



Team for Addiction Diagnosis Research  
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## 2025 US Bio Meeting

# Novel Patient-Centered Diagnostic Indicators for Substance Use Disorders

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# Current Diagnoses for Addiction –

## Lack bioindicators to reflect the physiological impairment

- The **diagnosis** of addiction or substance abuse is currently **based on external testing of urine, blood, and hair samples to detect addictive drugs or their metabolites**. This helps determine the specific substance the patient has been abusing. However, polysubstance abuse occurs in a high proportion of patients, and there may be omissions in testing.
- The **purpose of this diagnosis** is to **determine the schedule of the addictive substance** used, which helps **assess the severity of legal charges** rather than providing treatment.
- **In psychiatry, DSM-IV diagnosis** is based on questionnaires that assess how patients perceive the impact of their condition. Since it **relies on self-reported data**, there is **an inherent risk of subjectivity**.
- There is a **lack of blood biomarkers** that **reflect the severity of a patient's condition**, making it difficult to objectively assess the disease state of individuals with addiction.
- **Identifying reliable biomarkers for diagnosing addiction is an unmet medical need** in clinical practice. These biomarkers could improve objective assessment and enhance treatment strategies.

## Business opportunity 1

### Licensing the indicators and integrating them into novel technologies for technology transfer

1. These bioindicators include neurofilament light chain (**NfL**), Nectin-4, C-C motif chemokine ligand 11 (**CCL11**), myeloperoxidase (**MPO**), **caspase-10**, A disintegrin and metalloproteinase domain-containing protein 10 (**ADAM10**), and interleukin-7 (**IL-7**).
2. A biotechnology **manufacturer specializing in these bioindicators of antigen-antibody protein production**, leveraging AI technology to accelerate the development of matched bioindicators.
3. **A device manufacturer specializing in the development of POCT (point-of-care testing)** rapid diagnostics, capable of conducting fast and quantitative detection using matched bioindicator antigen-antibody pairs.
4. A medical device manufacturer with expertise in **developing non-invasive diagnostic instruments**.

## Business opportunity 2

### Co-development of IVD applications for clinical diagnostic purposes

- NHRI research team may provide Laboratory Developed Tests (LDT) platform to clinical researchers **for studying and validating various neurological and psychiatric disorders.**
- LDT may assess the scope of **indications and market applications.**
- Providing the biotechnology industry with research findings for use, including **comparisons with commercially available products.**
- Assisting companies that license biomarkers in **conducting preliminary research for IVD (In Vitro Diagnostic) medical device applications.**
- **Promoting objective biomarker-based diagnosis** to support the observation of pathological changes in addiction, neurological, and psychiatric disorders.

## Business opportunity 3

### Assisting Drug Trials with Objective Bioindicators

- **Minimizing Enrollment Bias** in Drug Clinical Trials
- **Assessing Neuroprotective Effects of Drugs** in Clinical Trials
- Determining the Relationship Between **Neuroinjury Severity** and **Treatment Effectiveness**
- These bioindicators are designed to match the research interests of NHRI and other institutional researchers with the needs of clinical trial organizations, **fostering increased industry collaboration.**