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Background & Unmet Need

- Cigarette smoking accounts for one of every five deaths in the US
- While counseling and medication therapies can be effective, only 7.5% of smokers successfully quit each year due to the highly addictive nature of nicotine
- One therapeutic approach is to develop an antinicotine vaccine, in which nicotine is administered to induce antibodies which can later sequester nicotine
- Clinical trials of anti-nicotine vaccines show varied immune responses among participants, and only a small percentage successfully quit smoking
- Anti-Nicotine mAbs have shown efficacy in sequestering nicotine in animal models, but repeated antibody administration may lower adherence
- **Unmet Need:** An effective strategy to induce a persistent immune response to nicotine and aid in smoking cessation

Technology Overview

- The Technology: An adeno-associated virus (AAV) vector encoding an anti-nicotine antibody to induce immune response against nicotine
- **PoC Data:** Mice injected with this vector produced high concentrations of antibodies with high specificity and affinity for nicotine
- The antibodies effectively sequestered serum nicotine with systemic administration in mice, reducing brain nicotine concentrations to only 15% of those in untreated mice
- Nicotine-induced suppression of the cardiovascular and locomotive activity were abolished or greatly reduced in mice that expressed the antibodies

Inventors: Stephen Kaminsky Martin Hicks Jonathan Rosenberg Bishnu De Ronald G. Crystal Robin L. Davisson

Patents: US Patent <u>10,093,947</u>

Publications: <u>Hicks et al</u>. *Sci Tranl Med*. 2012.

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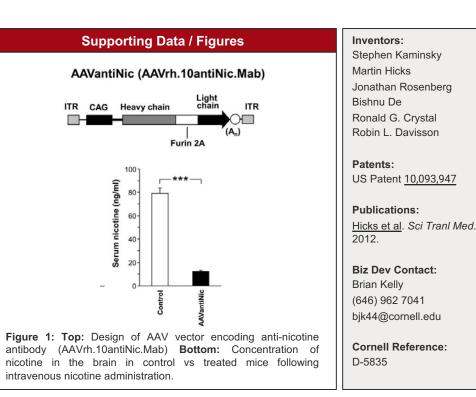
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- · Gene therapy for smoking cessation
- Gene therapy for clinical indications associated with smoking, such as Critical Limb Ischemia or Buerger's Disease

Technology Advantages

- Produces high-titer, high-affinity and specific antibodies against nicotine
- Induces persistent expression of anti-nicotine antibodies
- Less demanding treatment regimen than repeated administration of monoclonal antibodies



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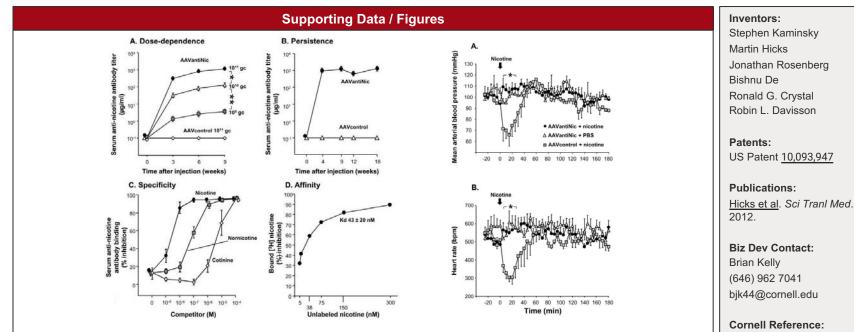


Figure 2: Left: Properties of anti-nicotine antibody following AAVrh.10antiNic.Mab treatment in mice **Right:** Prevention of nicotine-induced cardiovascular effects following AAVrh.10antiNic.Mab treatment in mice

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