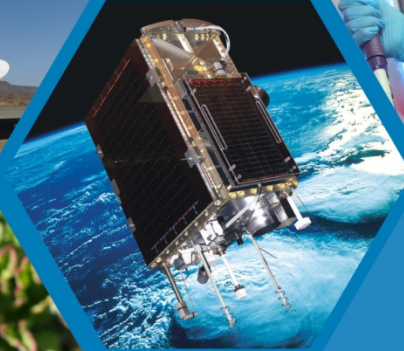


# Building API manufacturing in South Africa



science  
& technology

Department:  
Science and Technology  
REPUBLIC OF SOUTH AFRICA



# Problem

- Rise of low price generic manufacturers in the Asia Pacific regions
  - China dominating the fine chemicals sector - critical intermediates, reagents, high quality solvents and packaging
  - Indian dominate the API side
- Since 2006 SA government concerned about the security of supply of ARV APIs & high cost to the fiscus.
- Initiated concerted effort to attract global API to establish operations in the country.
- Despite incentives such as grants, tax rebates, co-funding and preferential offtake agreements -- little success was achieved
- Some API capacity: Fine Chemicals Corporation and emerging new API manufactures: Chemical Process Technology Pharma and Inicio.





# Challenges

- **High cost of local manufacturing**
  - High cost of equipment (glass lined vessels, valves, instruments, purification units, etc) due to lack of local engineering and manufacturing capabilities
  - dire shortage of process and project engineers & construction companies experienced in API (cGMP) plant
  - Waste regulations in South Africa contribute to both high capital and manufacturing (waste mitigation) costs.
  - nearly all reagents, intermediates and specialized solvents would have to be imported from far off regions at high logistics costs.
- **Lack of national API focus**
  - needs to demonstrate capability in either producing new/modern APIs cost competitively or achieves radical innovation in existing high demand APIs
  - silo approach by researchers (own publications, patents or pet projects)





# Challenges

- **Lack of relevant skills**
  - process chemistry, process engineering (cGMP standards), project engineering, project management, process operations, maintenance and process quality control and assurance.
  - platform for skills development - to enable a sustained pipeline of multidisciplinary skills for the envisaged API industry expansion.
  - entrepreneurial thinking
  - attract young talent in establishing niche businesses within the API manufacturing sector.
- **Small local market size**





# Options

**Strategy A:** Attract large API manufacturers to establish manufacturing capabilities in South Africa.

- Tried with little success
- main hurdles: high cost of investment, manufacturing costs and lack of skills
- IF want to pursue: much attractive incentive basket that address key investment decision drivers, e.g.
  - dedicated API and fine chemicals industrial park with pre-approved environmental license,
  - established infrastructure -- central waste processing facilities,
  - competitively priced and secure utilities supply,
  - fast tracked licenses and approval processes,
  - skills incentives and expat support,
  - capital incentives, manufacturing rebates, export incentives and other tax incentives
- However will need additional support: operational cost subsidies or rebates, price premiums and/or preferential procurement





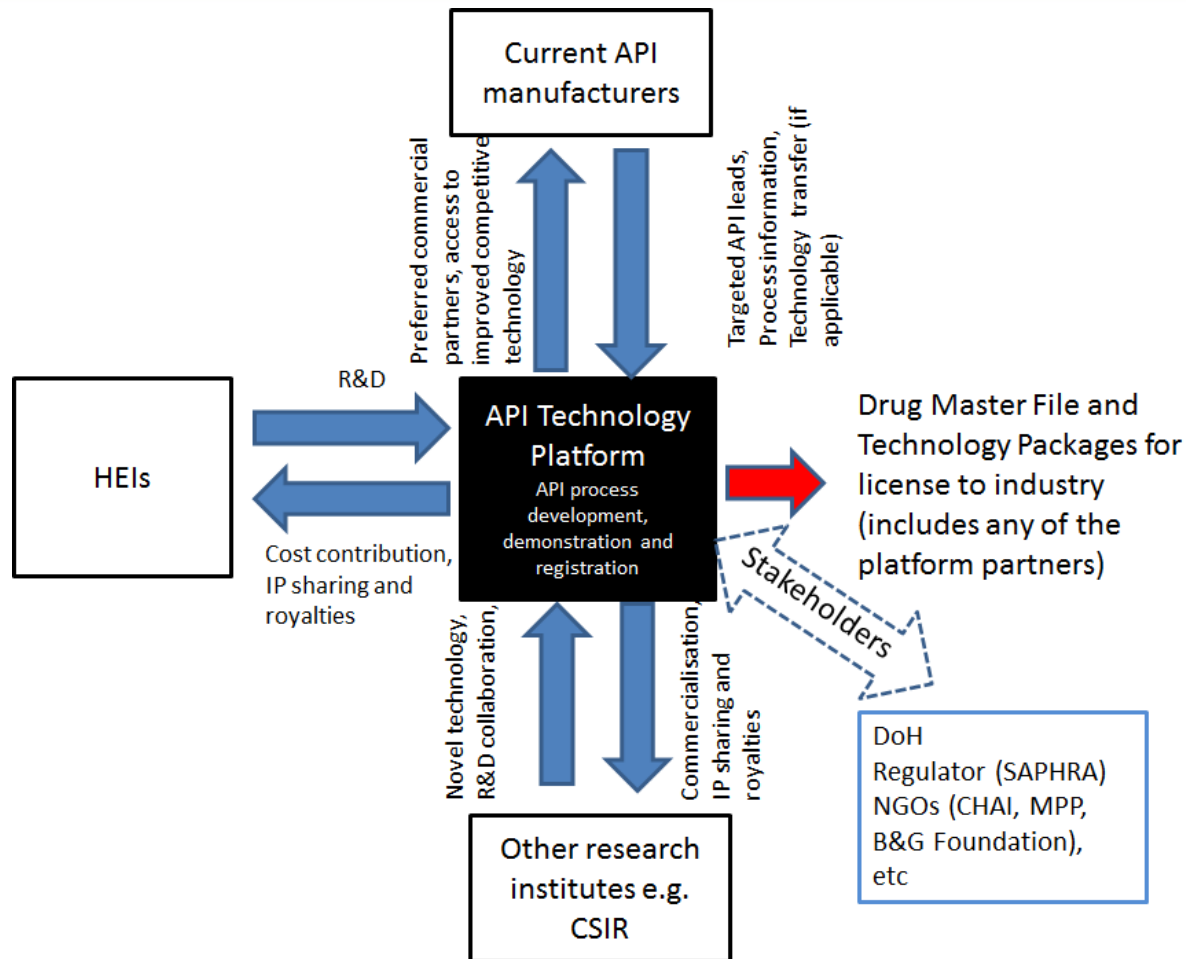
# Options

**Strategy B:** Adopt an aggressive home developed technology strategy which can be used to lever collaboration and partnership with large multinational API producers.

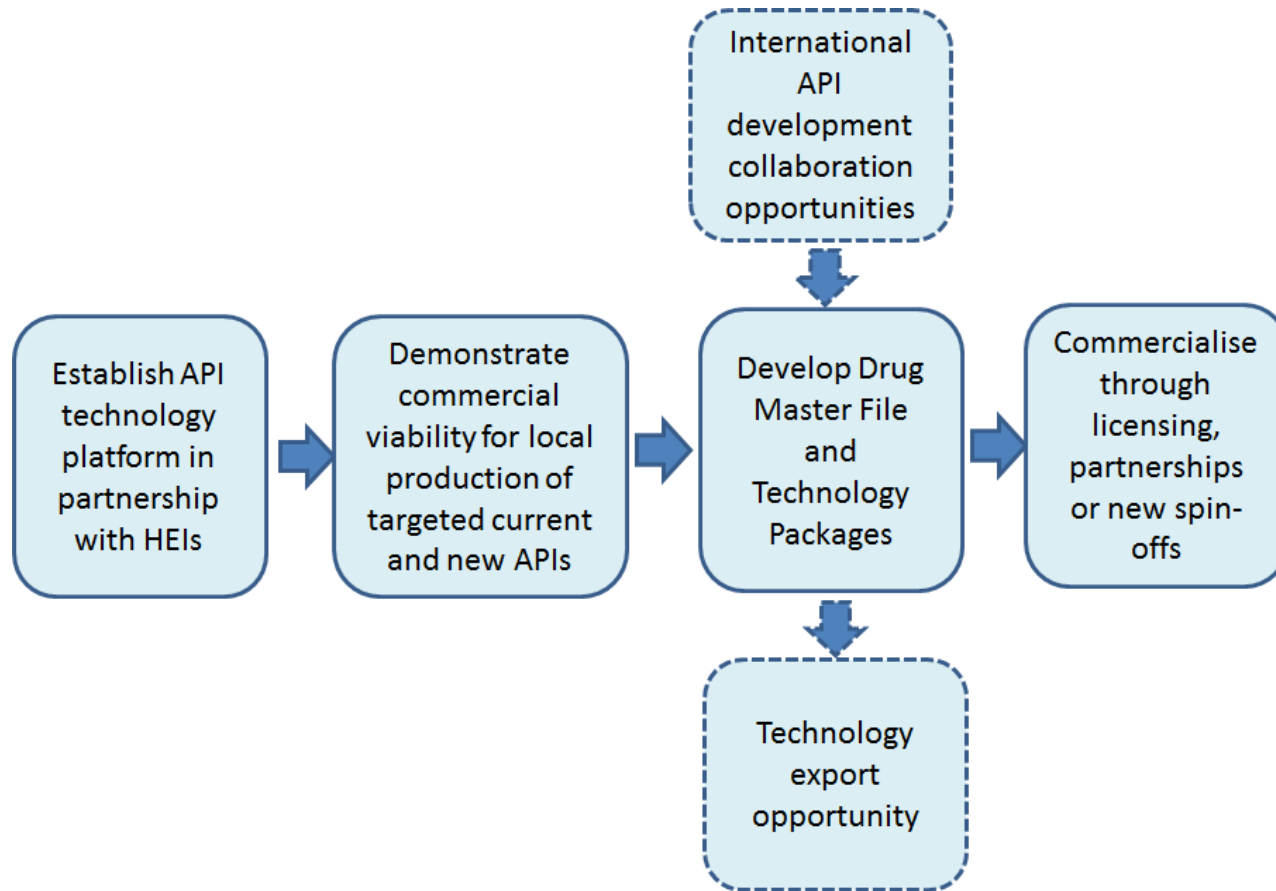
- realigning current capabilities residing at various HEI and other research institutes towards a focused API process synthesis and engineering platform,
- developing drug master file for competitive manufacturing of targeted APIs
- leveraging this to set-up a commercial pipeline for local API manufacturing



# Envisaged platform and main role-players



# Proposed API development model for South Africa







*NRF,  
DST special  
project.  
Company  
sponsored*

**Current academic program (Universities)** **A**

- Basic synthetic chemistry
- Drug discovery
- Drug delivery
- Therapeutic drug monitoring for treatment design
- QA development ?

*SPII  
TIA  
NIPP (investment and subcontracting, tech transfer)  
Revenue through contract manufacturing and niche sales*

*Black Industrialist Program,  
IDC, NEF  
NIPP, dti grants and IPAP instruments,  
SADC Pharma Development priority*

*TIA,  
Provincial funding instruments e.g. EDTEA (KZN),  
Focused DST project*

**API technology development platform** **B**

- 50/50 eng/Sci driven **process** development program
- Target new APIs or ones with supply risks
- Demonstrate current commercial patented route.
- Develop new optimised routes – competitive advantage
- New technologies (flow chemistry) – competitive advantage
- Waste elimination, recycling, re-use
- Contract research and process development
- Engineering and commercial focused

**National cGMP Pilot Plant (CoC)** **C**

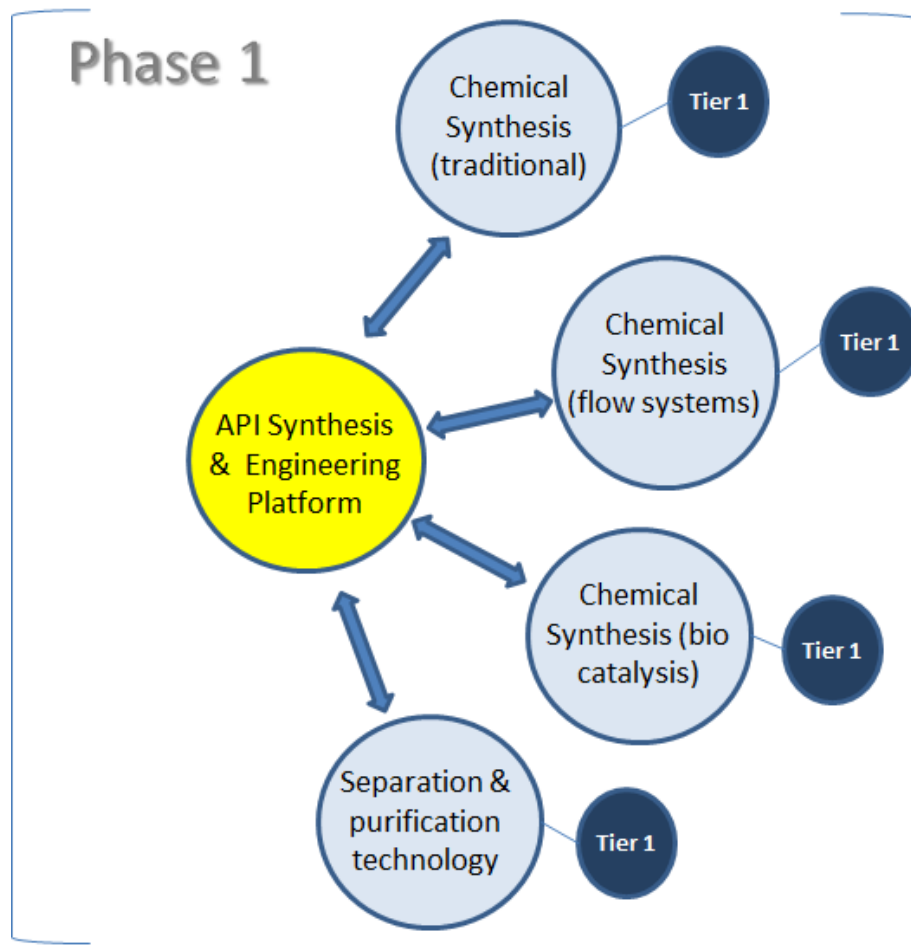
- Technology demonstration
- Tech transfer for tech licensing
- Post tech acquisition development
- Product and process registration
- Small scale production for clinical trials and niche sales
- Niche contract manufacturing – APIs and intermediates
- Contract process scale-up work

**Commercialisation** **D**

- New start-ups or spinoffs leveraging black industrialist and NEF programs
- Partnership with local and international industry players
- Optional state participation
- Toll manufacturing for originators based on new process engineering developed



# API technology platform phase 1 strategy



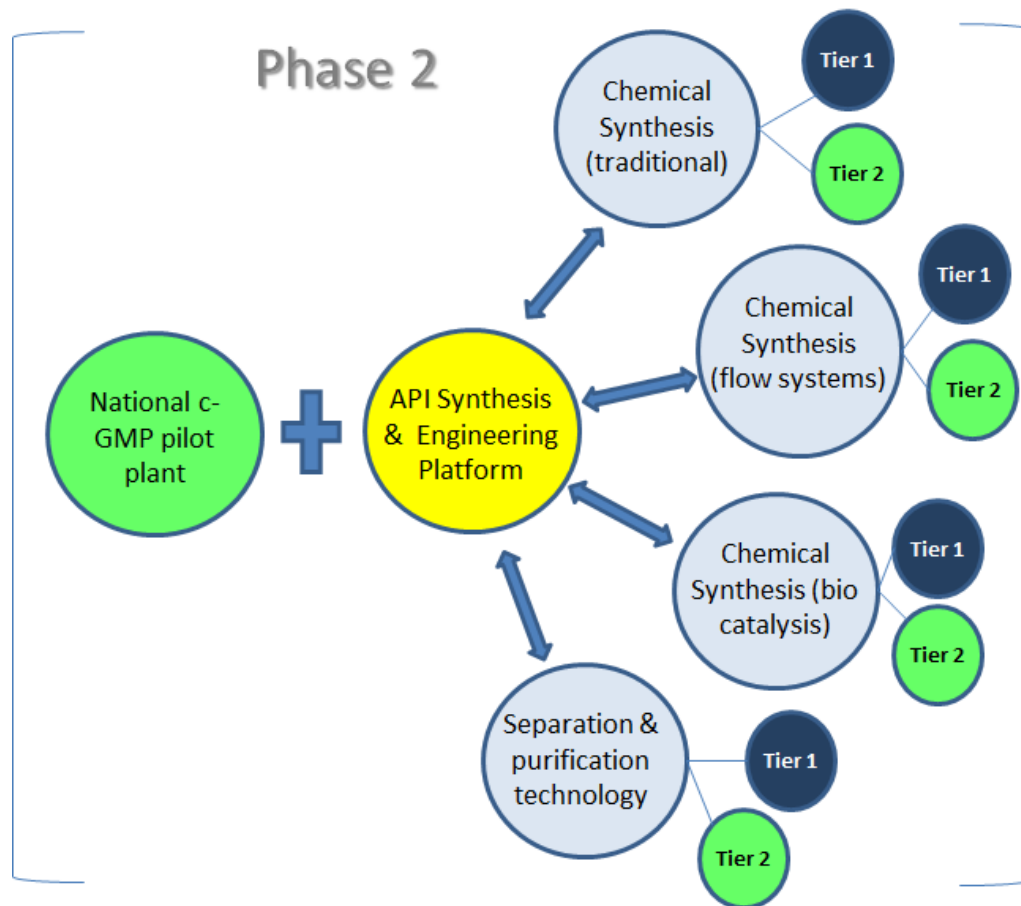
## Aims

- Establish the API tech platform
- Establish desired network with synthesis research groups (Tier 1) and develop tech development distribution model
- Test candidate API screening process

## Outputs

- Process synthesis technical report (TRL-3) of nominated APIs.
- Proposal on national pilot plant strategy.

# API technology platform phase 2 strategy



## Aims

- Incorporate Tier 2 players into the platform
- Establish national cGMP pilot plant
- Promote platform for collaboration with industry players
- Promote platform for collaboration with international API research groups

## Outputs

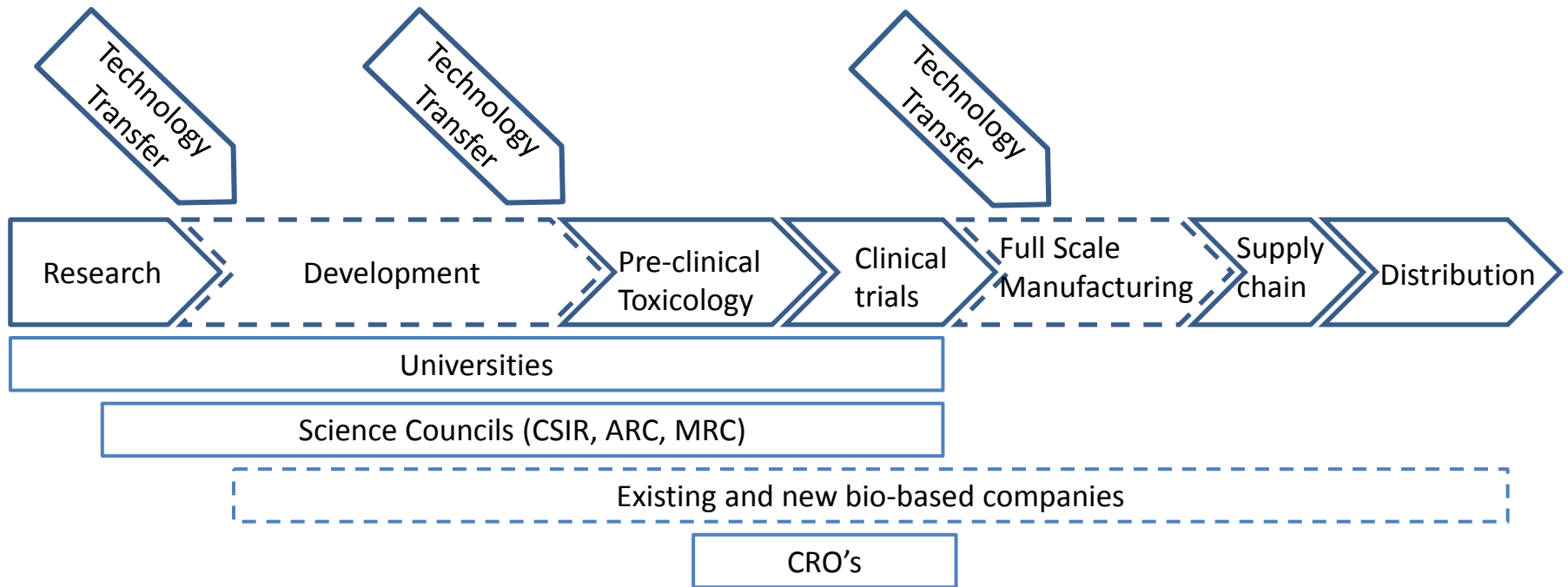
- Drug Master Files
- Process synthesis technical report (TRL-3) of at least 2 nominated APIs.
- Proposal on pilot plant strategy.



# Vaccines and Biologics



# South African Vaccines and Biologicals Value Chain and its Players



--- Areas that need optimisation

