Alzicure:
A Patch to Remember

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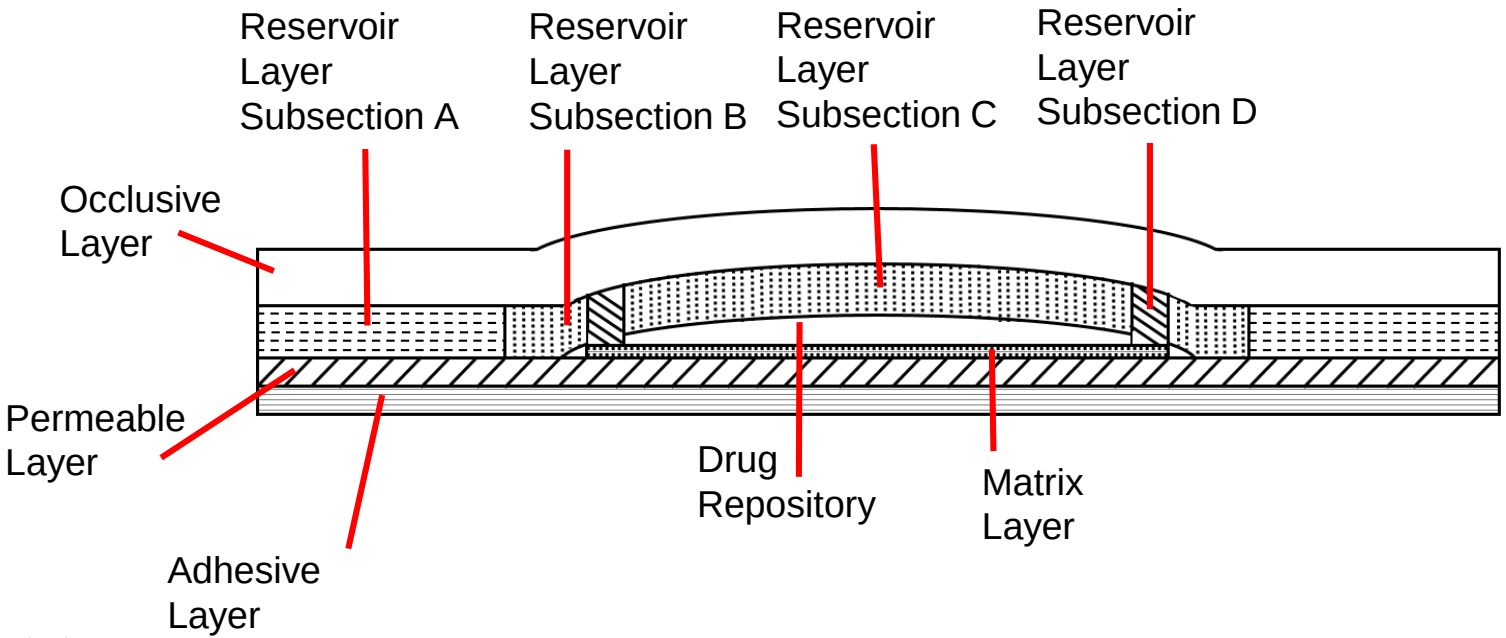
Exelon – Our Benchmark Product

Exelon is a cognition-enhancing medication with Rivastigmine as the bioactive agent

- Issues:
  - Requires frequent replacement (every 24 hours)
  - Has health hazards:
    - Adverse gastrointestinal reactions
    - Skin related issues

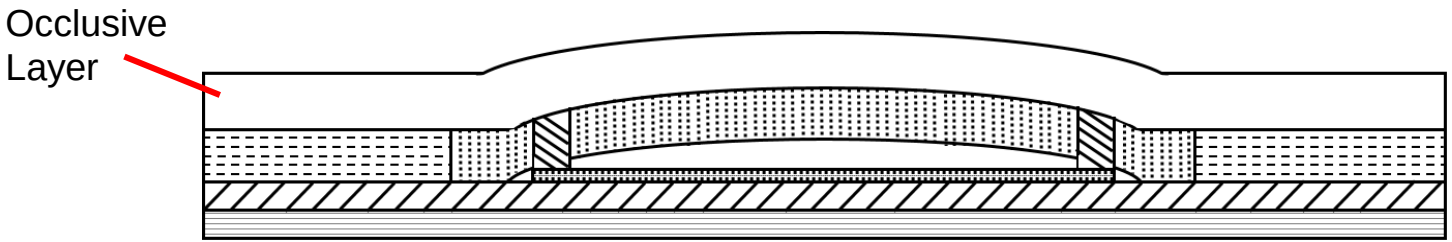
The Invention

A Transdermal Reservoir- Matrix Patch with Combinatorial Drugs for Alzheimer's



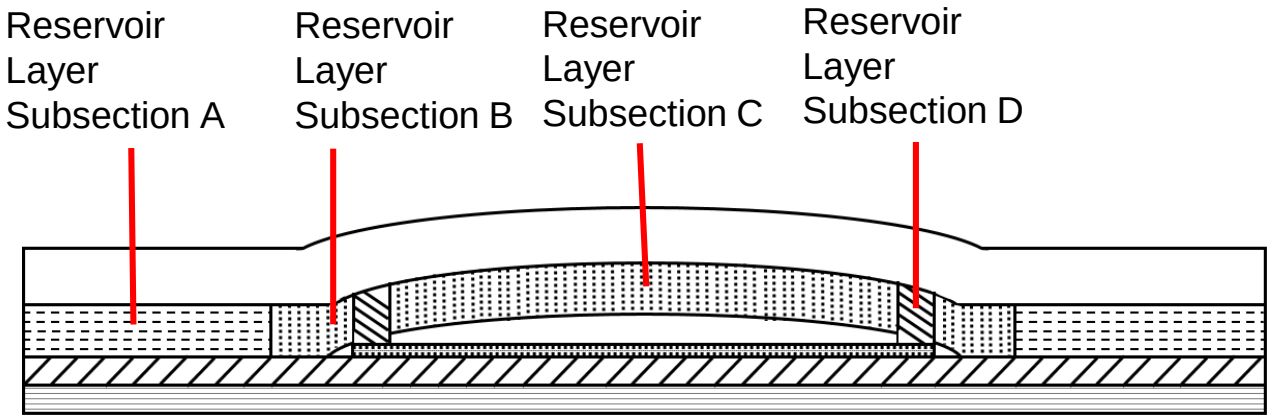
Occlusive Layer

The foremost protective layer



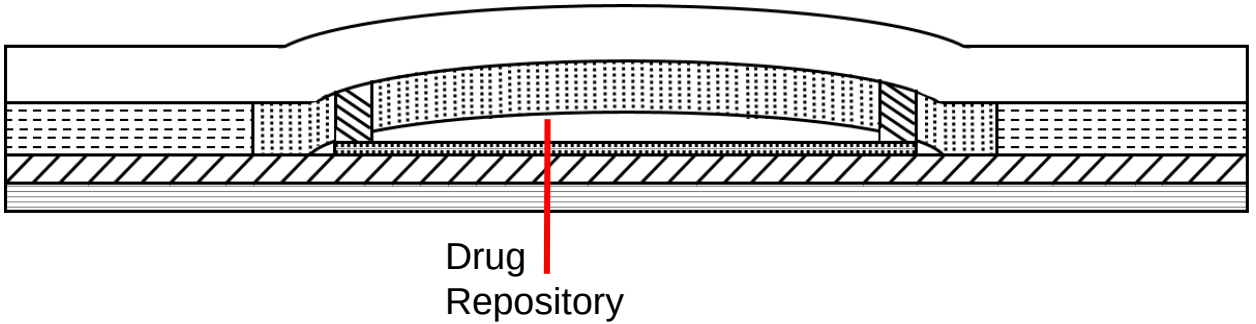
Reservoir Layer

Houses the therapeutics



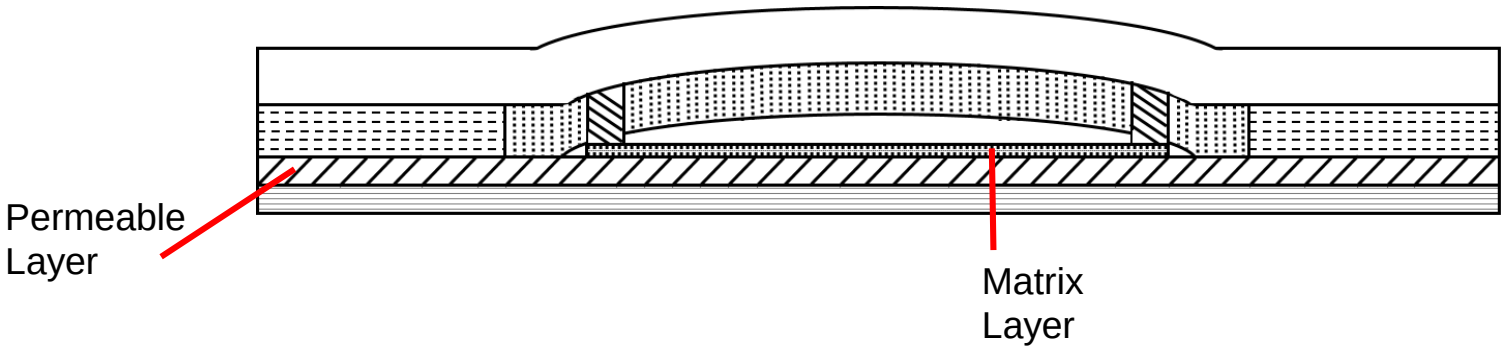
Drug Repository

Contains a mixture of Curcumin and Winter Cherry Extract



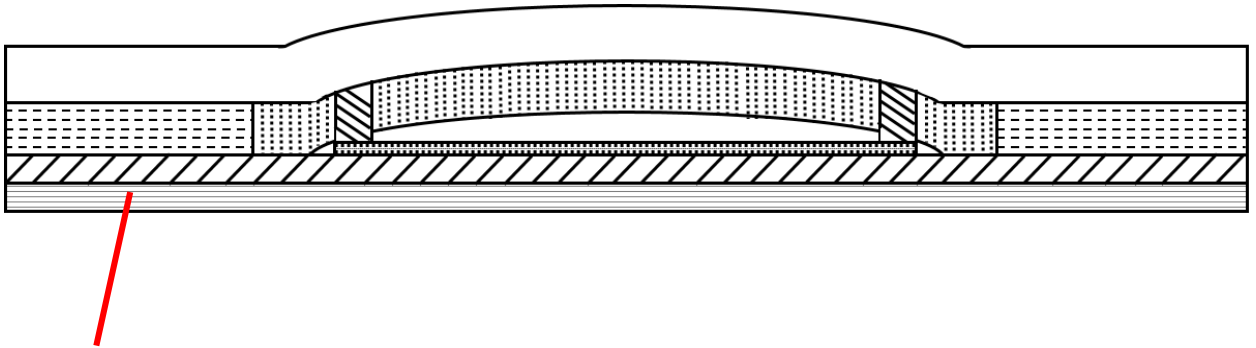
Matrix Layer & Permeable Layer

Diffuses the drug to the skin in a sustained manner



Adhesive Layer

Ensures stable contact over the course of drug delivery



Developing our Patent Claims – Initial

A transdermal patch, comprising:

a. An enclosed reservoir that contains the bioactive substances, between the occlusive backing layer and the matrix layer

b. A matrix layer, that lies between the reservoir and the permeable layer

c. The layer next to the permeable layer, which allows the therapeutics to pass through, is the first of adhesive that sticks to the skin

The reservoir consists of:

a. A formulation consisting of two drugs [Curcumin from Turmeric and extract of Winter Cherry] that act in synergy

b. The reservoir of claim 1, stores the drugs and the diffuses through the matrix to reach the skin

c. The matrix of claim 1, releases the drugs to the skin in a sustained manner

Developing our Patent Claims – Final

A transdermal patch, comprising:

a. An occlusive outer layer, a reservoir enclosing one or many bioactive agent(s), a matrix layer which is permeable to the drugs,

b. The peeling layer lies adjoining the permeable layer, wherein lies the adhesive

c. A matrix layer comprising of one or more polymeric blend(s)

The reservoir consists of:

a. A semi liquid formulation containing Curcumin or/and Winter Cherry Extract in the reservoir of Claim 1

b. The matrix of claim 1, releases the drugs to the skin in a sustained manner

Trademark

Trade Secret

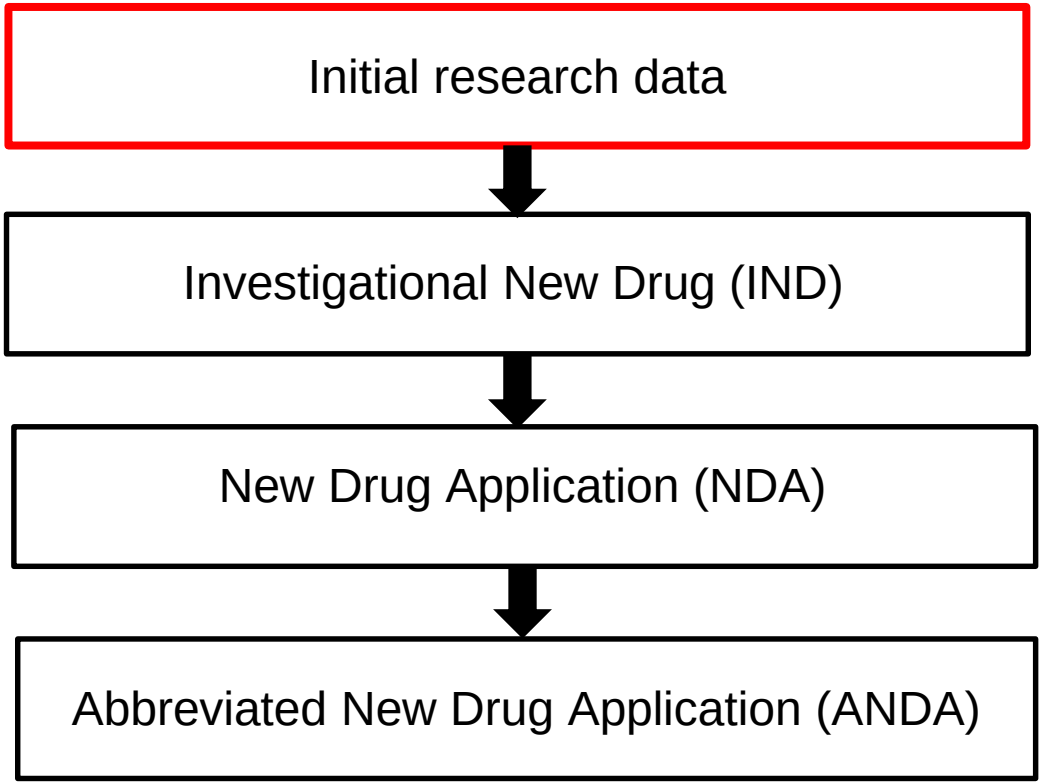
Trade Secret

- The semi-solid formulation present in the reservoir
- The optimal Curcumin/Winter Cherry ratio
- The order of operations to assemble the product

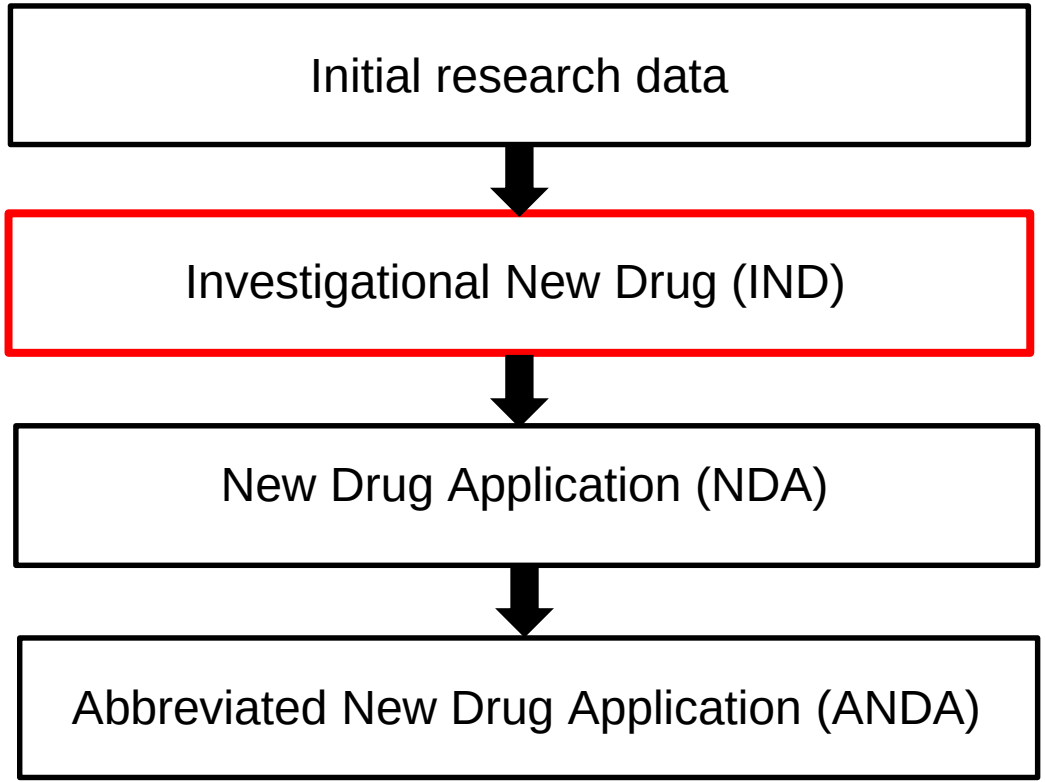
FDA Procedure

- Center for drug evaluation and research (CDER)
  - Prescribed drugs
  - Over The Counter drugs (OTC)
- Responsible for deciding class of medical device
  - Class 1 – Least risk, mild approval process
  - Class 2 – Moderate risk, strict approval process
  - Class 3 – Highest risk, most severe approval process

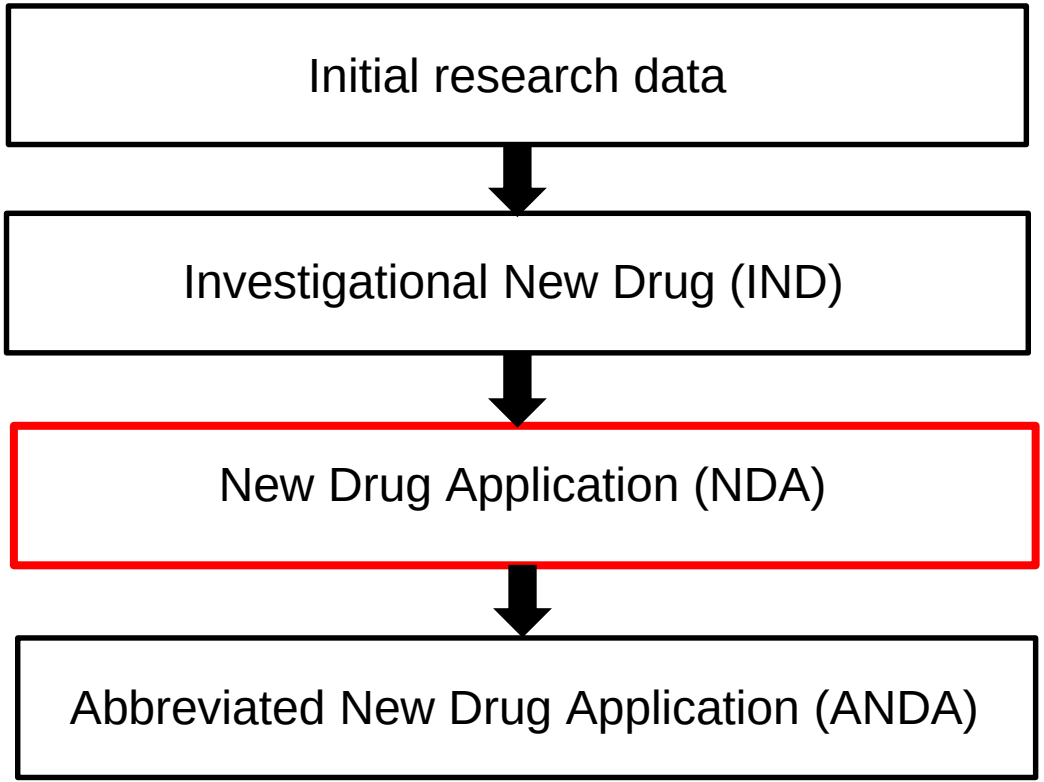
General Drug Approval Process



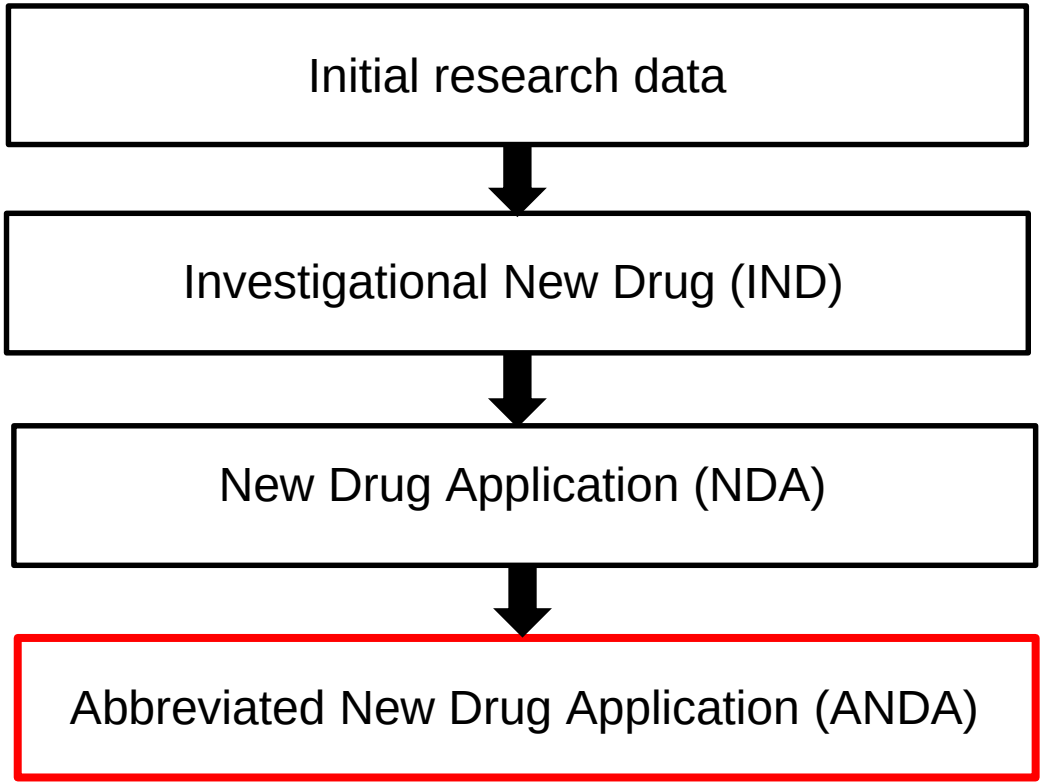
General Drug Approval Process



General Drug Approval Process



General Drug Approval Process



2017 USA Alzheimer’s Disease Facts and Figure

- Older African-Americans and Hispanics are more likely than older whites to have Alzheimer’s or other dementias.
- Females are more likely than men to have Alzheimer’s or other dementias.
- Death certificates for individuals with Alzheimer’s often list acute conditions such as pneumonia as the leading cause of death rather than Alzheimer’s.

CDC WONDER Database

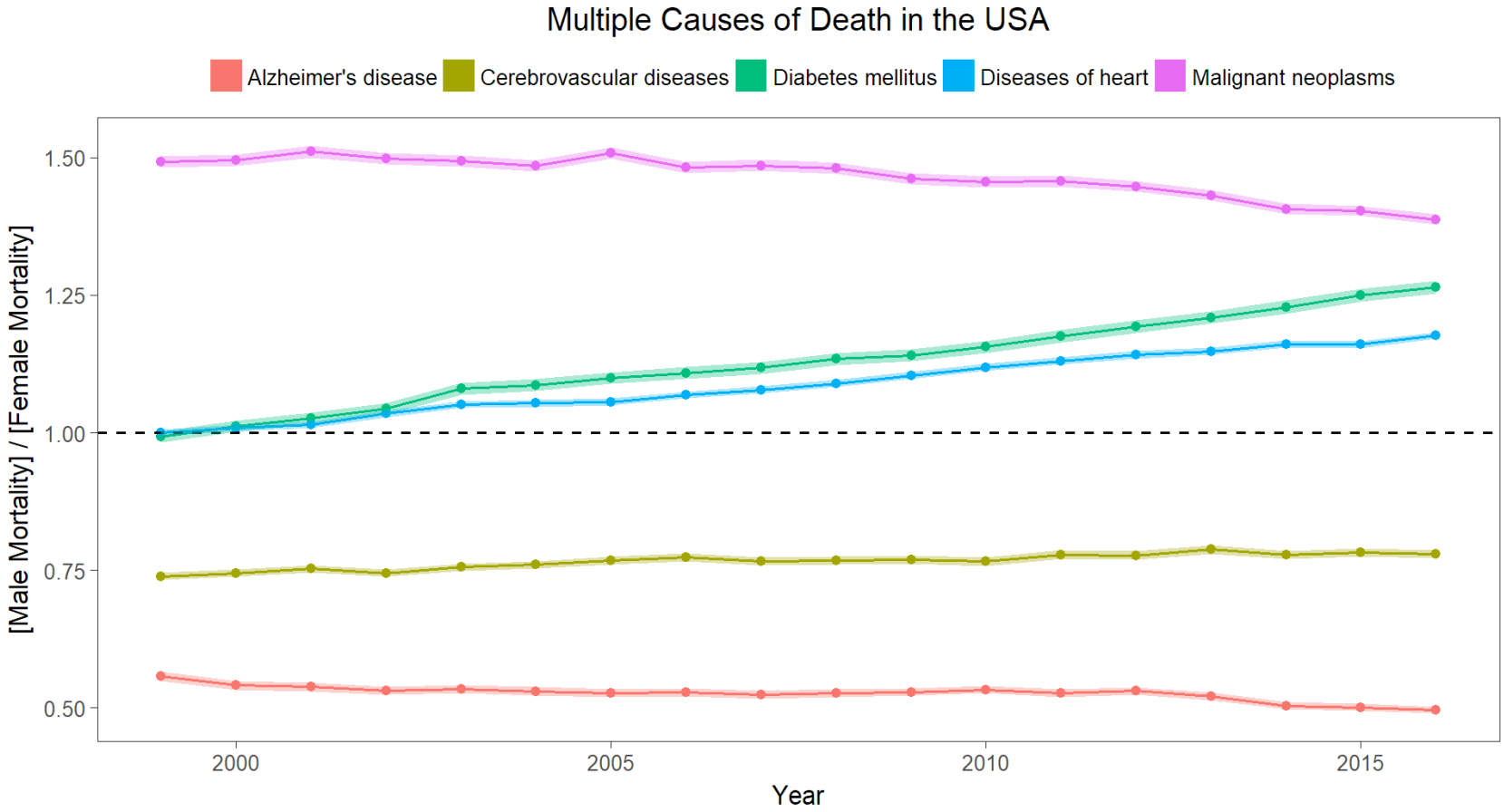
- Wide-ranging OnLine Data for Epidemiologic Research
- The information in USA death certificates have been collected by the National Center for Health Statistics of the Centers for Disease Control and Prevention
- This database contains the leading cause of death as well as multiple causes of death.

Studying Multiple Causes of Death

- Test the hypothesis that the odds of either population dying with a certain cause of death is equivalent.
- Statistically, this is testing the null hypothesis that the odds ratio is equal to a value of 1.
- The odds ratio in these tests is computed as:

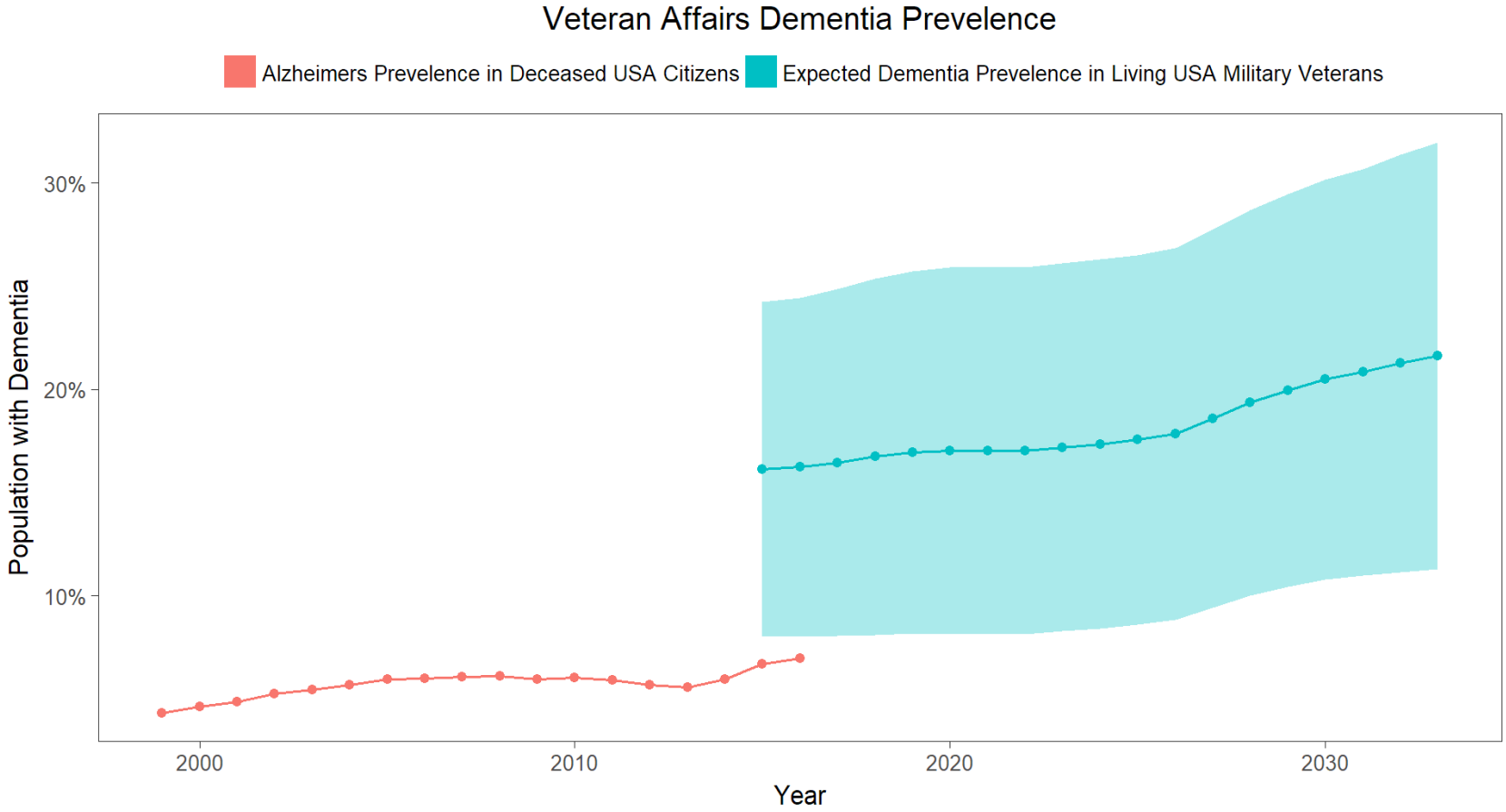
  (Population 1 Mortality) / (Population 2 Mortality)
- The mortality of a population p for a cause of death d is computed as:

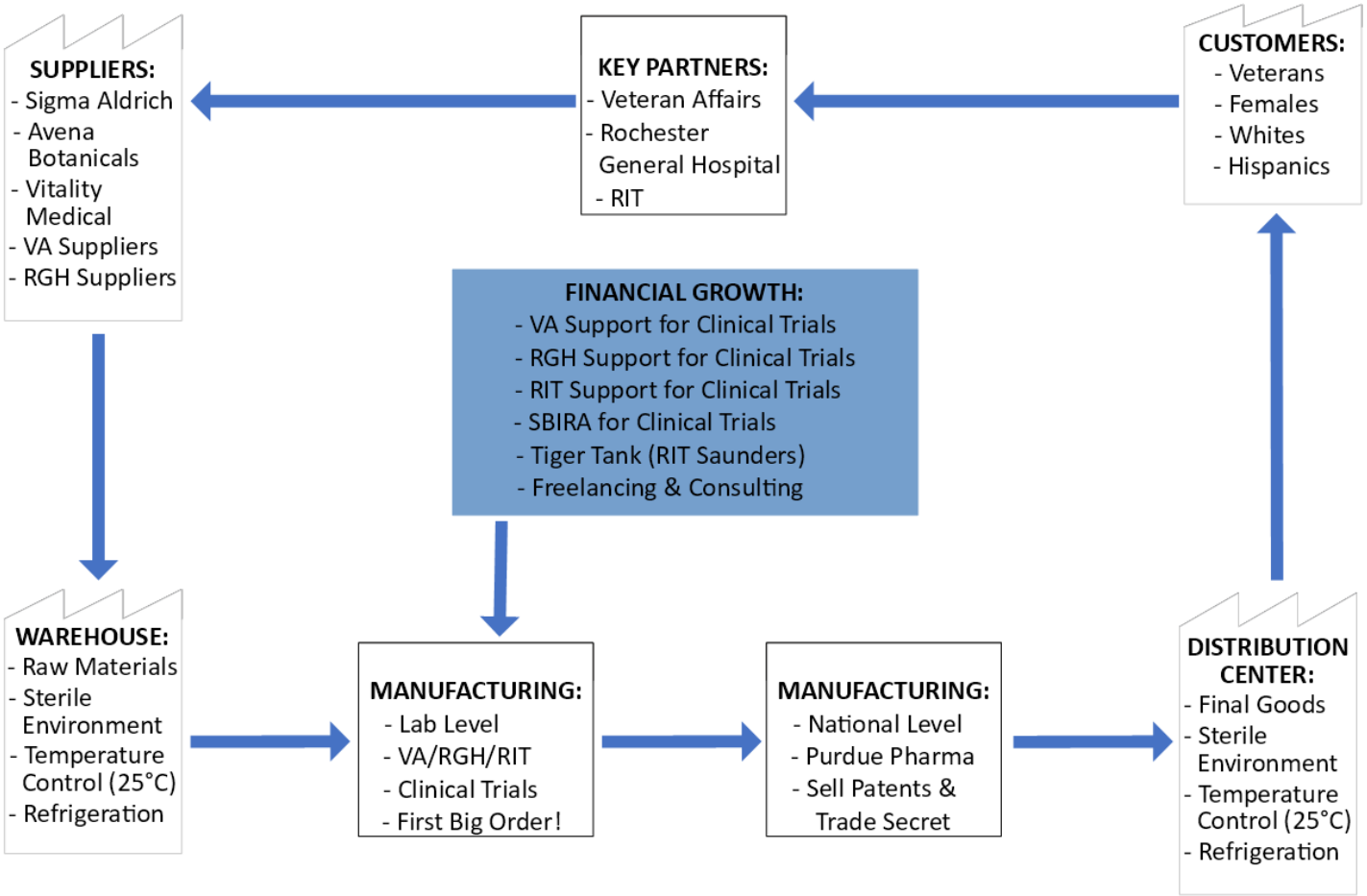
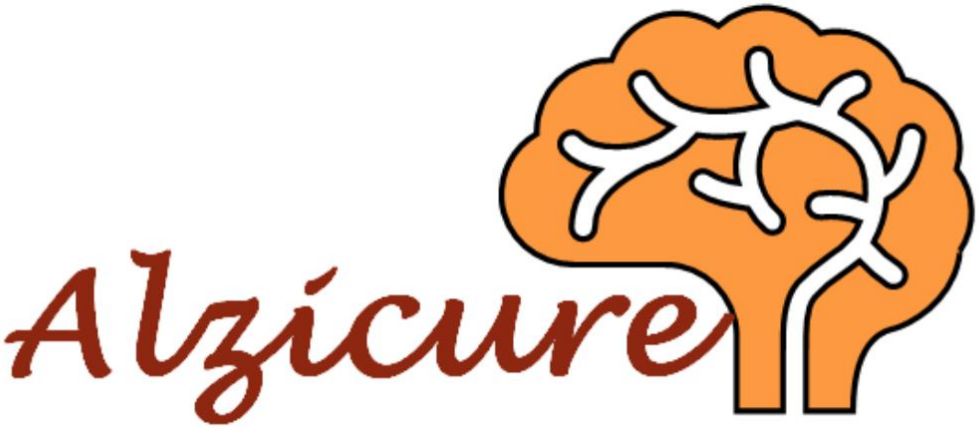
  (Population k deaths with cause d) / (Total deaths in Population k)


Multiple Causes of Death in the USA
Alzheimer's disease
Cerebrovascular diseases
Diabetes mellitus
Diseases of heart
Malignant neoplasms
[Male Mortality] / [Female Mortality]
1.50
1.25
1.00
0.75
0.50
2000
2005
2010
2015
Year

Demographic Disparity in Alzheimer's

Ratio	Distance
[Male Mortality] / [Female Mortality]	-0.4950128
[American Indian or Alaska Native Mortality] / [Hispanic or Latino Mortality]	-0.3759219
[American Indian or Alaska Native Mortality] / [White Mortality]	-0.3503594
[White Mortality] / [Hispanic or Latino Mortality]	0.305531
[Black or African American Mortality] / [Hispanic or Latino Mortality]	-0.274823
[Black or African American Mortality] / [White Mortality]	-0.2540251
[Asian or Pacific Islander Mortality] / [Hispanic or Latino Mortality]	-0.2041456
[American Indian or Alaska Native Mortality] / [Asian or Pacific Islander Mortality]	-0.2038348
[Asian or Pacific Islander Mortality] / [White Mortality]	-0.1824165
[American Indian or Alaska Native Mortality] / [Black or African American Mortality]	-0.1291994


Veteran Affairs Dementia Prevelence
Alzheimers Prevelence in Deceased USA Citizens
Expected Dementia Prevelence in Living USA Military Veterans
30%
20%
10%
Population with Dementia
2000
2010
2020
2030
Year


SUPPLIERS:
- Sigma Aldrich
- Avena Botanicals
- Vitality Medical
- VA Suppliers
- RGH Suppliers
KEY PARTNERS:
- Veteran Affairs
- Rochester General Hospital
- RIT
CUSTOMERS:
- Veterans
- Females
- Whites
- Hispanics
FINANCIAL GROWTH:
- VA Support for Clinical Trials
- RGH Support for Clinical Trials
- RIT Support for Clinical Trials
- SBIRA for Clinical Trials
- Tiger Tank (RIT Saunders)
- Freelancing & Consulting
WAREHOUSE:
- Raw Materials
- Sterile Environment
- Temperature Control (25°C)
- Refrigeration
MANUFACTURING:
- Lab Level
- VA/RGH/RIT
- Clinical Trials
- First Big Order!
MANUFACTURING:
- National Level
- Purdue Pharma
- Sell Patents & Trade Secret
DISTRIBUTION CENTER:
- Final Goods
- Sterile Environment
- Temperature Control (25°C)
- Refrigeration

Questions?