

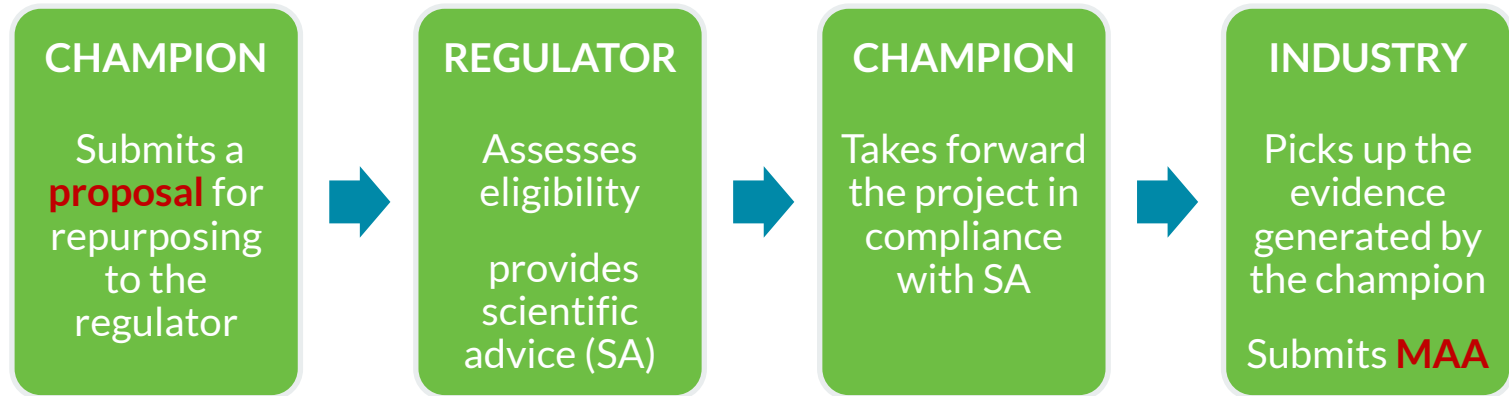
PILOT for the repurposing framework

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OVERALL AIM

Assessment of the proposed framework





OBJECTIVES

- Test run the framework with real life examples
- Evaluate the added value of the framework
 - for public health: societal relevance?
 - for stakeholders??

Stakeholder specific objectives

- Clarity of the core components: need for specific repurposing guidance?
- Feasibility of getting access to the required information
- Willingness of key clinical investigators to collaborate
- Applicability of databases to identify MAH

champion



- Identification of potential candidates for label extension
- Existing SA route: applicable for “unexperienced” champion?
- Quality and completeness of the information?
- Professional sounding board?
- Uptake of scientific advice, translation into a proper clinical trial

regulator



- Identification of potential candidates for label extension
- Quality of the evidence provided by the non-profit: compliant with the regulator?
- Feasibility of engagement with a champion?
- Economic feasibility of bringing forward a new indication: ROI or CSR?

industry



DELIVERABLES

short term

- Identification of potential candidates for repurposing and respective champions
- Application(s) for SA ⇒ outcome letter
- Continuation of treatment development (clinical trial) in compliance with SA

DELIVERABLES

long term

- Uptake of repurposing candidate(s) by business companies
- MAA by a business company
- No uptake by industry of appropriate evidence generated by champion ⇒ communication?

The Anticancer Fund: real life examples in oncology

- Hard repurposing: non-cancer drugs ⇨ cancer indication



- Soft repurposing: oncological drug ⇨ new cancer indication

Hard repurposing: build on of the increasing knowledge of the tumor biology ⇒ **Microenvironment:** immunological, metabolic, inflammatory pathways



"Efforts to eliminate cancers may actually hasten the emergence of resistance and tumour recurrence."

A change of strategy in the war on cancer
Patients and politicians anxiously await and increasingly demand a 'cure' for cancer. But trying to control the disease may prove a better plan than striving to cure it, says **Robert A. Gatenby**.

Soft repurposing: unmet needs in rare cancers, especially paediatric oncology

REDO DB


The Repurposing Drugs in Oncology Database

Drug repurposing is a drug development strategy predicated on the reuse of existing licensed drugs for new medical indications. Based on extensive literature research, the REDO project has identified 268 licensed non-cancer drugs with published evidence of anticancer activity.

268 DRUGS

Generic
known safety ✓
cheap ✓

cardiovascular insecticides
 anti-parasite alimentary tract
 nervous system hormones
 sensory organs anti-infectives
 respiratory genito-urinary system
 dermatologicals metabolism
 musculo-skeletal system blood




190


LATE STAGE ONCOLOGY TRIALS


brain & CNS
gastro-intestinal
gynaecologic
pediatric

dermatologic
breast
lung




Aspirin 14%
Zoledronic Acid 11%
Metformin 9%
Vitamin D3 6%
Celecoxib 6%





Any questions? Please contact the ACE at info@anticancerfund.org



Characteristics of potential candidates

- Early versus late entry? \Rightarrow Extent of the pilot project
- Primary indication approved nationally or centralised? \Rightarrow choice of country?
- Hard versus soft repurposing?
- Combination of drugs versus monotherapy

Early-stage entry

- propranolol and etodolac in pancreatic cancer
- acetylsalicylic acid and atorvastatin in castration resistant (CR)-prostate cancer
- zoledronic acid and serolimus in osteosarcoma
- propranolol in angiosarcoma
- 9 non-cancer drugs in glioblastoma

Late-stage entry

- zoledronic acid in breast cancer
- letrozole in ovarian cancer
- docetaxel in hormone sensitive prostate cancer
- clarithromycin in Multiple Myeloma

National approval

- propranolol and etodolac in pancreatic cancer
- letrozole in ovarian cancer
- acetylsalicylic acid and atorvastatin in CR-prostate cancer
- propranolol in angiosarcoma
- clarithromycin in Multiple Myeloma
- 8/9 non-cancer drugs in GBM

Centralized approval

- zoledronic acid in breast cancer
- zoledronic acid and serolimus in osteosarcoma
- docetaxel in hormone sensitive prostate cancer

Hard repurposing

- clarithromycin in Multiple Myeloma
- propranolol in angiosarcoma
- propranolol and etodolac in pancreatic cancer
- Acetylsalicylic acid and atorvastatin in CR-prostate cancer
- 9 non-cancer drugs in glioblastoma

Soft repurposing

- zoledronic acid in breast cancer
- letrozole in ovarian cancer
- docetaxel in hormone sensitive prostate cancer
- zoledronic acid and serolimus in osteosarcoma

Combinations

- propranolol and etodolac in pancreatic cancer
- acetylsalicylic acid and atorvastatin in CR-prostate cancer
- zoledronic acid and serolimus in osteosarcoma
- 9 non-cancer drugs in glioblastoma

Monotherapy

- zoledronic acid in breast cancer
- letrozole in ovarian cancer
- docetaxel in hormone sensitive prostate cancer
- propranolol in angiosarcoma
- clarithromycin in Multiple Myeloma

REPURPOSING PILOT MONITORING BOARD

- WHY? The champion is unexperienced and will need support
The added value of the framework (contribution to public health, societal relevance) should be evaluated
- WHO? Interested members of the current STAMP working group
- HOW? Advisory role on a voluntary base, troubleshooting, monitoring progress, compiling a final report
- WHEN? Convene as determined at start OR upon request by the champion



Thank you