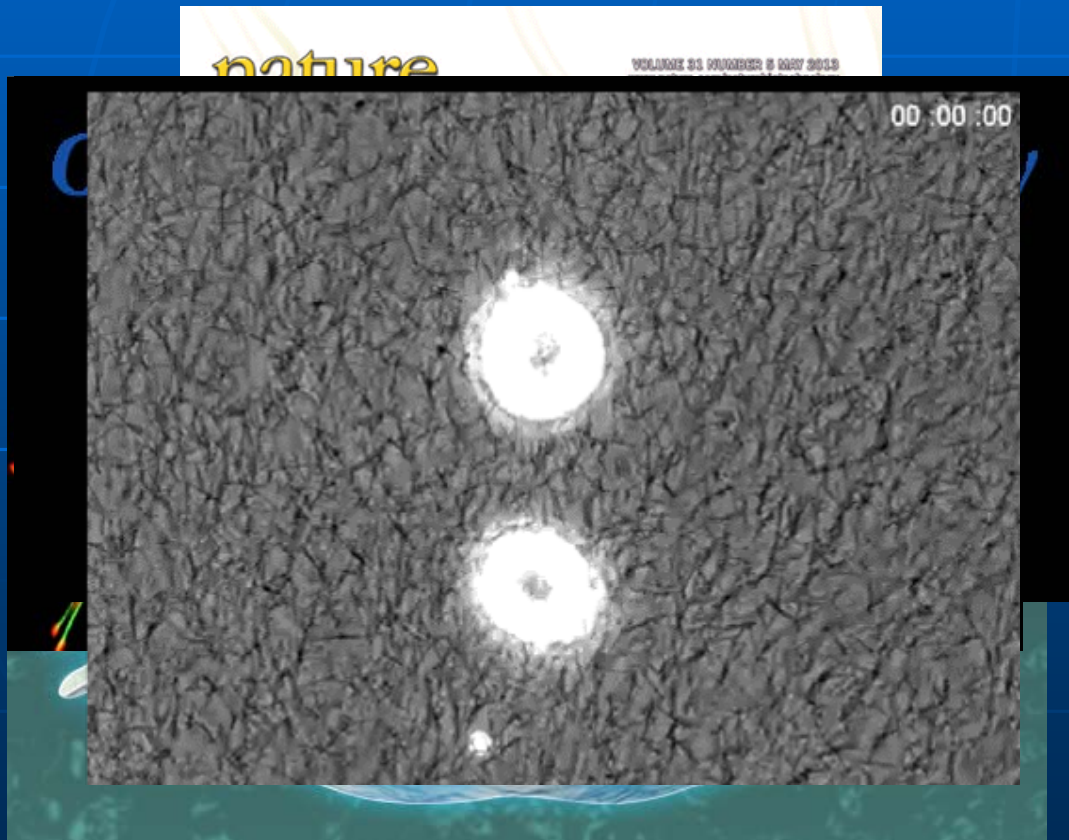


# CELL MEASUREMENT ASSURANCE: Quantifying Biological Response

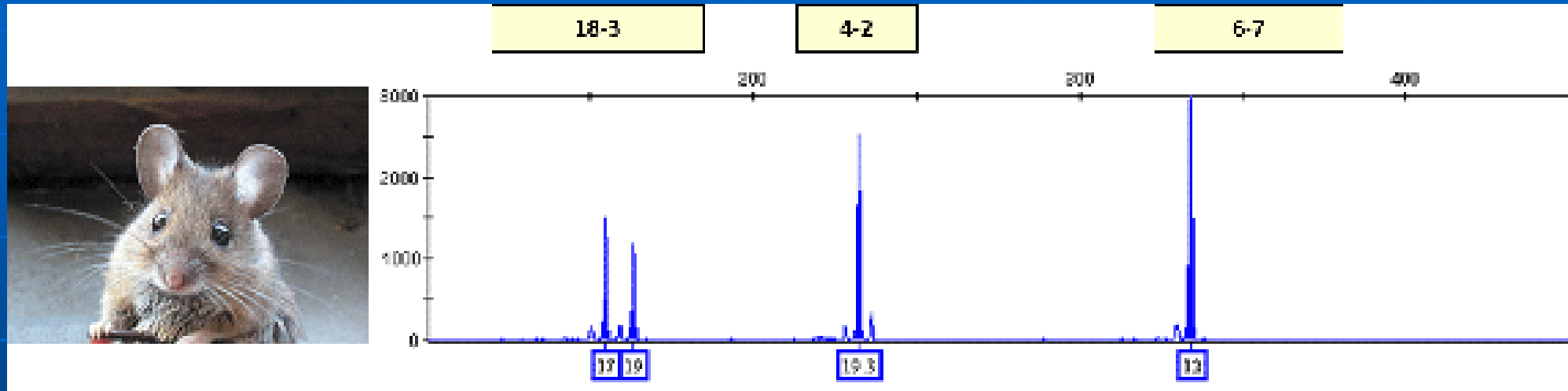
A view of the cell:



## Applications of Cells

- Production of commodity chemicals (Synthetic Biology)
- Production of therapeutic proteins
- Screening potential pharmaceuticals
- Regenerative medicine
- Personalized diagnostics and treatment
- Research to feed innovation

## CELL MEASUREMENT ASSURANCE: Cell Line Identification



**Drug Development: Raise standards for preclinical cancer research**  
**C. Glenn Begley and Lee M. Ellis** propose how methods, publications and incentives must change if patients are to benefit.

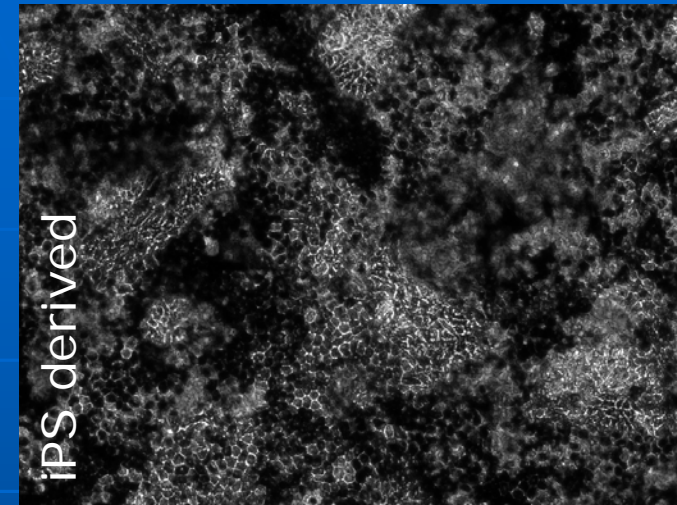
“Unquestionably, a significant contributor to failure in oncology trials is the quality of published preclinical data...The results of preclinical studies must ... be very robust to withstand the rigours and challenges of clinical trials, stemming from the heterogeneity of both tumours and patients.”

## CELL MEASUREMENT ASSURANCE: Quantifying Critical Quality Attributes

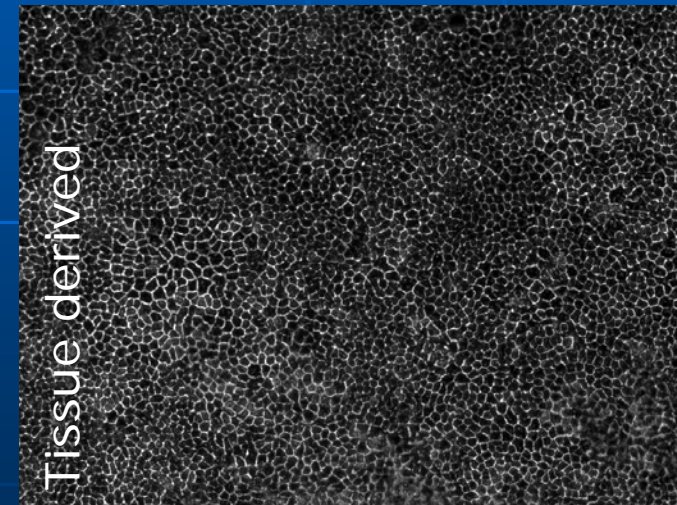
### Age-Related Macular Degeneration



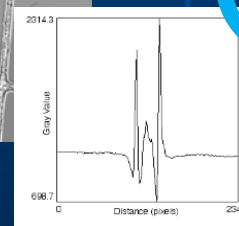
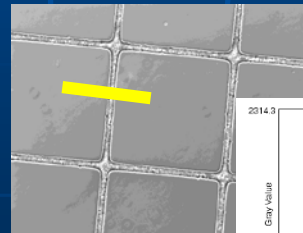
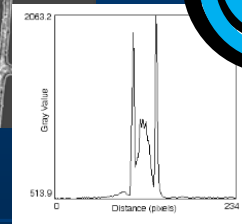
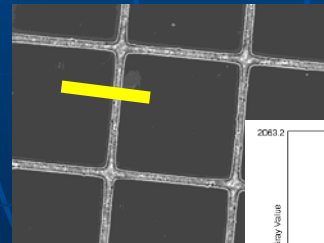
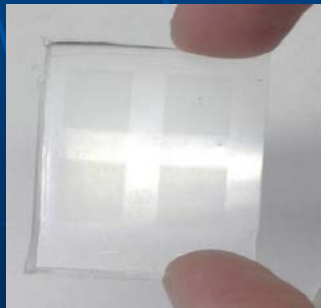
- 11 million affected people, and expected to double by 2050; direct health care costs in the Americas ~US\$98 billion



iPS derived



Tissue derived



*A benchmarking material makes sure phase rings are aligned every time.*



# CELL MEASUREMENT ASSURANCE: Drivers

## Legislative and Initiative Drivers:

Precision medicine  
21<sup>st</sup> Century Cures  
Engineering biology  
Biomanufacturing

## Industry Needs:

Biomanufacturing  
Novel therapies and diagnostic

## Basic Science:

Fundamental principles of biology

