EPTRI underpins medicines development for Paediatric Clinical Studies

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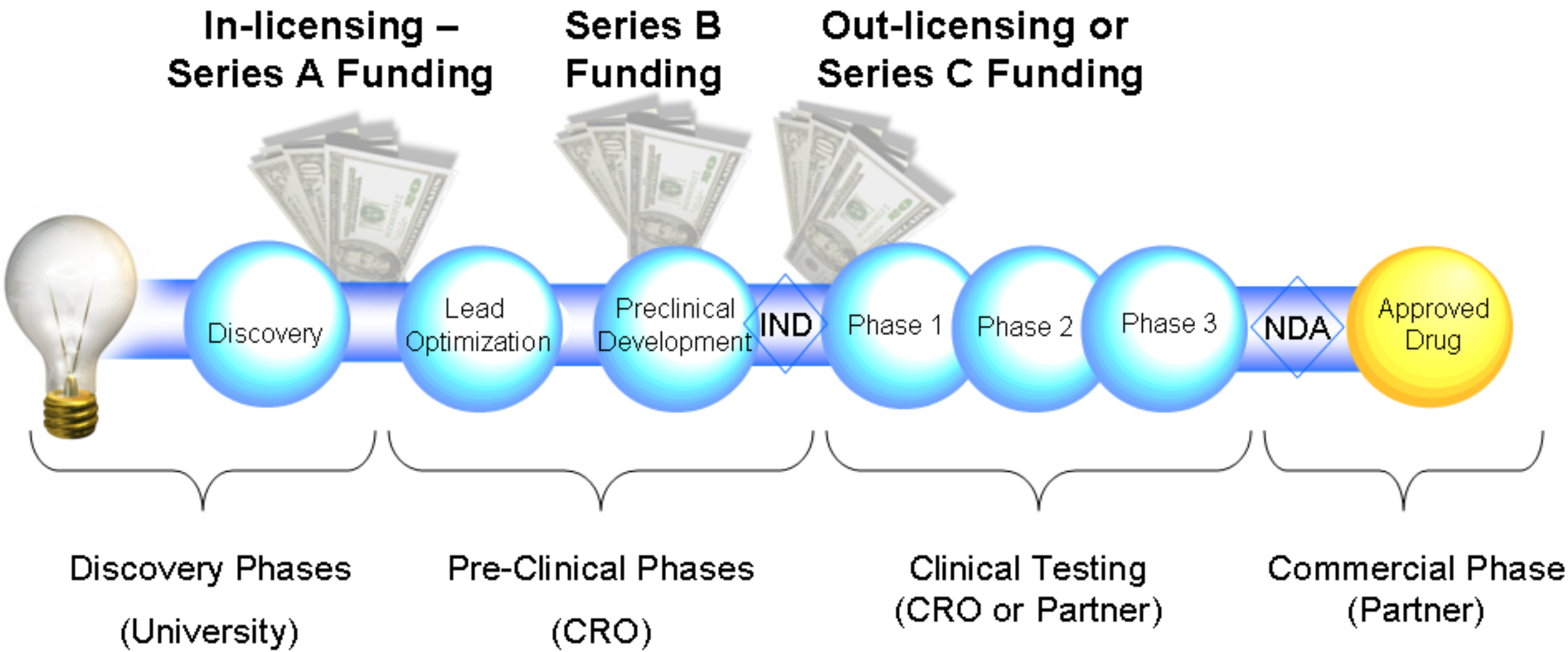
Key Points

- Medicines development has multiple steps
- Each step needs to be:
  - High quality
  - Coherent with other steps
- The current fragmentation leads to:
  - Missed opportunities
  - Inefficiency
- EPTRI will work with other groups to overcome fragmentation

Drug Development Pipeline



https://www.amethystls.com/biotechpro.shtml

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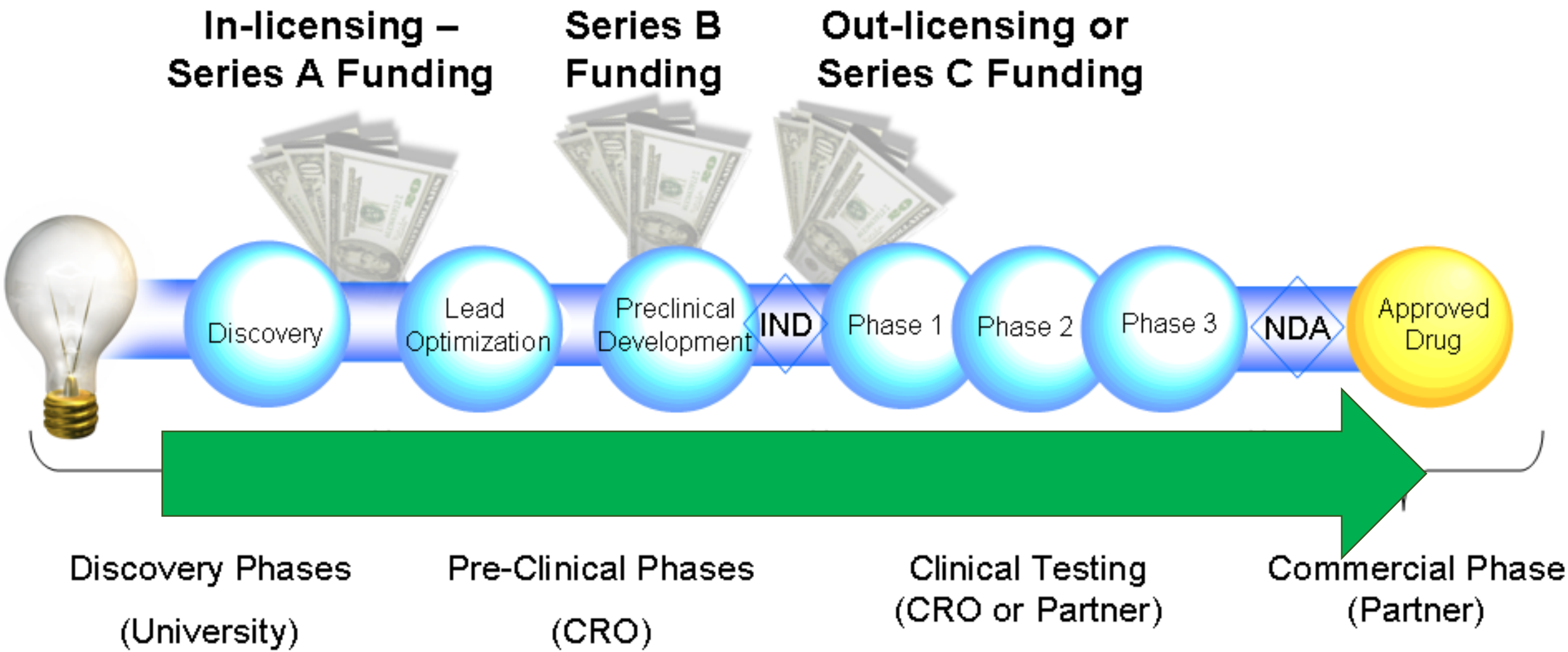

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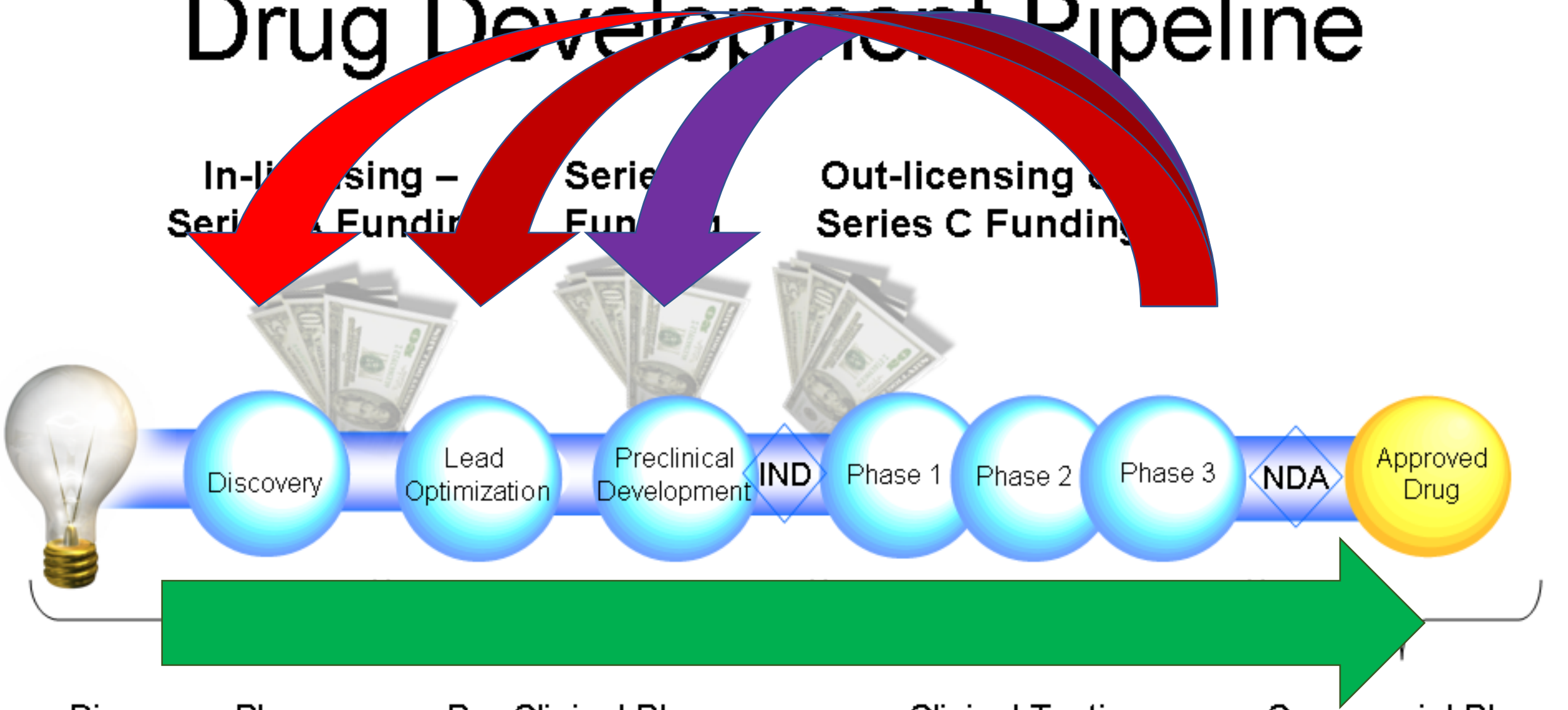

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EPTRI can support clinical studies in two ways

1. Apply underpinning research to clinical studies
2. Use clinical understanding to shape underpinning research

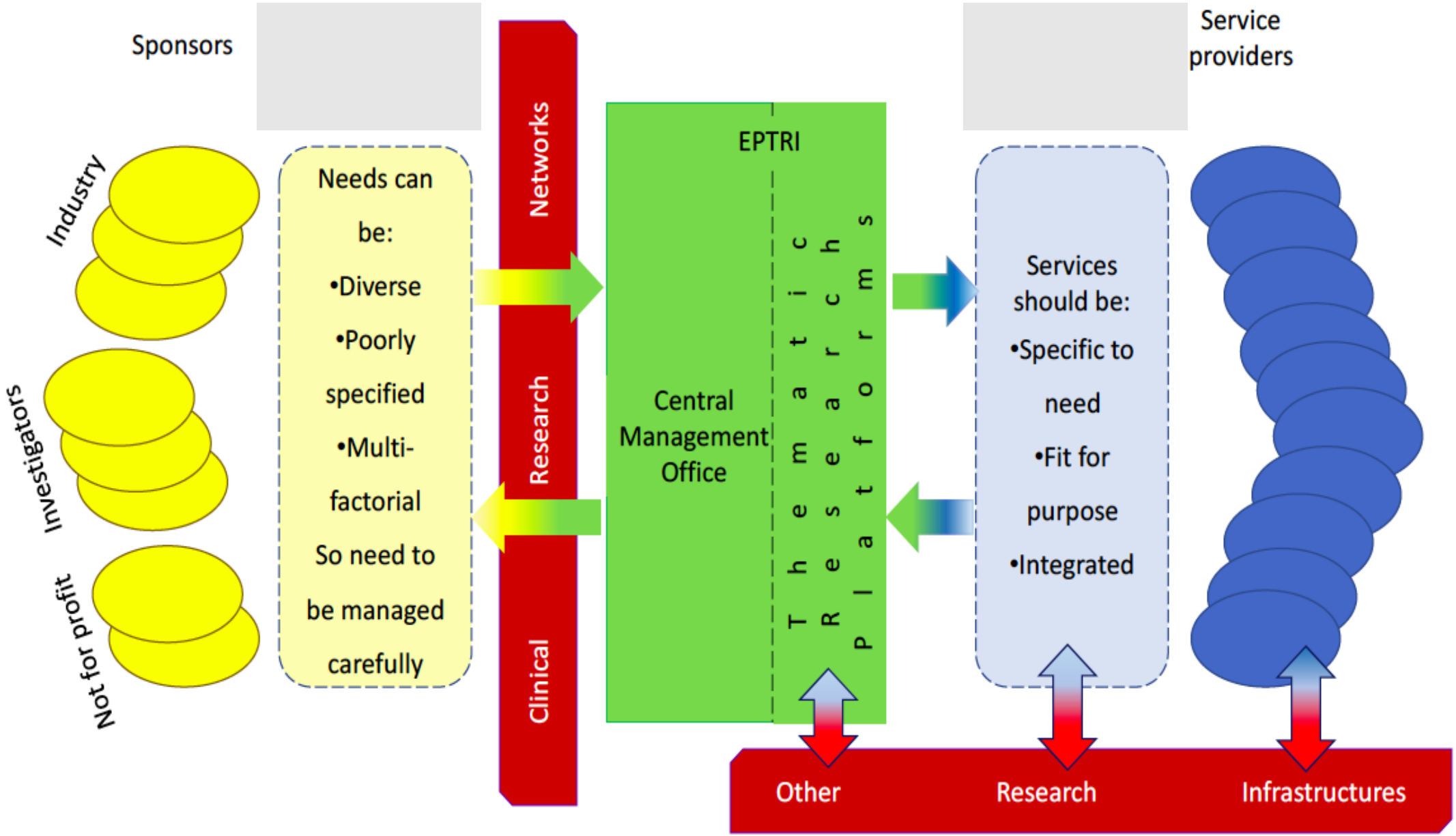
This support will be:

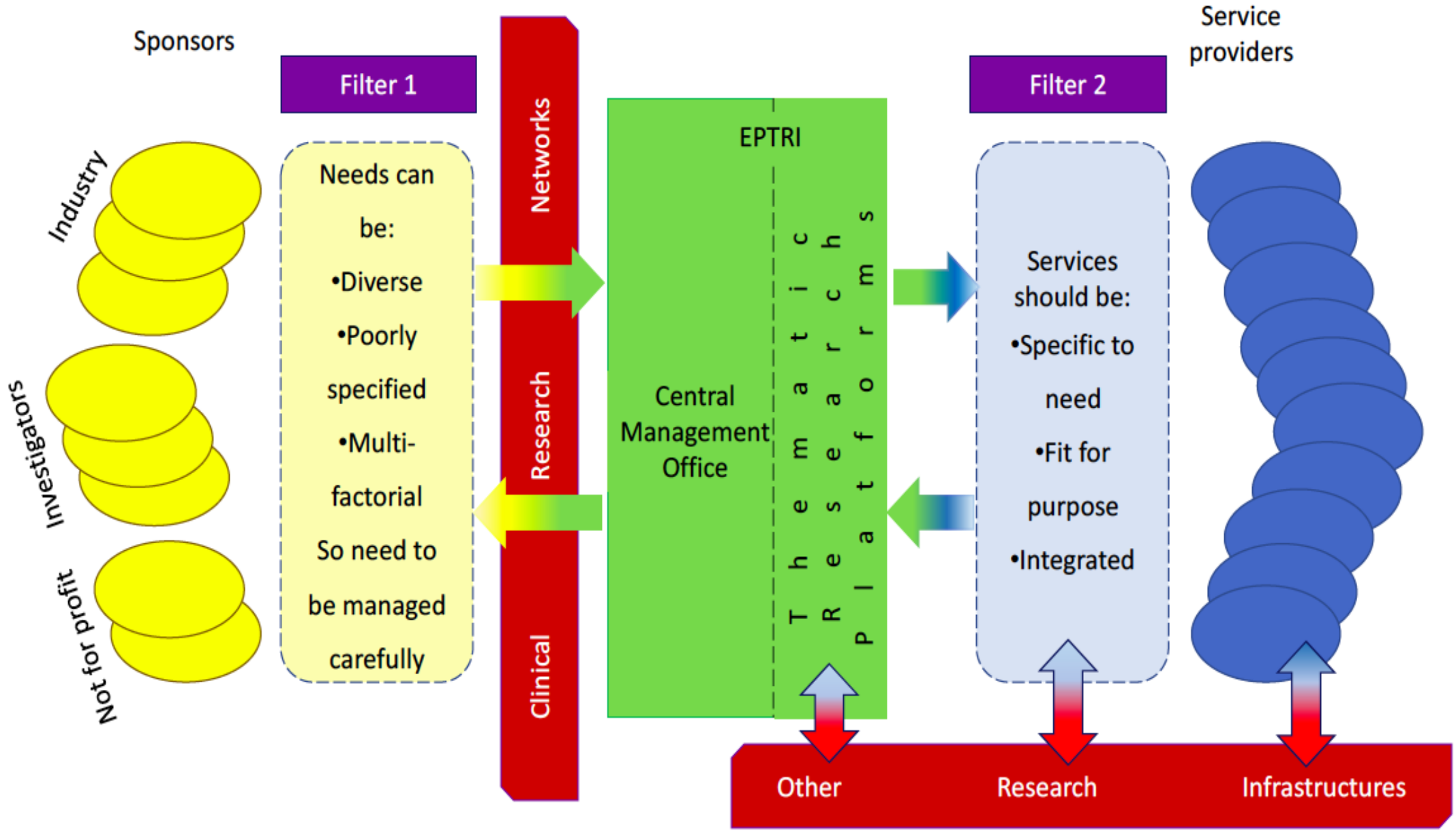
a) Information sharing

b) Introductions to expertise

c) Mediating collaborations

EPTRI will receive requests from many sources including individuals and organizations, including commercial entities.


Sponsors
Service providers
Industry
Investigators
Not for profit
Needs can be:
•Diverse
•Poorly specified
•Multi-factorial
So need to be managed carefully
Networks
Research
Clinical
EPTRI
Central Management Office
Thematic Research Platforms
Services should be:
•Specific to need
•Fit for purpose
•Integrated
Other
Research
Infrastructures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EPTRI Policy Principles for interfacing with clinical studies

- D9.1, D9.2, and D9.5 suggest that EPTRI will:
  - 1. Work on specific requests from Investigators
  - 2. Address the specific issues identified by Investigators, supplemented with relevant issues identified by EPTRI
  - 3. Work with other initiatives that act beyond EPTRI's scope

EPTRI will follow these operational principles:

1. EPTRI will share information and expertise relating to a request in a timely, specific and appropriate way
2. EPTRI processes relating to clinical studies will be moderated to ensure the correct information is passed between Investigators and EPTRI service providers
3. Responses to Investigators from EPTRI service providers will have action plans (who, what, when) that are monitored by the EPTRI CMO (Central Management Office), according to single service contract signed by Investigators, Service Providers and EPTRI
4. At the request of Investigators and/or Service Providers, EPTRI may integrate the part or all of the responses from Service providers
5. EPTRI will not manage relationships between Investigators and Service Providers once contracts are made
6. EPTRI will identify and capture value that arises from collaboration, including intangible costs
7. EPTRI will develop and act according to agreements with other relevant initiatives and RIs

EPTRI CMO will:

1. Act as single point of contact for requests from information about science that underpins clinical trials
2. Conduct filtering, moderation and triage of requests from Sponsors/Investigators
3. Broker relationships between Sponsors/Investigators and EPTRI Service Providers, through interactions with EPTRI TRPs
4. Coordinate and integrate responses

EPTRI CMO will forward any requests relating to clinical aspects of to its centralized services and/or one or more relevant clinical research network according to existing agreements.

EPTRI TRPs will:

1. Contribute to filtering, moderation and triage of requests from Sponsors
2. Identify relevant Service Providers and support the CMO when the CMO asks for experts to work on requests from Sponsors/Investigators
3. Assist the CMO to select which Service Providers are passed to the Sponsor/Investigators
4. When relevant, assist in the integration of responses from multiple Service Providers
5. Review performance of Service Providers

EPTRI research units acting as Service Providers will:

1. Work to pre-specified standards for work done through EPTRI
2. Use best endeavours to meet the needs of Sponsors/Investigators
3. Recognise that the information they provide is linked to expertise within EPTRI and TRPs

Dimensions of success for EPTRI

1. Depth and breadth of brokerage – geographically, across clinical specialties, across methodologies, including nurses, study coordinators and all relevant disciplines
2. Process of brokerage – timely, user-friendly, effective
3. Moderation and curation of brokerage – identification of added benefits through structured sharing that is specific to the needs of the clinical study team and to paediatrics
4. Cultural aspects of working with, through and for EPTRI: shared norms and communication

Critical Success Factors

- Accurate parsing of requests to provide specific information about core services (introductions), framework and added benefits
- Timely involvement of people who can provide useful input about cultural and pragmatic aspects of specificities of research that recruits children
- Relevance of content provided to Sponsors
- Rapid communication, even if only to explain what is happening
- Integration of inputs to Sponsors by EPTRI services and individuals / organizations that contribute to those services
- Relationships with clinical research networks that add value to the Sponsor and clinical research network

Conclusion

- Content is important
- Process needs to be fit for purpose
- Appropriate governance is needed

Principles can be defined: detailed work is now needed