

Tender No.: 招標號碼:	AUISET(01)
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## **TENDER DOCUMENT**

### 招標文件

## **INVITATION FOR PRODUCT REGISTRATION AND CLINICAL TRIAL PROJECT BY WAY OF PUBLIC TENDER**

### 公開招標產品註冊與臨床試驗項目

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Tenders are invited for the product registration and clinical trial project in  
現招標產品註冊與臨床試驗項目

### **Personal Hormone Detection Device (PHDD)**

### 個人激素檢測裝置

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The e-version of the Tenders/Tender Documents must be submitted during the Tender Period (as defined in the Tender Notice) to the contact email (as contact email in the Tender Notice) and marked “**Public Tender For The PHDD**”. 2 copies of paper qualification documents should be delivered by courier or sent to Room 625, 6/F, Core Building 17W, Hong Kong Science Park, Shatin, N.T., HK before Noon at 18 Mar, 2022 (subject to the postmark date).

在招標期間（定義見招標公告），將投標書/投標檔电子版发送至联系人邮箱（郵箱見招標公告），並清楚註明「**PHDD公开招標**」。2份纸质资质文件在 2022 年 3 月 18 日前快递或派人送达香港科學園科技大道西17號6樓625室（以郵戳日期為準）。

**Contracting Party:**

**AUISET Biotechnology Company Limited**

招標方：

歐艾賽特生物科技有限公司

Room 625, 6/F, Core Building 17W, Hong Kong Science Park, Shatin, N.T., HK

香港科學園科技大道西17號6樓625室

Enquiry Hotline: 3465 0519

查詢熱線：3465 0519

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## **PART 1: TENDER NOTICE**

### **第 1 部份：招標公告**

#### **1. Definitions** **定義**

In this Tender Document, the following expressions shall have the following meanings except where the context otherwise permits or requires:

在本招標文件中，除非上下文另外准許或規定，下列詞語應具有下列含義：-

<b>“Agreement”</b> 「正式合約」	means the formal agreement for the product registration and clinical trial project in Personal Hormone Detection Device executed by the Contracting Party and the Tenderer. 指招標方與投標方就個人激素檢測儀產品註冊及臨床試驗項目簽訂的正式協議。
<b>“Letter of Acceptance”</b> 「接納書」	means the Contracting Party’s letter regarding acceptance of the Tenderer’s tender pursuant to the Tender Notice 指招標方根據投標通知書關於接受投標人投標的書面通知
<b>“Tender Document”</b> 「招標文件」	means this Tender Document comprising :- 指本招標文件，由以下部份組成：-  (i) Tender Notice 招標公告 (ii) BIDDER ELIGIBILITY REQUIREMENTS 投標人資格要求 (iii) BIDDING DOCUMENT(S) 投標文件 (iv) ANNEXES(S) 附件
<b>“Tender Notice”</b> 「招標公告」	means the Tender Notice set out in Part 1 of this Tender Document; 指本招標文件第 1 部份的招標公告；
<b>“Tender Period”</b> 「招標期間」	means, the period between the Tender Commencement Date and Time and Tender Closing Date and Time; 指招標開始日期及時間至招標截止日期及時間的期間；

## 2. Procedures of Tender

- 2.1 The Contracting Party does not bind itself to accept the highest or any tender and reserves the right to accept or reject any tender at its sole discretion.  
招標方不一定接納出價最高的投標書或任何一份投標書，並保留按其全權酌情決定接納或拒絕任何投標書的權利。
- 2.2 The Contracting Party reserves the right to, at any time before the Tender Closing Date and Time, accept any tender submitted.  
招標方保留權利在招標截止日期及時間之前的任何時間接納任何已遞交之投標書。
- 2.3 Tenderer(s) should submit the tender(s) in accordance with the terms and conditions as set out in this Tender Document and **the criteria (if any) set out under the Schedule to the Tender Notice.**  
投標者應按照載於本招標文件的條款及細則及**載於招標公告附表的準則（如有）**遞交投標書。

## 3. Acceptance of Tender 接納投標

- 3.1 If a tender is accepted, the successful Tenderer shall become the CRO of the Project.  
投標書如獲接納，中標者即成為本專案的 CRO。

## 4. Miscellaneous 其他事項

- 4.1 The Contracting Party reserves the right, in its sole discretion, to disqualify any Tenderer who submit any non-conforming tenders or who does not submit a valid or properly executed document according to this Tender Document. Tenders submitted which contain alterations and/or additions of any kind to the documents required to be submitted under the Tender Document shall be treated as non-conforming tenders.  
招標方保留權利按其酌情權將任何遞交不符合規定的投標書的投標者或沒有按本招標文件的規定遞交有效或妥善簽署文件的投標者的資格取消。如所遞交的投標書載有對於根據本招標文件所須遞交的文件任何種類的改動及／或增加，該投標書將被視為不符合規定的投標書。
- 4.2 In this Tender Document unless the context otherwise requires (i) words and expressions importing the masculine, feminine or neuter gender include every other gender, (ii) words and expressions in the singular include the plural, and words and expressions in the plural include the singular and (iii) words and expressions shall extend to the grammatical variations and cognate expressions of such words and expressions.  
在本招標文件中，除非文意另有所指，否則(i)凡指男性、女性及不屬於男性或女性者的字及詞句 亦包括每一其他性別，(ii)凡指單數的字及詞句亦指眾數，而指眾數的字及詞句亦指單數，及(iii) 所用字及詞句擴及指該字及詞句的文法變體及同語族詞句。
- 4.3 In the event of any discrepancy between the English version of this Tender Document and the Chinese translation of this Tender Document, the English version shall prevail.  
如本招標文件的英文文本與中文譯本有任何不一致，則以英文文本為準。

## 5. Contact Person 聯繫人

姓名 Name	聯繫電話 Contact Number	郵箱 Email
張保坤 Markus Cheung	+852 3465 0519	Markus.cheung@auiset.com

6. **Mailing information for paper documents**  
**紙質版權郵寄資訊**

姓名 Name	張保坤 Markus Cheung
聯繫電話 Contact Number	+852 3465 0519
公司名稱 Company Name	歐艾賽特生物科技有限公司 AUISET Biotechnology Company Limited
郵寄地址 Mailing address	香港科學園科技大道西17號6樓625室 Room 625, 6/F, Core Building 17W, Hong Kong Science Park, Shatin, N.T., HK

## **PART 2: BIDDER ELIGIBILITY REQUIREMENTS**

### **第 2 部份：投标人资格要求**

合格的投标人必须具备以下条件：

Qualified bidders must meet the following conditions:

1. The bidder shall be a CRO company with independent legal personality, and shall provide the corresponding enterprise qualification certificate (electronic and paper version) before bidding.  
投標方應為具有獨立法人資格的 CRO 公司，並在競標前提供相應的企業資質證書（電子版及紙質版）。
2. Familiar with and abide by the current Chinese laws and regulations in relevant fields.  
熟悉並遵守相關領域現行的國際、國內法律法規。
3. The bidder has rich domestic high-end expert resources in related fields.  
投標方具有豐富的國內相關領域高端專家資源。
4. The bidder has a complete medical team.  
投標方有完善的醫學團隊。
5. The bidder has rich experience in project research and development in the field of in vitro diagnostics.  
投標方具有豐富的體外診斷領域項目研發經驗。
6. The bidder has rich experience in Phase II clinical trial projects.  
投標方具有豐富的II期臨床試驗項目經驗。
7. The project manager of the bidder has more than 3 years of experience in domestic multi-center clinical trial project management.  
投標方項目經理具有 3年 以上從事國內多中心臨床試驗項目管理工作經歷。
8. The bidder has a good BD team\person for project coordination.  
投標方具有良好的 BD 團隊\人員進行項目協調。
9. The bidder can provide good service and technical support. During the self-inspection and verification of clinical trials in 2021, there was no record of bad violations..  
投標方能提供良好的服務和技術支持。在 2021 年度臨床試驗自查核查過程中無不良違規記錄。

## **PART 3: BIDDING DOCUMENT(S)**

### **第 3 部份：投标文件**

1. **Company profile (including relevant qualifications and clinical research-related performance certificates).**  
公司概況（包括相關資質以及臨床研究相關業績證明）。
2. **Clinical Research Development Strategy.**  
臨床研究開發策略。
3. **Clinical Trial Protocol Summary.**  
臨床試驗方案摘要。
4. **Project clinical operation instructions, including the standard operating procedures (SOP) of each clinical trial department.**  
該項目臨床操作說明，包括臨床試驗各個部門的標準化操作程序（SOP）目錄。
5. **Project execution plan and description (please specify the specific time point).**  
項目執行計劃及說明（列明具體的時間節點）。
6. **Clinical Quality Assurance Measures.**  
臨床質量保證措施。
7. **Project service type and overall budget (with cost description).**  
項目服務類型以及整體經費預算(並附費用說明)。
8. **Qualifications and resumes of key personnel in the operation team.**  
操作團隊主要人員資質介紹及簡歷。

**PROJECT BASIC INFORMATION**

項目基本信息

序號	名稱	內容
1	儀器名稱	
2	規格	
3	註冊類別	
4	臨床研究批件號	
5	項目編號	
6	研究題目	
7	試驗分期	
8	患者人群	
9	作用機理	
10	本品國外臨床試驗情況	



## Appendix 2 of the Tender Notice

### 招標公告附錄 2

#### "Keep Money Laundering Away from Hong Kong" Leaflet

#### 嚴禁清洗黑錢宣傳單張

Additional information may be necessary for complex or unusually large transactions.

**What is meant by suspicious transaction?**

Lawyers will look into the nature, complexity and scale of the transaction when ascertaining whether it is suspicious. Examples of suspicious transactions are those involving—

- A secretive entity
- Unusual instructions
- Unusual settlement requests

**What if I do not want to disclose my information?**

If lawyers are unable to obtain the required information from their clients, they may refuse or cease to act for them.

**What will my lawyer do with my documents? Will my personal documents be kept confidential and not passed to other parties?**

Client information will as always be kept in strict confidence and in compliance with the Personal Data (Privacy) Ordinance. However, if lawyers detect suspicious money laundering or terrorist financing activities, they will be required by law to report the same to the law enforcement authorities.

disclose any transaction suspected to be connected with money laundering or terrorist financing is an offence under Hong Kong laws.

**Frequently Asked Questions**

**Why does the Law Society of Hong Kong require lawyers to request information for identification and verification from their clients?**

The purpose of requesting client identification is to detect and prevent money laundering and terrorist financing activities. The Law Society of Hong Kong is playing its part in helping Hong Kong to fulfil its international obligations as a member of the Financial Action Task Force on Money Laundering, an international governmental policy-making body that sets international standards and policies against money laundering and terrorist financing. Hong Kong has been a member of the Task Force since 1991 and is obliged to implement the Task Force's recommendations.

**Apart from requesting identification information, will my lawyer ask me further questions?**

Lawyers may ask further questions depending on the transactions. For instance, if you are buying a real property, they will ask you—

- What is the purpose of the transaction?
- What is your relationship with the intended owner (if you do not intend to be the registered owner)?
- What is the source of funding?

legal community's commitment to supporting the combat against money laundering and terrorist financing – an international obligation of Hong Kong. The Law Society of Hong Kong sincerely hopes that members of the public will cooperate with their lawyers and help maintain Hong Kong's integrity as an international financial centre.

Lawyers serve a key gate-keeping role in detecting and preventing money-laundering and terrorist financing. But lawyers will only be able to play this role effectively with the public's assistance.

By providing lawyers with the required information, members of the public are helping to make it harder for money launderers and terrorists to disguise their activities as legal transactions. The new requirement can deter money launderers and terrorists from abusing Hong Kong's legal services.

The new requirements for client identification and gathering information is not limited to common transactions such as property transactions and the administration of estates, but all business dealings conducted between lawyers and their clients, including litigation.

Client information provided to lawyers will be kept in strict confidence and in compliance with the Personal Data (Privacy) Ordinance. Only if lawyers detect suspicious money laundering or terrorist financing activities will they make a report to the law enforcement authorities as a statutory obligation. Failure to

**Keep Money Laundering Away from Hong Kong**

**Lawyers and Public to Play Key Roles**

To support Hong Kong in fulfilling its international obligations to combat money laundering and terrorist financing, lawyers will seek cooperation from the public in providing the following information before conducting transactions:

**For Individuals**

- Identification documents such as identity cards, passports or travel documents
- Address proof
- Particulars of occupation or business

**For Corporations**

- Documents of legal status such as Certificates of Incorporation and Business Registration Certificates
- Identification documents of directors or persons giving instructions
- Board resolution
- Details of the beneficial ownership or control structure

Lawyers will also need information on the nature, purpose, and source of funding for the transactions. More detailed information may be required for more complex or larger transactions. The new measures are now effective.

The requirement for lawyers to obtain client identification and gather information represents the



A secretive entity

Unusual instructions

Unusual settlement requests



No Money Laundering

## 律師與市民齊參與 打擊清洗黑錢活動

為配合香港履行打擊清洗黑錢及恐怖分子融資活動的國際責任，律師在接受市民委託辦理任何事務前，會要求他們合作提供以下資料：

### 個別人士

- 身份證明文件，如身份證、護照、旅遊證件
- 地址證明
- 職業或商業詳細資料

### 公司

- 法律狀況文件，如公司註冊證書或商業登記證
- 董事或委託人的身份證明文件
- 董事會決議案
- 實益擁有人或控制權結構

此外，律師必須向客戶查詢有關交易的性質、目的、資金來源等資料。如果是較複雜或金額較大的交易，律師可能需要向客戶索取進一步資料。這些新措施現已生效。

要求律師向客戶索取身份證明文件及其他資料代表法律界對支持打擊清洗黑錢及恐怖分子融資活動的一份承擔。香港律師會衷心呼籲市民與律師合作，合力維護香港作為國際金融中心的誠信。

法律界必須得到市民的支持，才能夠做好把關人的工作，協助政府打擊清洗黑錢和恐怖分子融資活動。

通過向律師提供所需的資料，公眾人士便能使不法分子更難把清洗黑錢和恐怖組織的融資活動，掩飾為合法業務。新措施對清洗黑錢及恐怖活動分子濫用香港法律服務，將發揮阻嚇作用。

向客戶索取身份證明及交易資料新措施，適用於市民委託律師處理的所有事務，包括資產交易和遺產管理，以至訴訟。

律師會依照個人資料(私隱)條例處理客戶提供的資料，確保資料絕對保密。律師只會於在發現可疑交易或恐怖分子融資活動時，才按法定規定向執法機構舉報。根據香港法例，若發現任何懷疑與清洗黑錢和恐怖分子融資活動有關的交易而不舉報，均屬違法。

### 常見問題

**香港律師為何要求律師向客戶索取有關身份證明及相關資料?**

索取客戶身份資料的目的，是為了偵查和預防清洗黑錢和恐怖分子融資活動。香港在1991年加入國際打擊清洗黑錢財務行動特別組織，該組織負責制定國際標準及政策，以打擊清洗黑錢和恐怖分子融資活動。香港作為成員之一，有責任履行組織的建議，香港律師會亦為此作出配合。

**除身份證明文件外，律師還會進一步索取其他資料嗎?**

律師將根據交易性質進行查證工作。例如辦理樓宇買賣時，律師可能會提出以下問題：

- 交易目的為何?

- 如將來的物業持有人並非客戶本人，雙方的關係是什麼?

- 資金的來源是什麼?

如果是較複雜或金額不尋常的交易，客戶可能需要提供進一步資料。

### 何謂「可疑交易」?

律師將根據交易性質、複雜程度和金額等因素作出判斷。舉例說，若下列情況出現，交易便可能有可疑成份：

- 身份不明
- 不尋常的指示
- 不尋常的結算要求

### 我可否拒絕提供資料?

假如客戶未能提供所需資料，律師可能會拒絕或停止為該客戶服務。

### 律師將如何處理我所提供的資料? 資料會否保密? 會否轉交第三者?

律師會依照個人資料(私隱)條例處理客戶提供的資料，確保資料絕對保密。律師只在發現可疑交易時，才會依法律規定向執法機構舉報。

身份不明

不尋常的指示

不尋常的結算要求



## 你我攜手為香港把關 Gatekeeping for HKSAR

配合香港履行打擊清洗黑錢之國際責任  
你的支持不可少

Your Support is Crucial to Hong Kong Fulfilling  
International Obligations on Anti-Money Laundering



[End : Tender Notice]

[招標公告完]