

# Hoodia, a case study

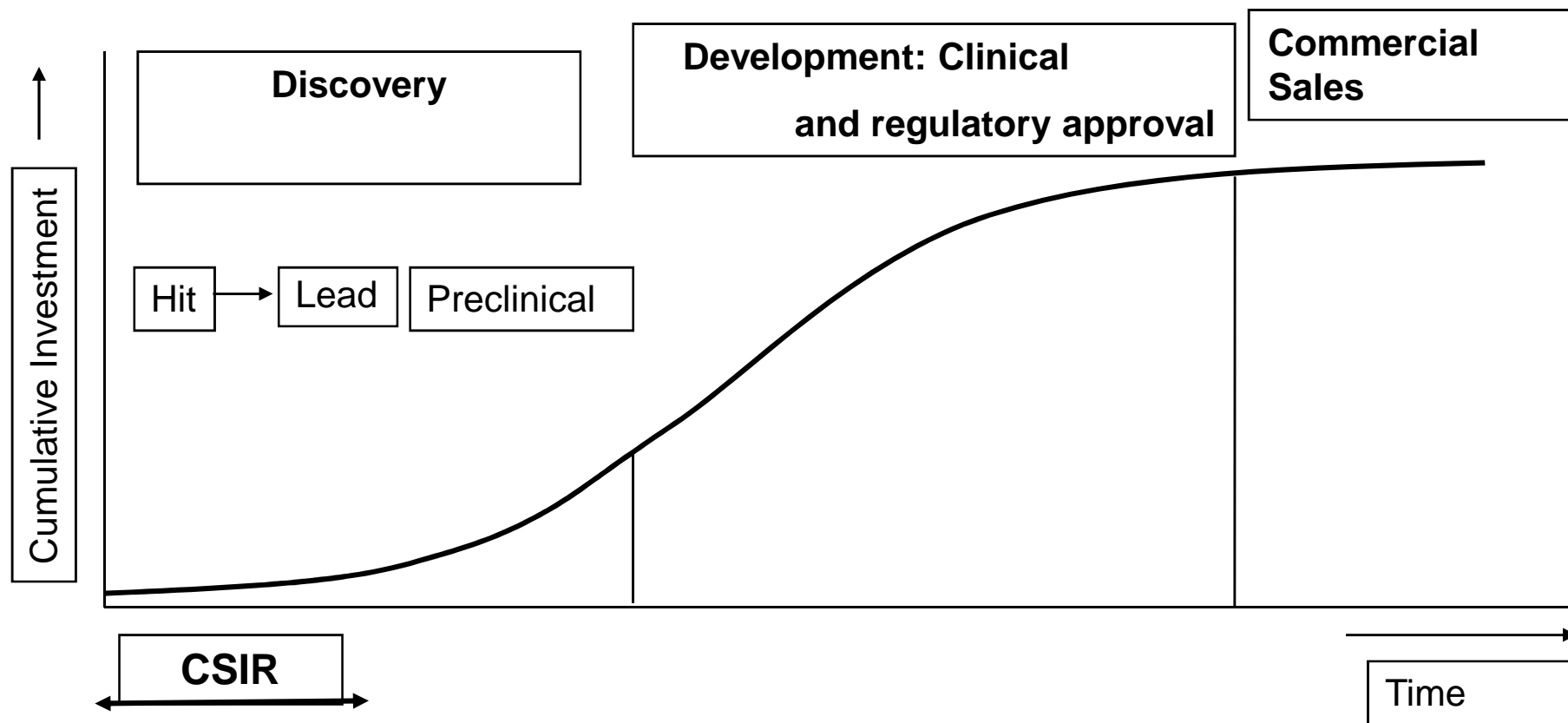
## 1963-2008

November 2008

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Research Group Leader  
CSIR, Biosciences



# Hoodia Development Cycle



# What is Hoodia?

Hoodia is a novel method of weight management derived from the Hoodia plant

- Based on formulations invented by CSIR
  - processed herbal extracts
  - purified chemical compounds or analogues thereof
  - synthetic or natural

# Hoodia:

## History of use

- Hoodia research was stimulated by traditional use of plant by San people
- Used by San people as substitute for food and water (Marloth, 1932: White and Sloan, 1937)
- Has an insipid taste and used to quench thirst (Pappe, 1862)



Hoodia in flower

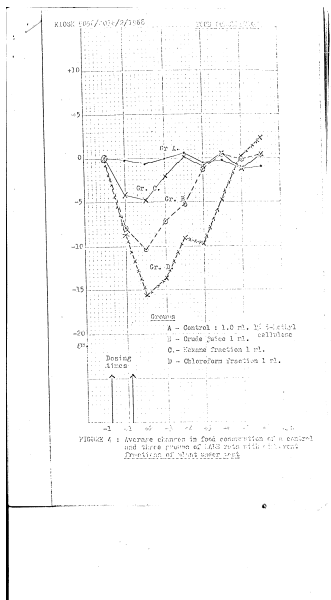
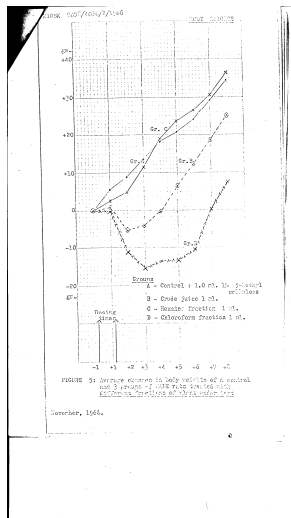


Hoodia in its natural habitat

# Hoodia: Early Research

1963-1971

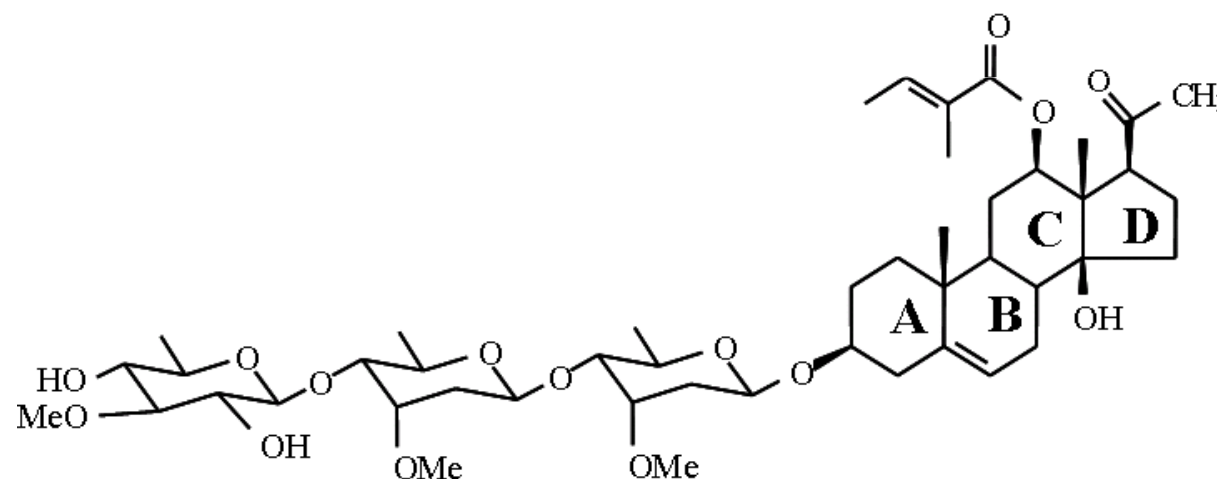
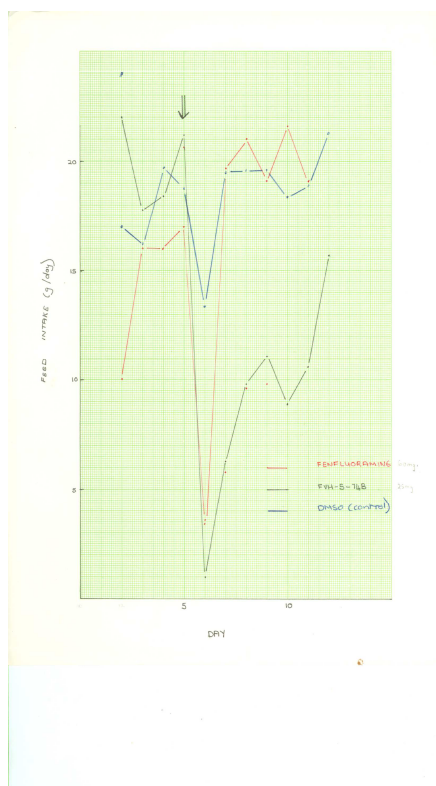
- NFRI of CSIR launched a project to investigate food from the “veld”
- Nutritional value and long term toxicity studies was the focus of study
- Hoodia was one of several 100 plants
- Prepared several extracts of the plant
- Extracts tested in rodents
- Appetite suppressant properties with weight loss
- No apparent side effects
- Data kept confidential



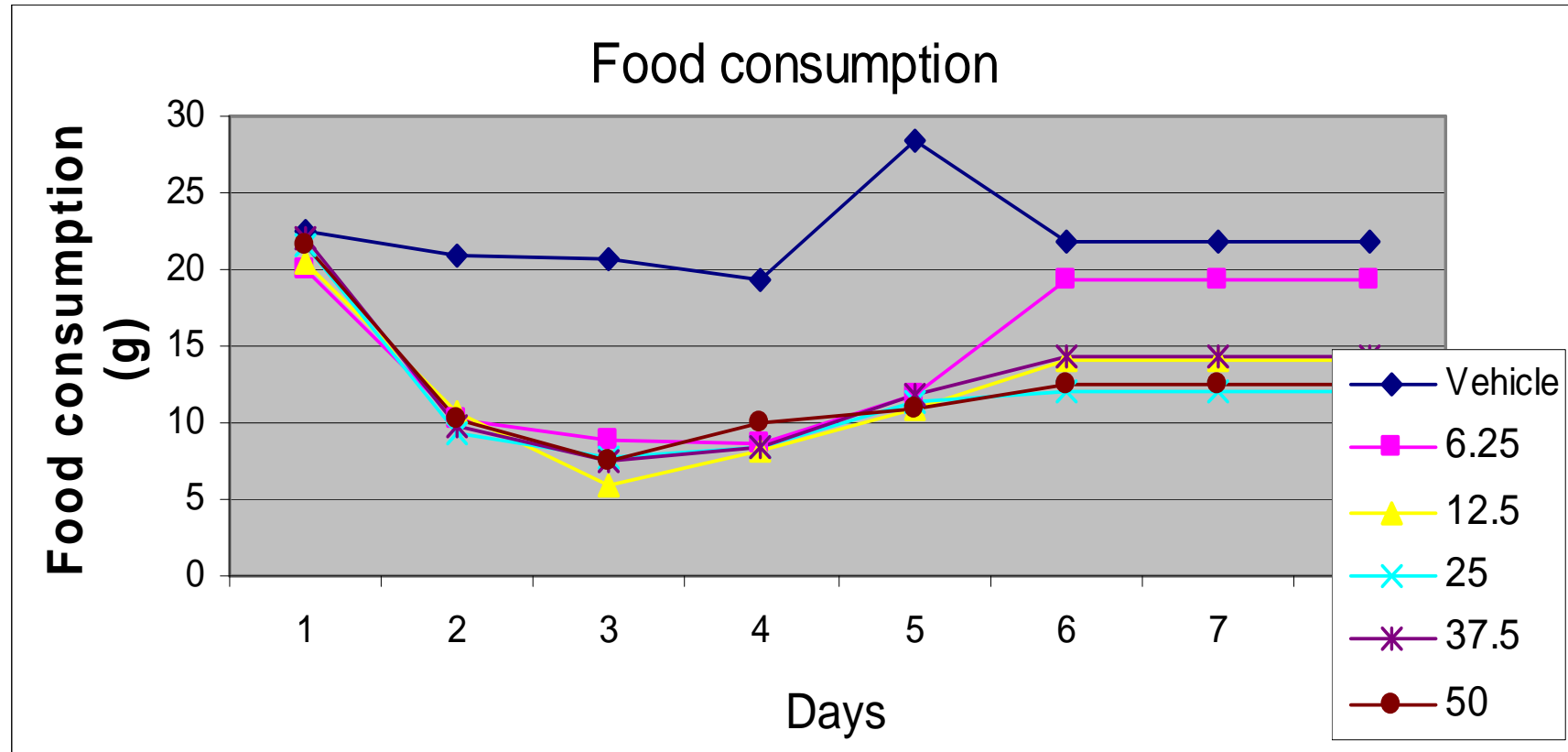
# Hoodia: Early Research

**1983-1986**

- Active isolated through bioassay guided fractionation
- Fractions tested in vivo
- Innovation made possible by acquisition of world-class instrumentation for structure elucidation



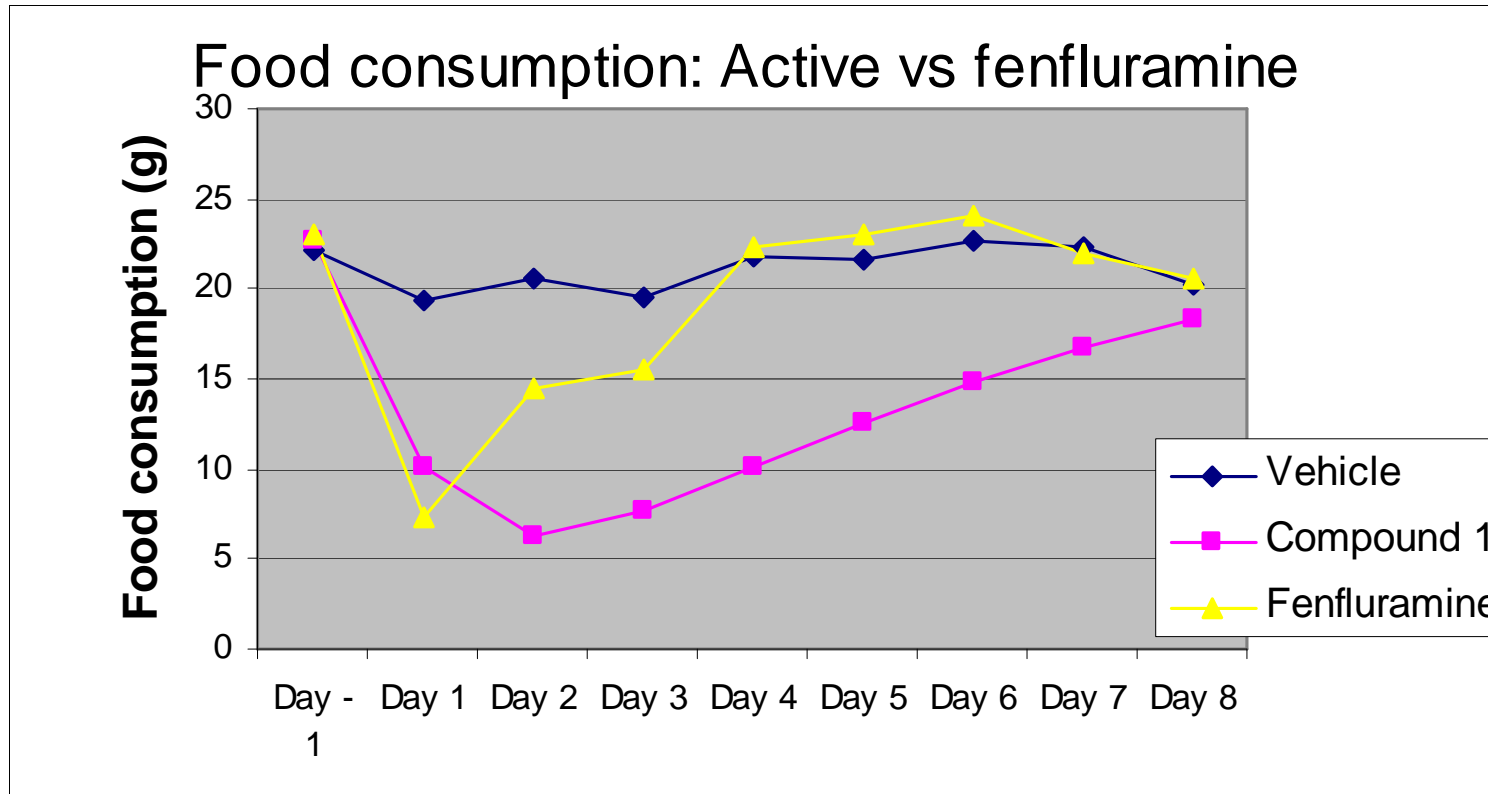
# Biological assaying



Dosage on days 1,2,3 given in mg/kg/day

Ref: *Phytochemistry*, 68, 2545–2553, (2007)

# Biological assaying



Dosage on days 1,2,3 given in mg/kg/day

- Active : 30 mg/kg
- Fenfluramine: 15 mg/kg

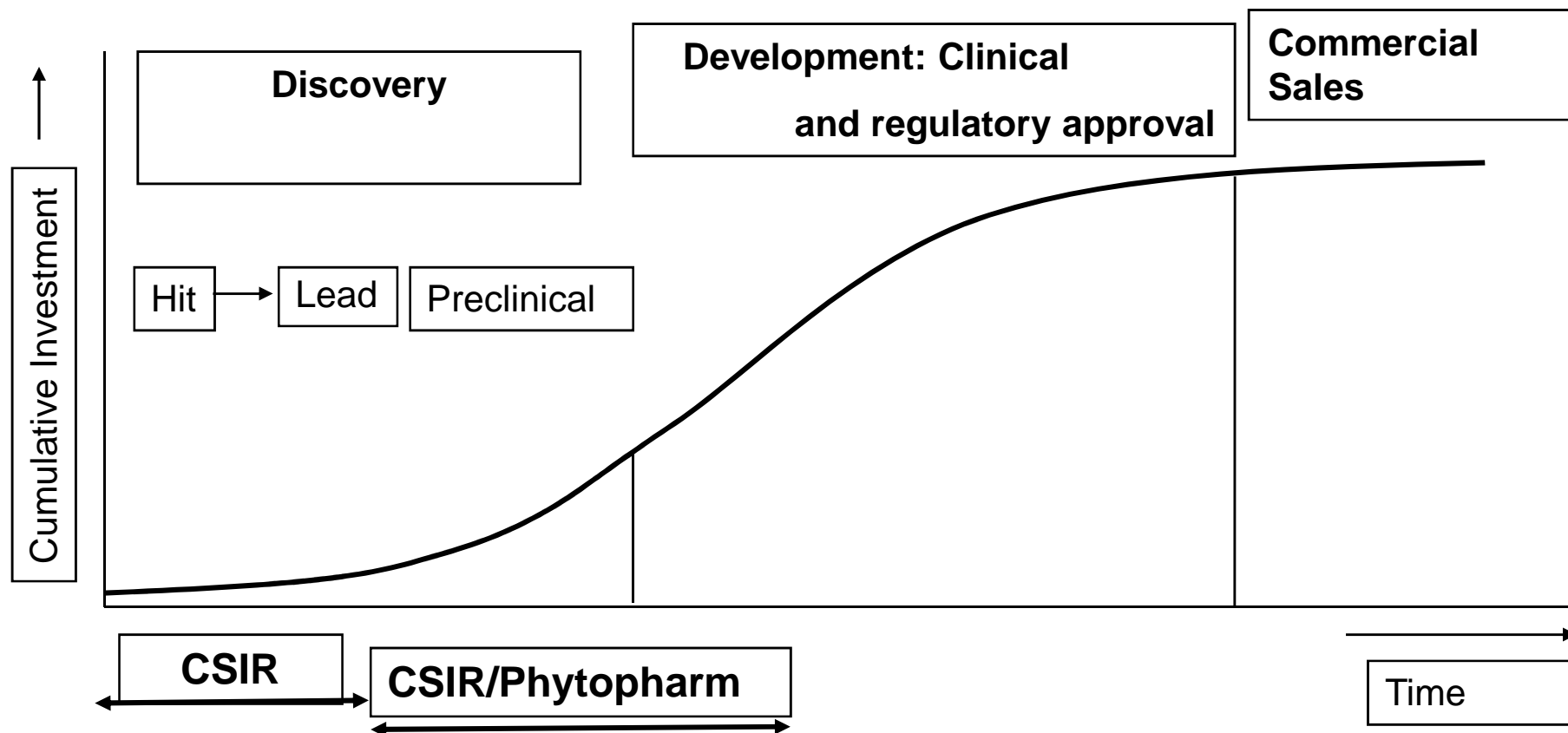


# Hoodia: Innovations

## 1990-1997

- Additional studies
  - Acute in vivo toxicity
  - Attempted synthesis
  - Efficacy confirmed in independent labs
  - Cultivation of plants with confirmation of active in plant extracts
- New formulation for obesity control invented and patented

# Hoodia Development Cycle



# Hoodia: Further development

- CSIR licensed patent to Phytopharm plc in UK
- CSIR/Phytopharm joint research programme focused on:
  - GMP manufacturing
  - Quality control
  - Safety and efficacy

# Hoodia: Manufacturing

- Botanical and Clinical Supplies Unit for the manufacture herbal extracts
- Manufacture extracts in compliance with GMP
- Material approved for clinical trials



Slide 12

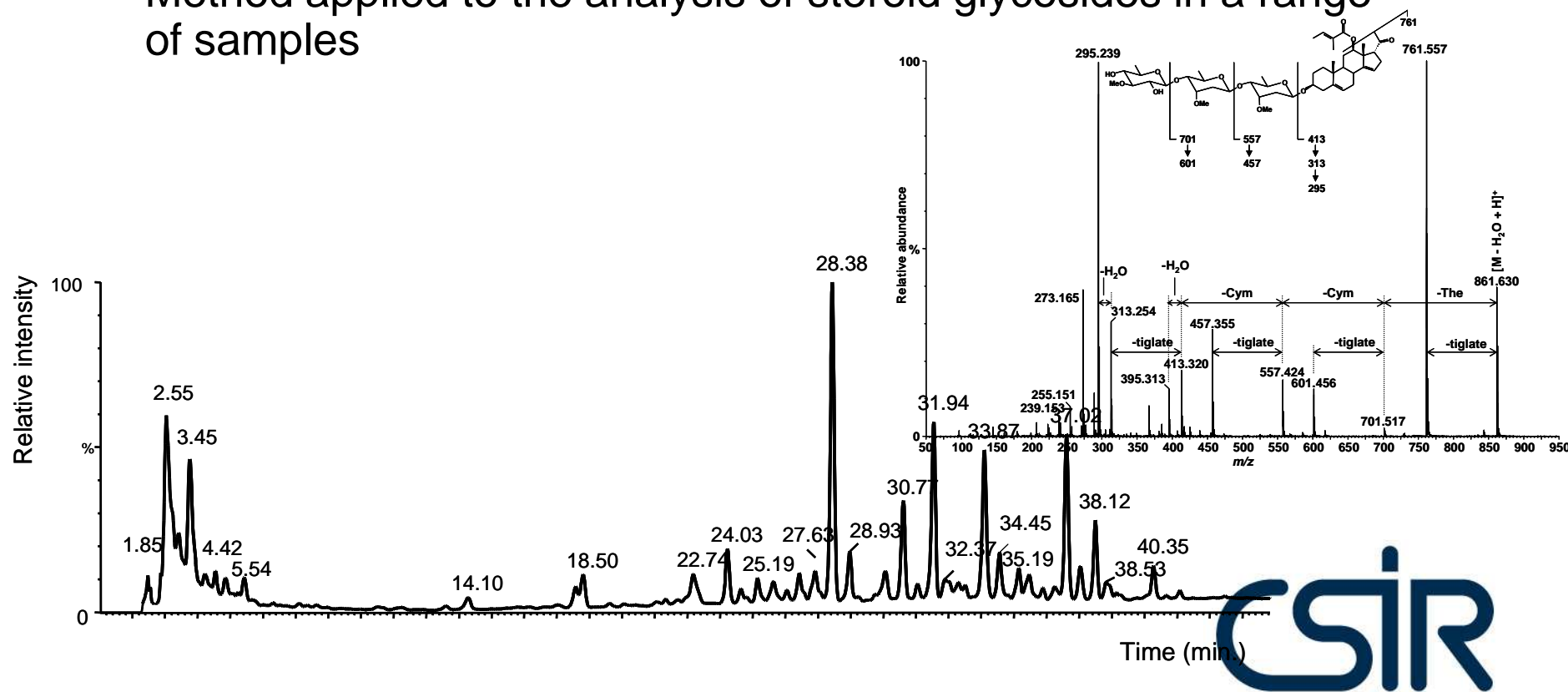
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# Hoodia: Quality Control

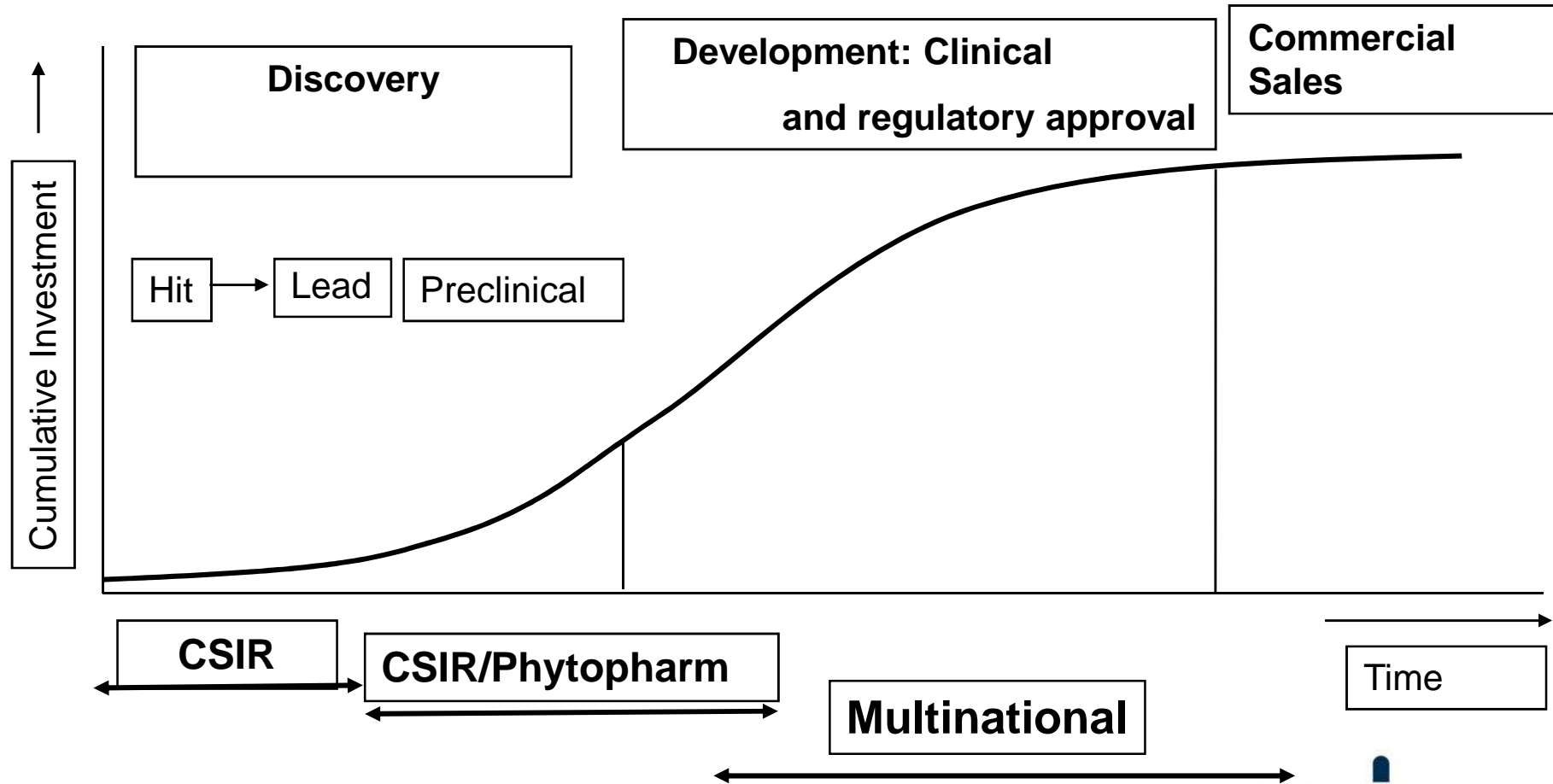
- HPLC method developed for the quantitative analysis of steroid glycosides
- HPLC MS used to confirm the compounds
- Method applied to the analysis of steroid glycosides in a range of samples



# Hoodia: Safety and efficacy

- Obtained preclinical data
  - Acute and chronic *in vivo* toxicology studies
  - pK data obtained
  - *In vitro* toxicology, metabolism
  - *In vivo* efficacy, 2 animal species

# Hoodia Development Cycle



# Hoodia: Further development

- Phytopharm further on licensed to Pfizer for further development and commercialization
- Completed early clinical studies
- Pfizer discontinued clinical development



# Hoodia: Further development

- Phytopharm sub-licensed to Unilever
  - Currently in development as a food ingredient for weight management
  - Safety and clinical studies on-going
  - Establishing a supply chain for product
  - Expect a commercial product in 2-3 years

# Hoodia cultivation-Supply Chain



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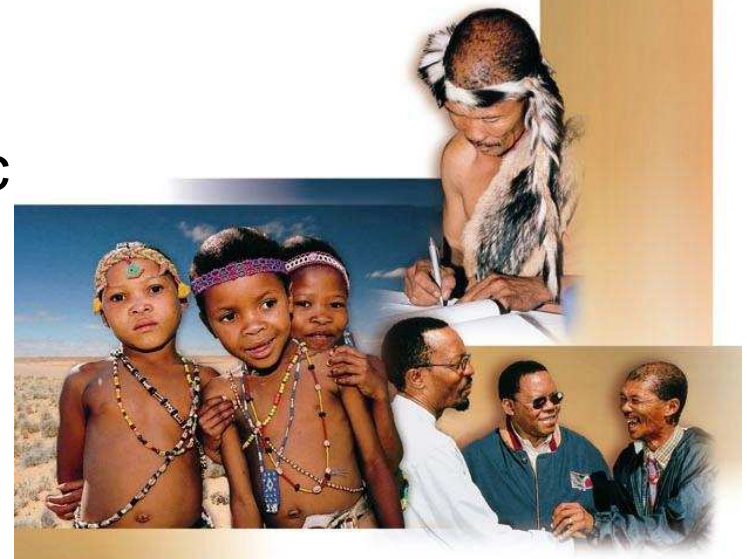
# Indigenous Knowledge & the CSIR/San Agreement

“..San people are custodians of an ancient body of traditional knowledge ...related inter alia to human uses of the Hoodia plant ...”,

“The CSIR acknowledges the existence and the importance of the traditional knowledge of the San people, and the fact that such body of knowledge, existing for millennia, predated scientific knowledge developed...”



S A San Council visits CSIR facilities



# CSIR/San Agreement: Numbers

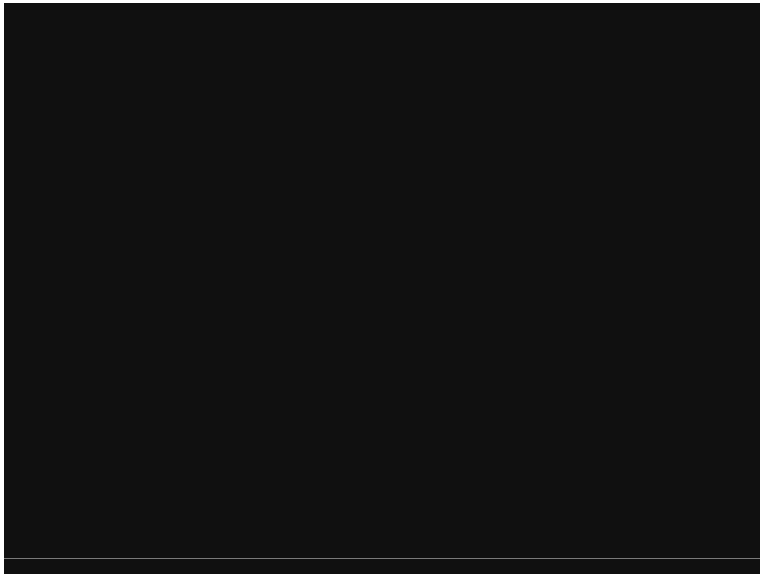
CSIR and San agreed for CSIR to pay **eight percent** of all **milestone payments** it receives from its licensee, UK-based Phytopharm plc, as well as **six percent** of all **royalties** that the CSIR receives once the drug is commercially available.

Potential income into a San Hoodia Benefit Sharing **Trust**  
**Trustees include:**

- SA Department of Science and Technology
- CSIR
- San Representatives (≠ Khomani, !Xun, Khwe)
- Other San in the southern African region
- Working Group of Indigenous Minorities in Southern Africa



# Hoodia Licensing: Benefits to SA



- Full involvement of South African scientists in development
- Transfer of state-of-the-art phyto-medicine production technology to South Africa

- Potential royalty revenue through licensing of patented technology; milestone payments linked to clinical trials
- Global recognition of SA's innovation capacity
- Agroprocessing businesses established in SA for both commercial and community farmers





# Summary of events

1963	CSIR includes <i>Hoodia</i> in research project on edible plants, based on ethnobotany
1971	<i>Hoodia</i> project mothballed, insurmountable technical problems
1983-1986	Technological advances. Scientific breakthrough at CSIR leads to discovery of active ingredient in <i>Hoodia</i> .
1986-1996	CSIR continues development of <i>Hoodia</i> , files world-wide patents to protect its invention of novel method of obesity control.
1997	CSIR licenses Phytopharm for further development of Hoodia
1998	CSIR publishes its Bioprospecting Policy, guaranteeing sharing of benefits with owners of Indigenous Knowledge
1998	Phytopharm sub-licenses Pfizer to complete Hoodia clinical development, obtain regulatory approval and commercialize

## Summary of events cont.....

1999	CSIR signs historical bioprospecting agreement with South African Traditional Healers, invited by UN to present details at Lyon Summit on Trade and Development
2001	UK newspaper reporter questions CSIR-Phytopharm-Pfizer collaboration, without involvement of San
2002-2003	CSIR and San meet regularly to share Hoodia information; involve independent experts in workshops; negotiate benefit sharing agreement
24 March 2003	CSIR and San sign Hoodia benefit sharing agreement
2003	Pfizer discontinues clinical development
2004	Phytopharm sub licenses Unilever to continue development
Today	Hoodia being developed as a food ingredient for weight management



# Thank you!

