

Good science for good health



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Animal Research & Drug Discovery: Why?

- Unmet medical needs: there are no treatments available for 60% of known diseases, while most existing treatments relieve symptoms and not the cause.
- Animal studies give us crucial information that cannot be obtained elsewhere:
 - How diseases start and develop – the role of genes
 - What effects, side effects and toxic effects drugs have;
- The use of animals is a regulatory/legal requirement
- Europe provides very high standards for animal welfare, use, housing and care.

Animal Research & Drug Discovery: How?

- Animals are only used in research when there are no alternatives

Current alternatives have reduced animal usage

- Unfortunately,

current alternatives can only provide part of the solution

- Industry is continuously developing alternatives which 3Rs (replacing, reducing and refining).
- We cannot predict where new science will take us

Discovery & development of new medicines



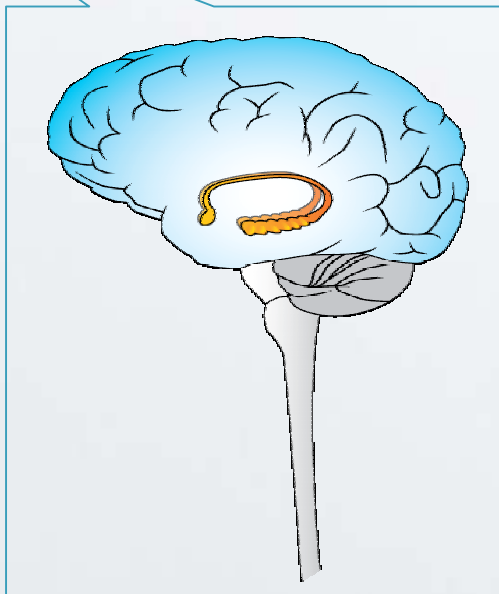
- Target to candidate – 4+ years
- Whole process ~10+ years on average

Drug Discovery is Difficult

- Scientific reasons
 - Thousands of novel proteins
 - Best ones are often the hardest to target
 - Unexpected toxicity
- Clinical reasons
 - Lack of disease understanding
 - Few biomarkers (plasma, imaging)
 - Difficulty of disease modification
 - Difficult to demonstrate safety



Drug Discovery: an example



- Serotonin 6 receptor blocker
- A good target??

Drug Discovery: an example



Optimal compound selected

- efficacy on learning
- clear separation from side effects

- Initial safety studies in animals
- Dose limits defined for man

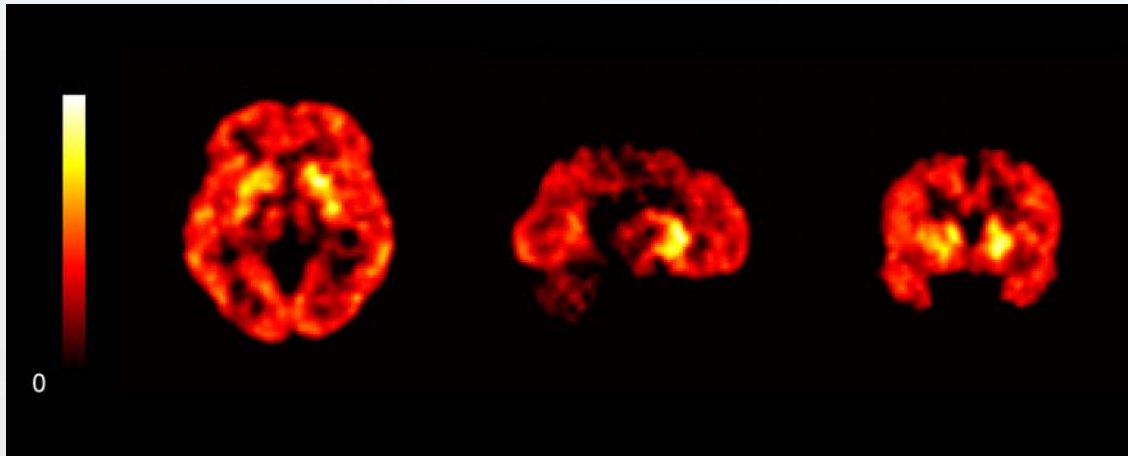
- Volunteer human studies
- Well tolerated
- No evidence of effect in normal people on learning and memory

Drug Discovery: its not easy!!



- 6 months dosing in patients needed longer toxicology studies in animals
- These showed adverse effects- not receptor related
- Pick new molecule – do long term toxicity early and then move to man

Drug Discovery: an example



- End 2005: start Phase II study
- 2007: positive data seen in two Phase II trials in dementia!

Conclusions

- There are still many health challenges to be addressed.
- Animals provide vital information that today cannot be obtained elsewhere.
- Industry is striving for alternatives
- But still must be capable of responding to emerging science
- Ultimate aim of research is patient benefit that is balanced with animal welfare