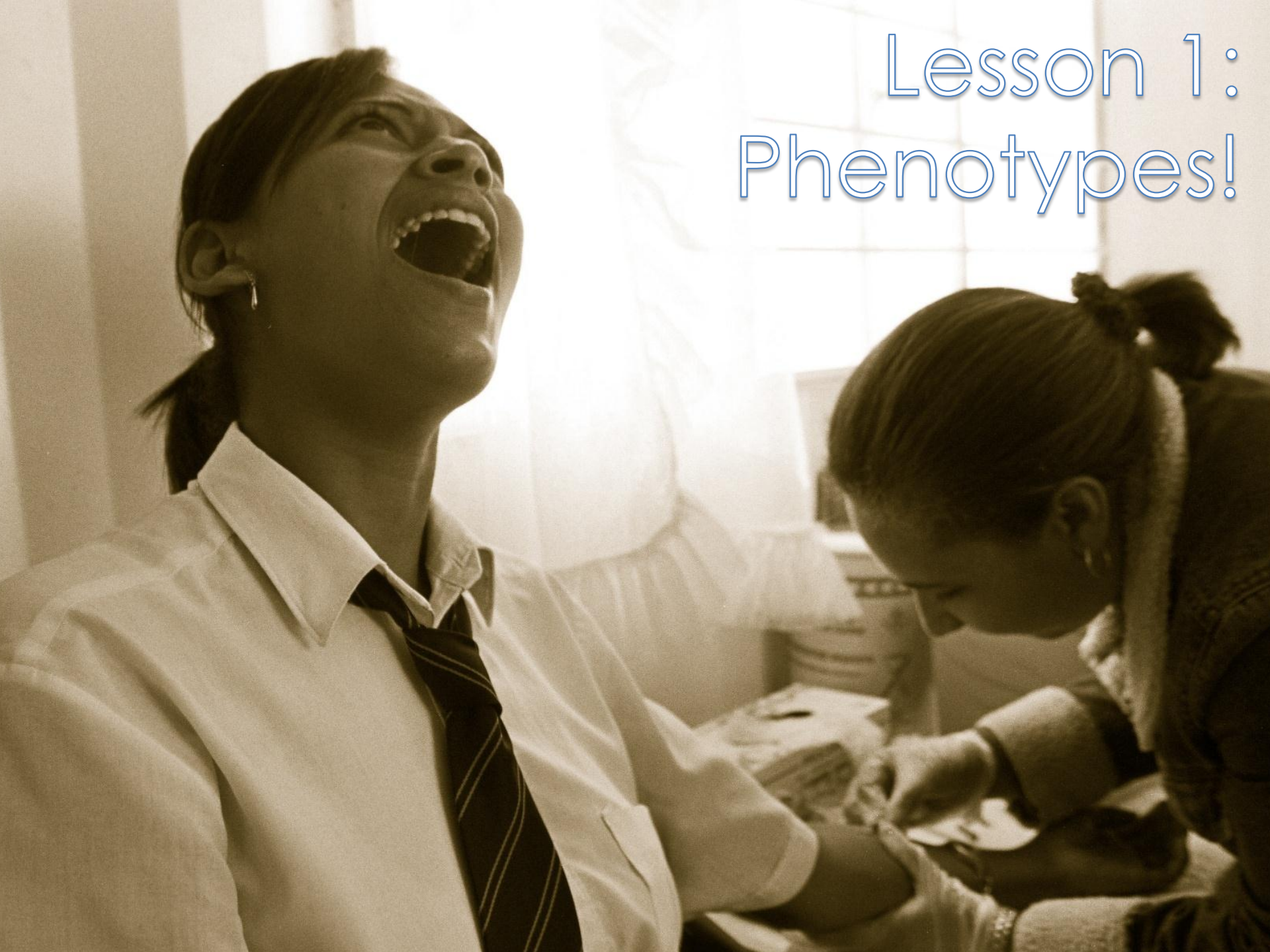
12-6 mo  
2.3x

24-18 mo  
2x

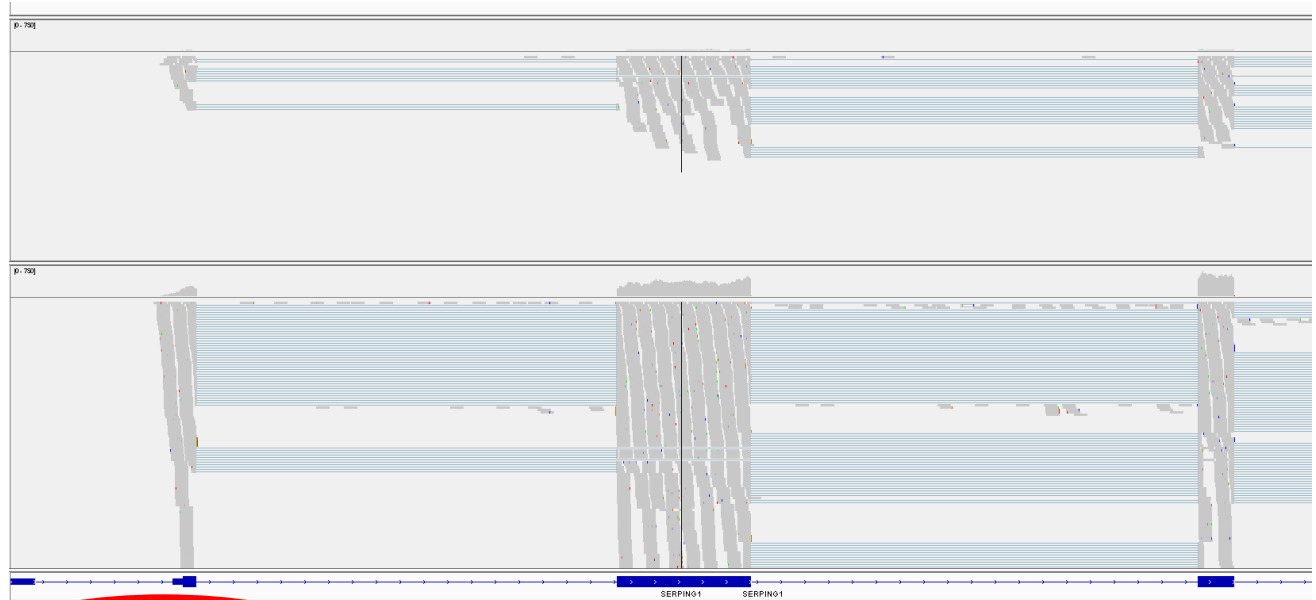


1. Technology for what?
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# Lesson 1: Phenotypes!



# Lesson 2: Sample size!



Cases: n=49  
Controls: n=98

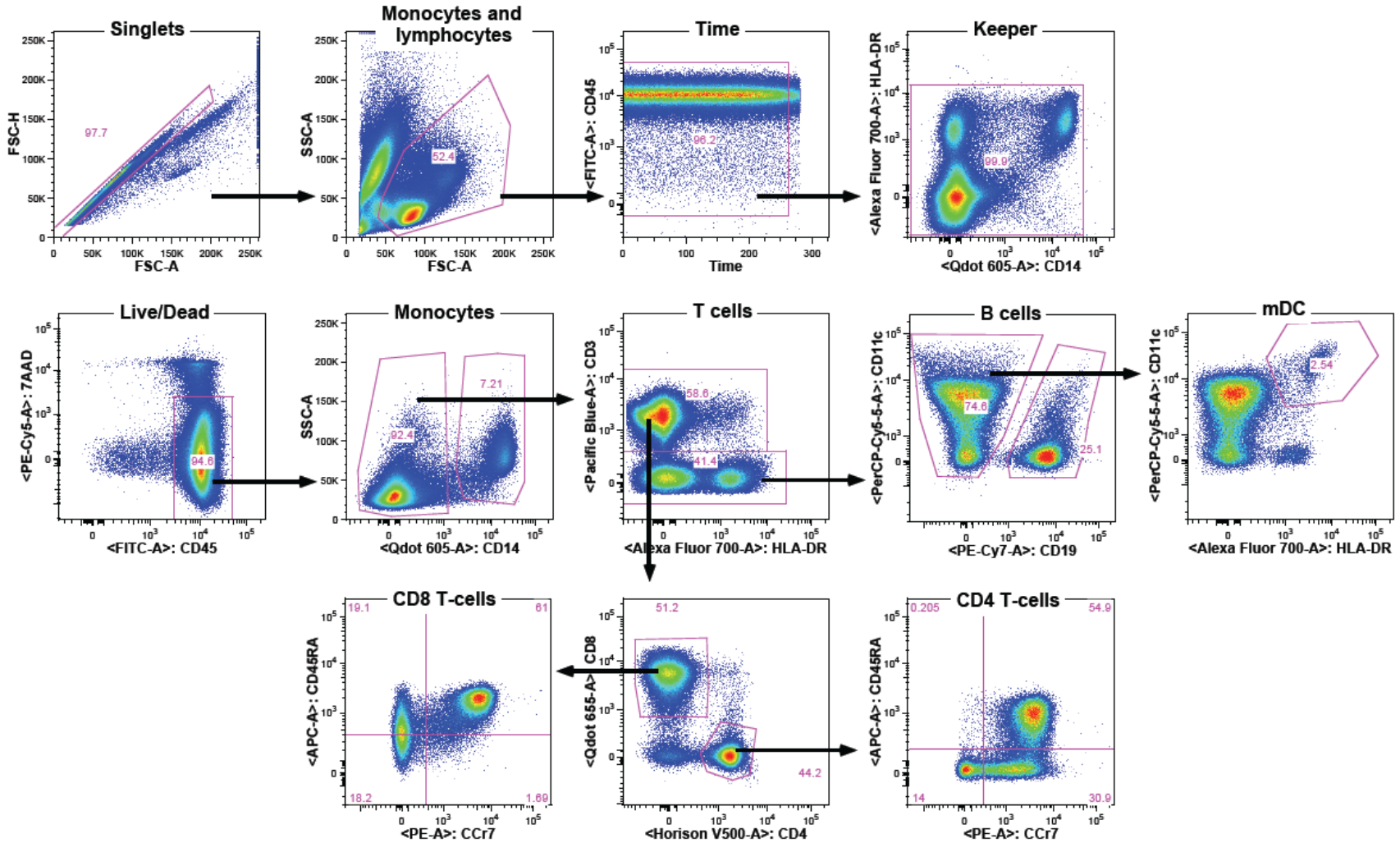
# Lesson 3: Quality!



GC6-2013

# Lesson 4: Analysis approach!

# Lesson 5: Cellular frequencies!



# Lesson 6: Curtail processing!

# Current practical package for correlates of risk or of protection studies

1. Paxgene RNA
2. 50uL for absolute numbers
3. PBMC\*
4. Plasma/serum  
(Paxgene DNA)