Adact Medical US

(786) 706-4316
sales@adactmedicalus.com
adactmedical.com
848 Brickell Avenue
Penthouse 5
Miami, FL. 33131

There is a Large Gap in the Argument in favour of FLAVOURED Vapes

So the industry needs to step up and close that GAP if we are to secure FDA approvals of these products, so we are asking you to:

Join our Multi-Company Effort to Close a Major Gap in the Flavours story and get that data needed to help your products through to PMTA Approval

There has been a lot to talk in the industry over MDO (marketing denial orders) for flavoured products. The FDA is concerned about the balance between the 'dangers' that flavours present to youth and the benefits they present to adult smokers looking to stay off combustible cigarettes.

There is quite an amount of work being done to look at the benefits of flavours to an adult population. But we want to take an additional approach and DISMANTLE the other side of the argument that flavoured ENDS products present a 'Danger to youth'

What's the solution then?

We plan on conducting a detailed review of the past vaping and smoking behaviours of a cohort of established smokers/vapers and matched demographic cohorts of non-nicotine users, ex smokers, ex vapours and ex dual users.

What are we tackling with this?

There is no denying that youth prefer flavours, but we want to show that there is no causation between flavours and overall nicotine behaviour. So break that causative argument, there are 4 possible beneficial outcomes that if we achieve will massively help in reframing the whole flavours argument with the FDA.

1. the use of flavoured E cigarettes was the same in smokers and non-smokers,
2. the use of flavoured E cigarettes was more common in subsequent smokers but was matched by the use of non-flavoured E cigarettes,
3. smoking prior to the use of E cigarettes was an extremely strong determinant of future cigarette smoking and so flavoured E cigarettes should be continued and used to encourage teenage smoking cessation, or
4. teenage smoking following initial e-cigarette use was not influenced by use of flavoured or non-flavoured E cigarettes

How can you get involved?

In order to have a compelling argument we need a large study conducted to the highest standards of independence and good clinical practice, and we need a large number of participants, we are expecting this study to cost in the region of US$250,000. So we are looking for around 10 companies that would be willing to give financial support to this work in return for the right to access the data and findings for their PMTAs. So you need to be prepared to fund between US$20,000 and US$40,000 of this cost (update we have got a number of committed companies already)

What are the next steps?

Let me know you would like to get involved, I will send you an NDA and then a study synopsis, there will then be an online event where the details of the study will l be presented in detail and you will be given the opportunity to ask questions. Then as soon as you sign up we will give you a letter of access to send to FDA giving the FDA access to the TPMF containing all the study details, this will be seen by FDA as a Positive step.

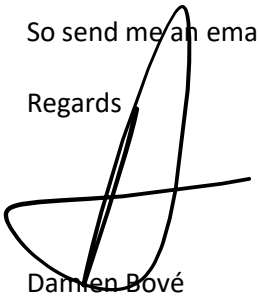
What will the study deliver?

- It will look to break the argument that flavours present a risk to youth
- It will demonstrate to FDA that you are working to resolve the biggest issue with regards to flavours (this could result a more favourable review process whist the study is ongoing with more time being made available to you)
- Only those companies that fund the research will directly benefit from the research
- Possible expansion to long term follow up to keep flavours alive in the long run
- A peer reviewed publication in the long run to aid in the acceptability and credibility of the data (only funding companies will be able to reference the actual study data)

We look forward to receiving your confirmation of interest.

So send me an email to say yes we want to get involved and give our PMTAs a strong boost

Regards



Damien Bové
Chief Regulatory Office
Adact Medical

P.S. this study is being organised by Adact on a not for profit basis, but will be run by a fully accredited clinical outcomes group and if we over subscribe it overall costs will come down for everybody.