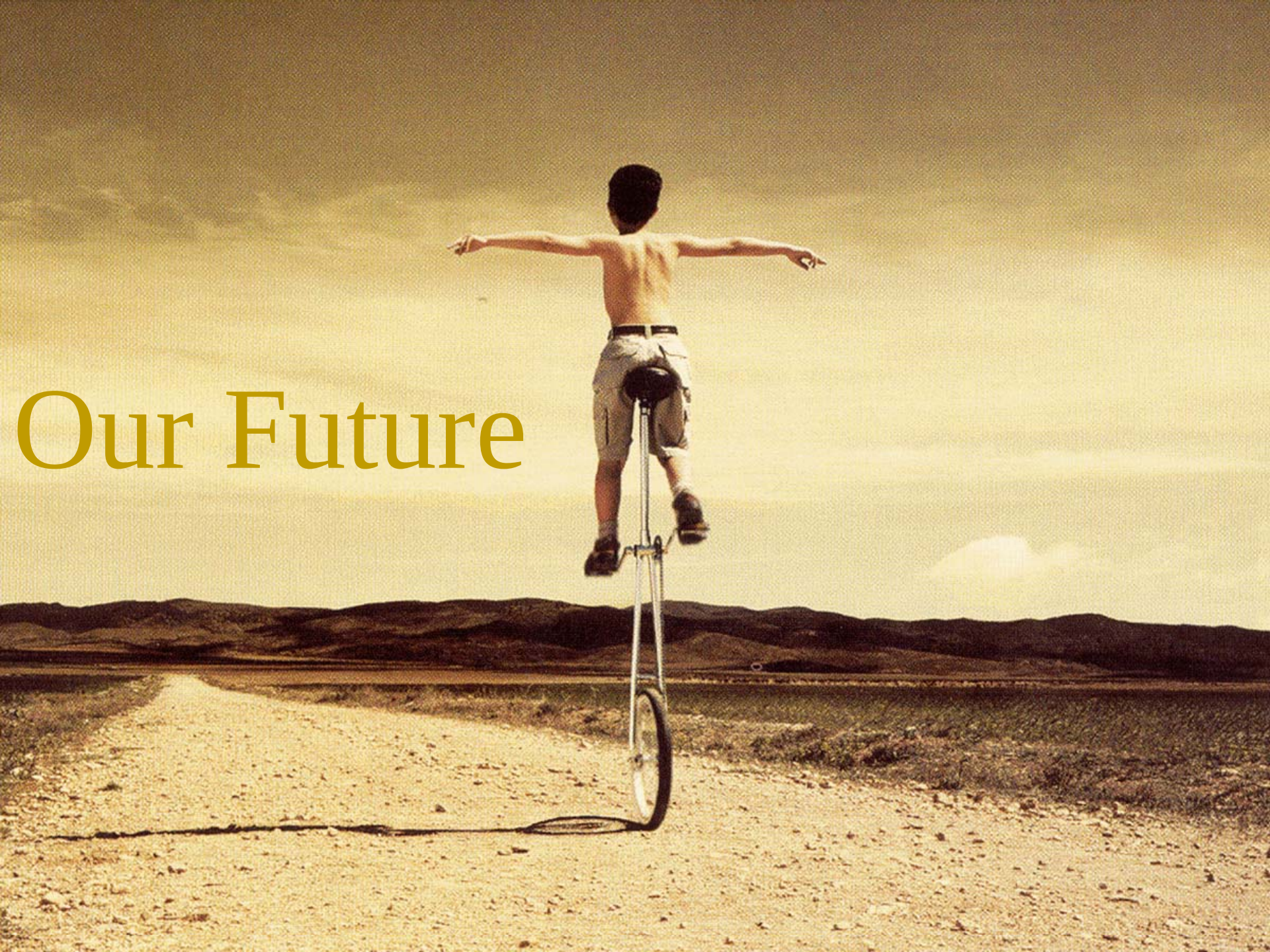
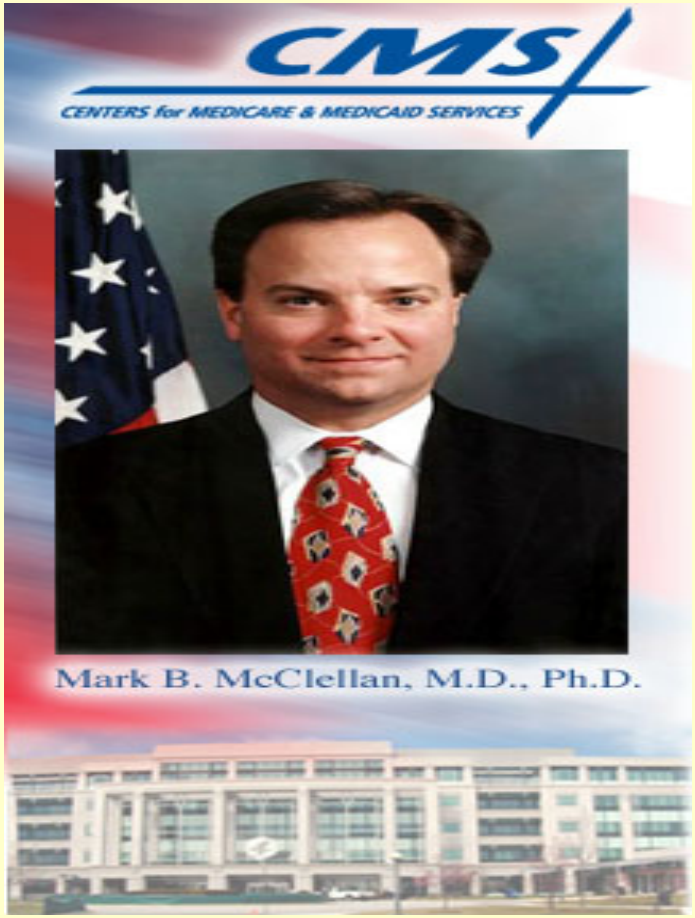

Our Future

Post-Market Registries

Registries can provide a unique perspective

Center for Medicare/Medicaid Prospective

- Pay for performance
- CMS NCD requires CMS Destination Therapy centers report outcomes to a national data base
  - Better quality and more efficiency
  - Better evidence after market
  - Access risk and cost



Collaboration

- Government - FDA, National Institute of Health (NIH), CMS (regulating, researching, reimbursing ventricular assist devices (VADs))
- DCC (data clinical coordinating center)
- Hospitals and clinicians (providing care)
- Industry (manufacturing VADs)
- Societies (overseeing standards of care of patients with the VADs)

Industry Issues

- Access to data in a timely manner allowing for analysis and potential publications
- Others having access to data which Industry does not
- Data is incomplete with little compliance
- INTERMACS does not meet FDA post market requirements
- INTERMACS does not meet CMS requirements

Industry Concerns

- Clarification as to who has access to data. If manufacturer does not have commercial pump they can not access data.
- Confidence that specific manufacturer data will not be provided to another manufacturer for pump to pump comparison

Industry Request

- Industry participation on Steering Committees and involvement on Operations Committee
- Creation of Publication Committee with Industry participation and review of articles which utilize data from their specific pump
- Creation of formal review committee who reviews request for data and reasons for request.

Today…a Little Reward

- A database which is in compliance with CMS and FDA requirements and provides guidance to improve outcomes

- Assurance of confidentiality regarding data

- Access to data reports and individual reporting.

- Standardized registry clinical and device definitions including AE between FDA, NIH, industry & clinical

Outstanding Issues

- FDA utilization of INTERMACS to meet all post-marketing requirements.
- Reconciliation of INTERMACS data. What has been reported and number of pumps provided by center.
- Method in transferring clinical trial data needs to be outlined.
- Publication and data access policies need to be open and transparent.

How INTERMACS Survive?

Jeff Haynes / AFP-Getty Images

INTERMACS Resource Analysis

1) 1000 new patients per year while maintaining the existing database.

2) Partial compensation for clinical site coordinators.

3) Quality assurance for the database. Thus 6 auditors and 3 clinical coordinators at the Data Coordinating Center.

4) Business development person to secure funding for the Center.

INTERMACS Resource Analysis

• Personnel (direct +Indirect)	1,200,000
• Materials	25,000
• Equipment	50,000
• Travel 2x1.0Kx 100 sites	100,000
• Other Direct	100,000
• Clinical Coordinators	300,000
• Consultants	100,000
Total Non-Government	1,875,000

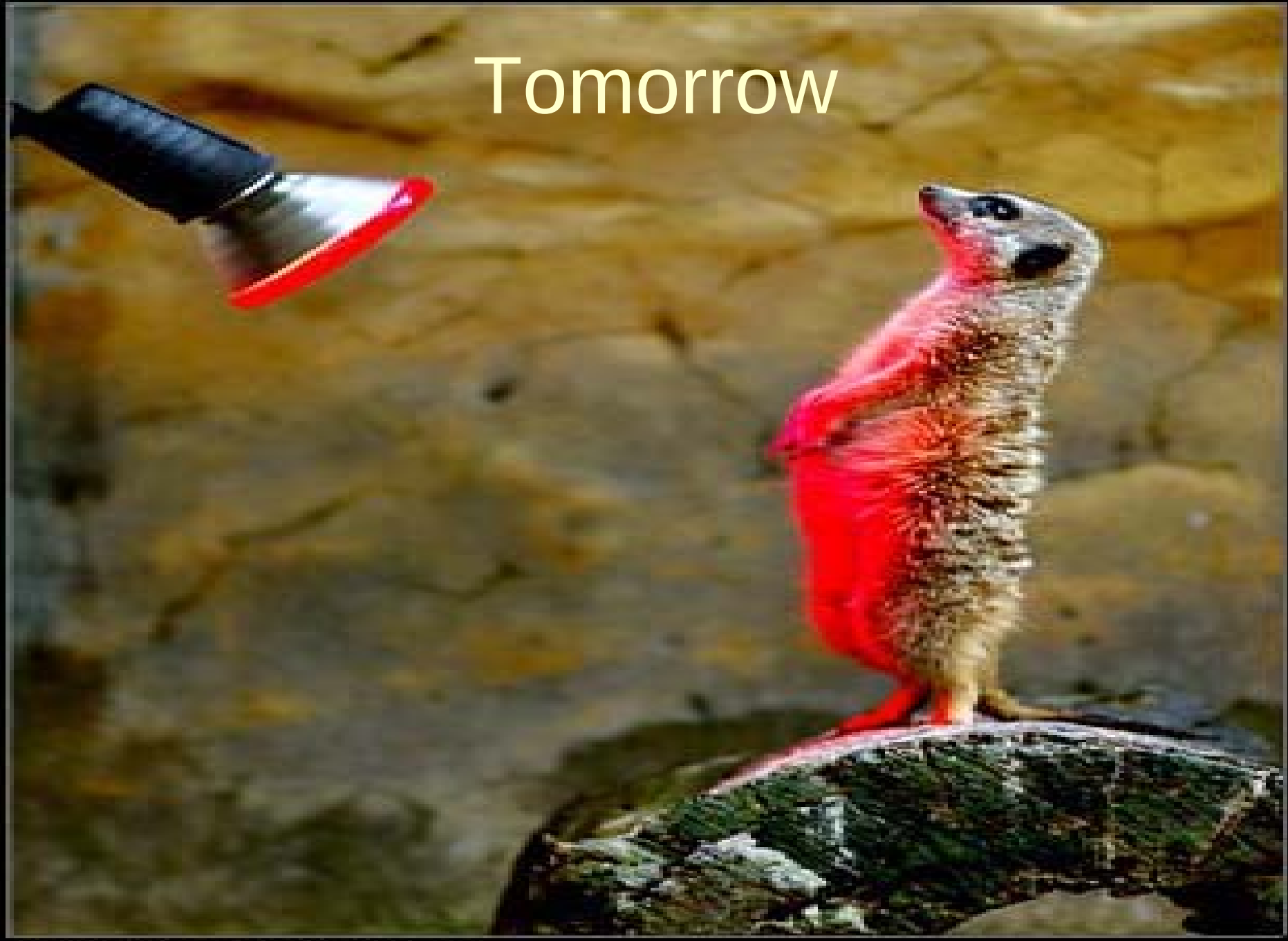
Potential Revenue Drivers

- Today
  - Data access
  - Data reports
  - Post market registries
- Future
  - Provide data collection and analysis for Manufacturer pre-market studies
  - NHLBI expanded studies
  - Establish subset of International registries

Potential Funding

- Societies (ISHLT, HFSA, STS/AATS, ACC)
- Industry
- Government (NHLBI, CMS)
- International government

Tomorrow



Will Burgess / Reuters

INTERMACS will feed

Those who govern

Those who treat

Those who create

To improve the duration and quality of life of patients with advanced heart failure.