

# Research Subcommittee Recommendations

## Voting Members

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## Non-voting Members

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## Themes of research recommendations

- Commit resources with accountability
- Accelerate basic and translational research toward development of effective treatments
  - Assess progress toward and update interim milestones
- Compress average time in the process of identification of therapeutic targets via public/private partnerships and enhanced regulatory clarity
- Meaningfully coordinate with global partners

## Changes from 2013

- Reduced # of recommendations from 10 to 6
- Update interim milestones (include 2013 accomplishments, evaluation & cost estimates, revision of milestones for 2014)
- Add ADRD related interim milestones based on 2013 Workshop and 2016 follow-up
- Refine Global Action Plan based on G8 London and recommend International Advisory Council on Research, Care and Services

## Changes from 2013

- Refine recommendations for regulatory (FDA) contribution to compression of drug discovery timeline
- Several 2013 were retired because they are either a) already addressed directly in the plan b) were incorporated into interim milestones

## Recommendation 1

In order to support the goal to prevent and effectively treat Alzheimer's Disease by 2025, and to continue to develop a clear roadmap of research and treatment discovery priorities and timelines, we recommend that the interim research milestones first established in 2013 be evaluated and updated each year, to assure continuing and successful progress toward achievement of this goal.

## Notes on Recommendation 1

- Milestones should describe respective public and private roles reflecting the true partnership
- Estimate the federal funding that will be required each year to successfully complete the interim milestones through completion of the 2025 research goal
- Prioritize reduction of health disparities
- Include a plan to identify and rectify the shortcomings of the data needed to assess the impact of AD
- Balance translational drug development and basic discovery

## Recommendation 2

The urgent need for increased annual federal research funding sufficient to fund the strategic research plan reflected in the NIH milestones and to achieve the breakthroughs required to meet the 2025 goal remains a top priority. Initial estimates of that level are \$2 billion per year but may be more. That investment would be applied to Alzheimer's research initiatives spanning basic, translational and clinical research.

## Recommendation 3

Based on the recommendations of the 2013 ADRD Research Workshop, interim milestones for achieving specific research goals for the study of Alzheimer's Disease Related Disorders (i.e., Frontotemporal Degeneration (FTD), Lewy Body Dementia (LBD) and vascular contributions to ADRD) should be explicitly added to the National Plan.

## Notes on Recommendation 3

- Recommend a follow-up ADRD Summit in 2016 in order to review and refine recommendations based on recent scientific discoveries

## Recommendation 4

We recommend that HHS, in partnership with experts from the research community and industry, take steps to accelerate public access to new therapeutic interventions by compressing the current average time in the process of identification of therapeutic targets, validation of those targets, development of behavioral and pharmacologic interventions, testing of efficacy and safety, and regulatory review.

## Notes on Recommendation 4

- Take up recommendations of Path to 2025 Summit Report.
- Provide regulatory clarity through the finalization and discussion of a Guidance document.
- Use scientifically sound regulatory mechanisms as appropriate to help expedite the approval of effective therapies for AD and other dementias,
- Actively engage in and facilitate AD related public/private partnerships to qualify both endpoints and biomarkers and help generate data standards that will help facilitate regulatory review as well as allow for the pooling of future trial data.
- Engage with patient communities and advocacy groups to help inform the regulatory decision making process.

## Recommendation 5

We recommend that the Administration build on the commitments issued at the G8 Dementia Summit in London on December 11, 2013 and take a leadership role in establishing a Global Alzheimer's Action Plan to respond to the global scope of the Alzheimer's challenge.

## Notes on Recommendation 5

- Provide leadership to accomplish goals set in G8 meeting
- Consider the appointment of a Dementia Innovation Envoy
- Support an International Advisory Council on Research, Care and Services composed of member nations from the G8, G20 and low and middle income countries and representative of the diversity of stakeholders in the Alzheimer's-serving communities.

## Recommendation 6

We recommend that the Administration designate a specific Office and officials within the White House with responsibility and accountability for effective implementation of, and timely, transparent reporting on, all aspects of the implementation of this National Alzheimer's Plan and of the commitments made by HHS at the G8 Dementia Summit, including any global action plan as it is developed.