NC STATE UNIVERSITY

Ad Astra Diagnostics

MMB Practicum Mid-Project Update

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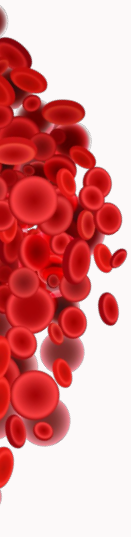
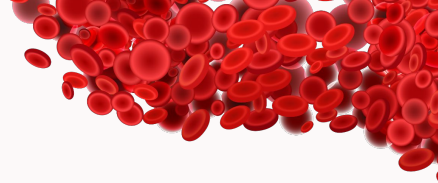
10/21/2025

1. Review of the original scope, goals, and priorities of the project
2. Status update:
    a. Actions and progress to date
    b. Ideas beyond original scope that have been identified
    c. Hurdles and potential solutions
3. Proposed plan for the remainder of the semester



Agenda:
Review scope and goals
Progress update
Hurdles
Questions
Schedule final presentation



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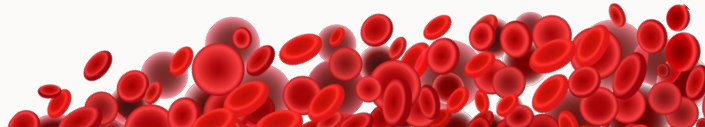
Scope and Goals



Project Scope/Problem

Regulatory

Challenges in expanding the clinical utility of a CLIA-waived hematology device for **parameters that have not been previously evaluated yet**

Clinical

Determine whether reporting these parameters at point-of-care **meaningfully improves patient care and decision making**

Project Goals

Goal 1 (25%)

Propose exact **Allowable Total Error (ATE)** standards for different parameters

Goal 2 (12.5%)

Quantify how each of these parameters impacts decisions at the **POC**

Goal 3 (12.5%)

Evaluate **risk-benefit** of each parameter for CLIA-waived patients

Goal 4 (25%)

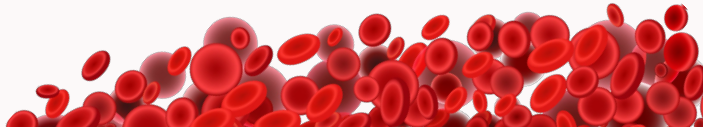
Create a **portfolio of case studies** that showcase the clinical value of these parameters

Goal 5 (12.5%)

Provide **regulatory and scientific justification** in a formal document with rationale for the **FDA**

2

Progress



Goal 1: Propose ATE Values

- Progress has been made in researching the prerequisite data required to create a proposable ATE
- Preliminary findings for ATEs of MCH, MCHC, and RDW
  - MCH→ ≈2.5%
  - MCHC→ ≈1.27%
  - RDW→ ≈4.6%
- Neutrophil and Lymphocyte counts seen separately in previous testing
  - Further research is needed to compile biological variance data to propose an ATE for the ratio.
- Research backing clinical significance of IG#
  - Need to compile more biological variance data

Goal 2: Quantify Value of Parameters of Interest

Direct/Tangible Costs

- Cost of test itself, equipment maintenance
  -Average cost of POCT tests was **$1.89 + labor + management**
  -**8-20% savings** in laboratory costs
- Staffing (highest)
- Transportation (eliminated)

*Small units benefit more from savings in direct costs
*Refuting evidence: majority of savings found downstream

Indirect/Intangible Costs

- Time
  -POC TAT **46 min less** than lab analysis
  Ex. iStat: 21 min, $3.11 saved; **20% reduced treatment time**; iStat+ CBC: 31 min, $14.96 saved
  Ex. Time to document CBC with differential: 1 min 42 sec = **13.3 hr manual entry per month**
- Patient satisfaction

Goal 3: Evaluate Risk-Benefit of Parameters

Goal 3: Evaluate Risk-Benefit of Parameters

MCH/MCHC
RDW
NLR
IG#/IG%

Goal 4: KOL/VOC Outreach & Case Study Portfolio Creation

- We are implementing suggested changes to the outreach script from Danielle
  - Updating the script to include more questions targeted to RBC indices.
  - Adding more emphasis in the script on the potential impact of having simple 2 minute beside CBC results
- Talked to some hospital nurses and got feedback on the potential use of this product
  - They were very excited about it, and thought it could be advantageous, especially in ER settings
- We will continue to reach out to clinicians, and will keep a running list of contacts to share with AAD.
  - Goal is 10-15 contacts each

Goal 5: Provide regulatory and scientific justification in a formal document with rationale for the FDA

This will be the last step of our project, so this will be completed at a later date.

We will compile our research and findings from the other goals to achieve this one.

0% Done

VOC/KOL Outreach

Made script for outreach and it has been approved by AAD

What is a CLIA waiver?

- CLIA (Clinical Laboratory Improvement Amendments) regulates laboratory testing in the U.S
- Permits use of simple, low-risk tests outside traditional labs
- Requires minimal training & no specialized equipment

Examples

CLIA-Waived QScout® CBC

Hematology device designed to provide a complete blood count in ~2 minutes from fingerstick or venous blood.

QScoutLab

- Imaging-based system
- Cell examination using **AI**
- **Compact, portable**
- Self-contained reagent

CBC Test

- **Screening** for anemia, leukemia, infection, bleeding, **sepsis early detection**

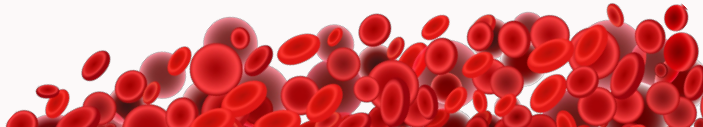
Previously submitted to FDA & rejected because of 5 biomarkers

Biomarkers of Interest

Acronym	Term	Definition	Purpose
MCH	Mean Corpuscular Hemoglobin	Average amount of hemoglobin in a single red blood cell	Helps evaluate oxygen-carrying capacity of red blood cells
MCHC	Mean Corpuscular Hemoglobin Concentration	Average amount of hemoglobin in red blood cells	Assesses the color and hemoglobin concentration of red blood cells
RDW	Red Cell Distribution Width	A measure of size variation in RBC	Can differentiate causes of anemia
IG#/IG% *Research parameter	Immature Granulocyte Count	Reflects early granulocytes in circulation	Can indicate infection/inflammation (early signs of sepsis)
NLR	Neutrophil-to-Lymphocyte Ratio	Ratio of neutrophils to lymphocytes	Used as a marker of systemic inflammation

3

Barriers



Hurdles/Potential Solutions

- Subjective analysis of intangible costs for CBC vs laboratory analysis
- POCT is conducted for a wide range of reasons, finding CBC specaific information can be challenging
- Making generalizations
- Evaluating studies taken from developing countries, how would this impact the development of the product/considerations for traditional Western medicine/healthcare systems
- Have there been any considerations about training/evaluations/worst-case scenarios/mitigation strategies (other idea category)
- Goal #5 cannot really be pursued until we make substantial progress on the other goals

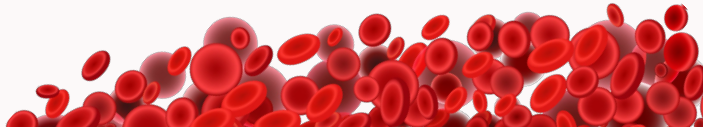
- Solutions

Hurdles

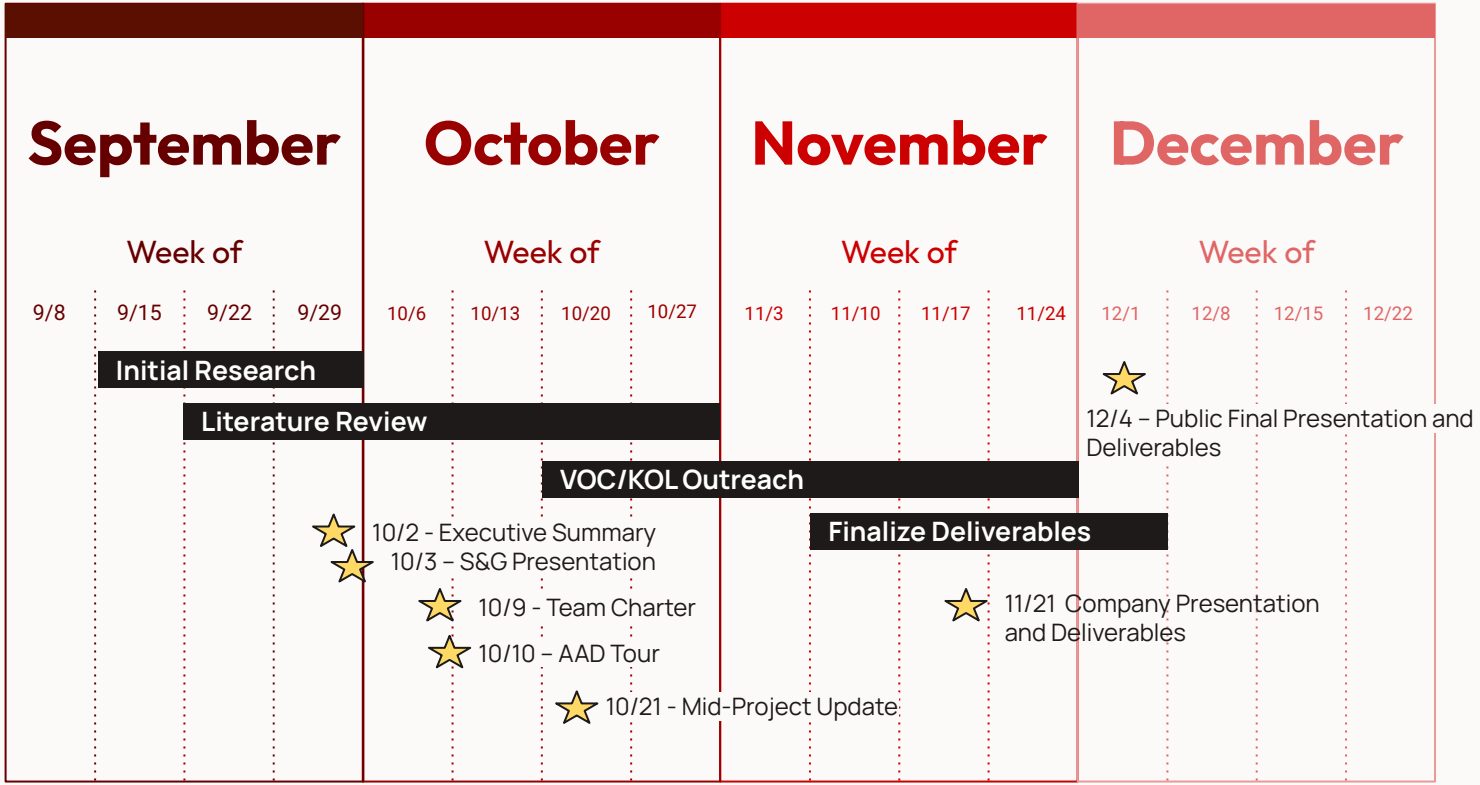
Current Challenges	Mitigation Strategy
Subjective analysis of intangible costs	Break down and consider the different populations and perspectives involved in the process of conducting a Point-of-Care CBC test
POCT Wide Scope	Evaluate key similarities and differences between operational factors among different POCT tests to make more informed generalizations.
Studies from resource-constrained areas	Analyze common factors among healthcare systems and highlight primary areas of need. Improve understanding of long-term implementation goals.

4

Updated Timeline



Project Timeline



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Questions?

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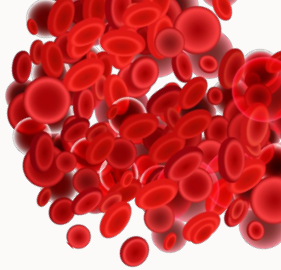

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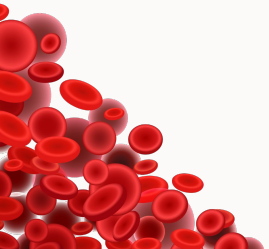


Biomarker	TEa95 Optimal (z=1.65)	TEa95 Desirable (z=1.65)	TEa95 Minimal (z=1.65)
MCH	1.25	2.5	3.75
MCHC	0.64	1.27	1.91
RDW	2.28	4.56	6.84
IG%	4.52	9.05	13.57
NLR	12.29	24.58	36.87

$$RCV = Z \times \sqrt{2} \times \sqrt{CV_A^{\,2} + CV_I^{\,2}}$$

Z score of 1.96 → Probability 95% → Significant

Z score of 2.58 → Probability 99% → Highly significant

About the disease

Mars

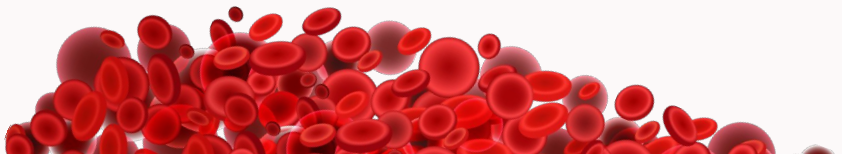
Despite being red, Mars is a very cold place. It's full of iron oxide dust

Jupiter

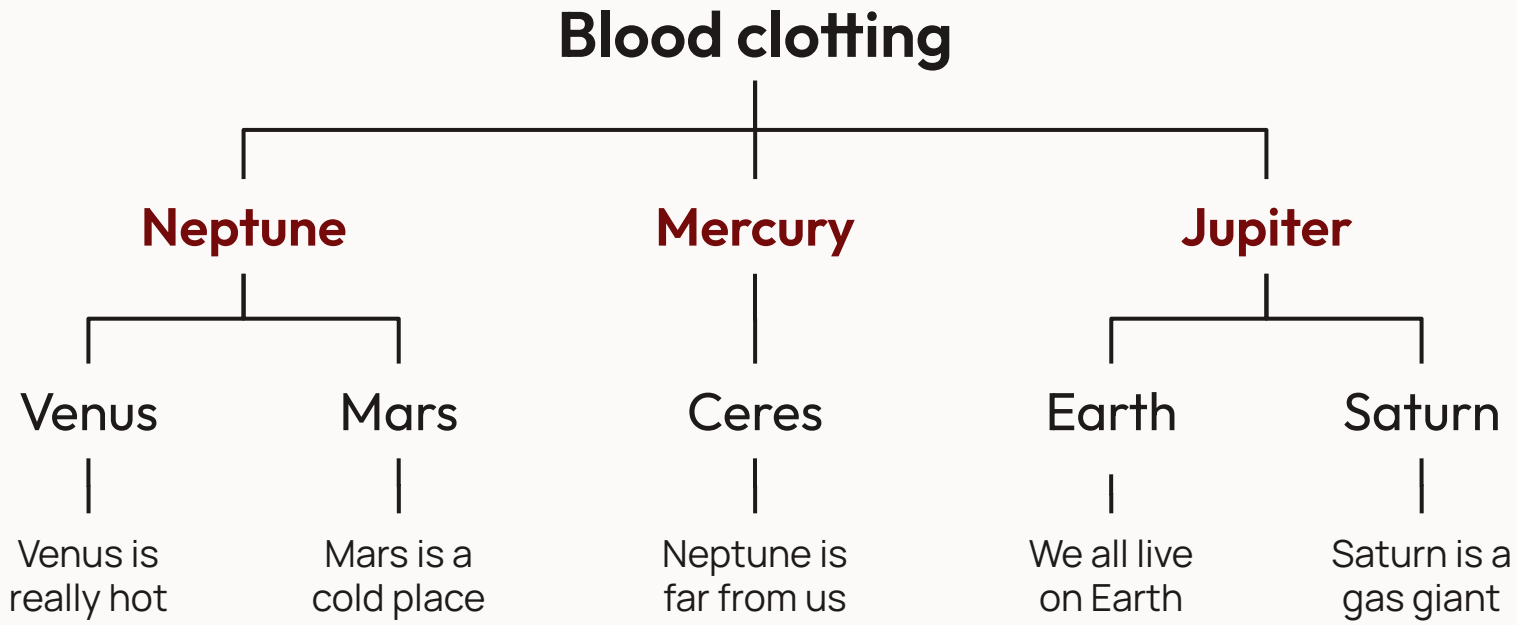
Jupiter is a gas giant and the biggest planet in the Solar System

Venus

Venus has a beautiful name and is the second planet from the Sun



About the disease

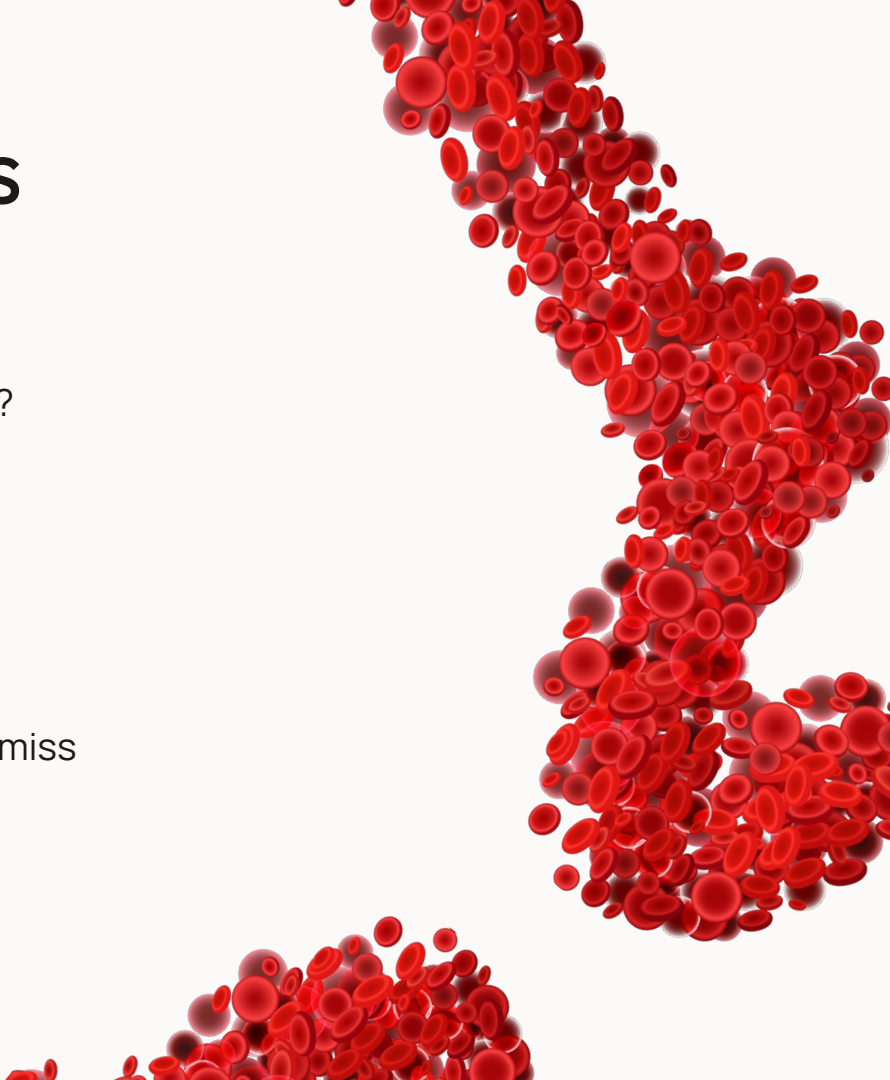


Some considerations

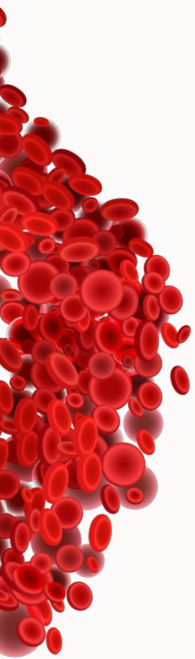
Do you know what helps you make your point clear?
Lists like this one:

- They’re simple
- You can organize your ideas clearly
- You’ll never forget to buy milk!

And the most important thing: the audience won’t miss the point of your presentation ever again



Concepts and typology



Type A

Neptune is the farthest planet from the Sun and the fourth-largest in the Solar System

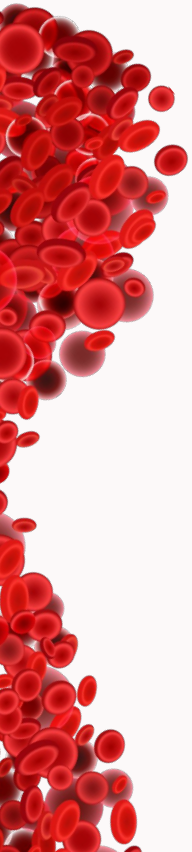
Type B

Mercury is the closest planet to the Sun and also the smallest one in the Solar System

Type C

Despite being red, Mars is a cold place. It's full of iron oxide dust, which gives the planet its reddish cast

Pathology



Mercury

Mercury is the closest planet to the Sun

Mars

Despite being red, Mars is a cold place

Venus

Venus is the second planet from the Sun

Jupiter

Jupiter is the biggest planet of them all

Symptoms of the disease

01 **Mercury**

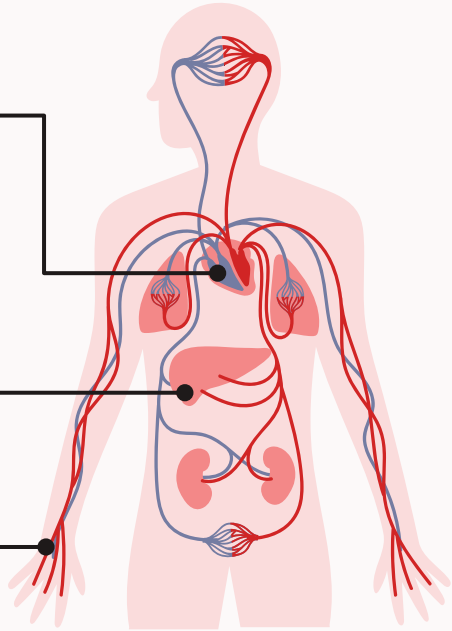
Mercury is the closest planet to the Sun

02 **Jupiter**

Jupiter is the biggest planet of them all

03 **Neptune**

Neptune is the farthest planet from the Sun

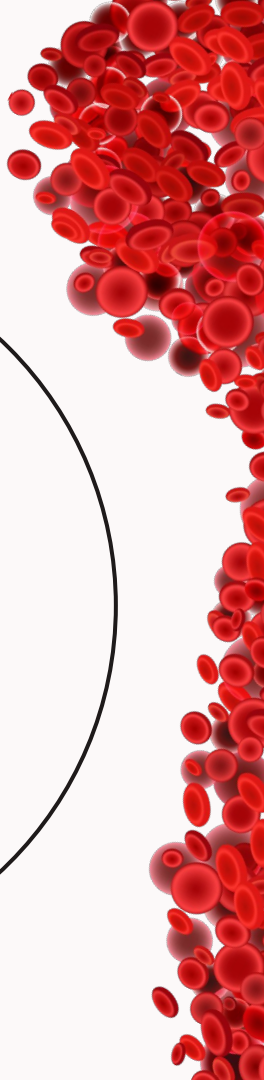


Awesome words

A picture is worth a thousand words

To reinforce the concept, try using an image

Images reveal large amounts of data, so remember: use an image instead of a long text. Your audience will appreciate it



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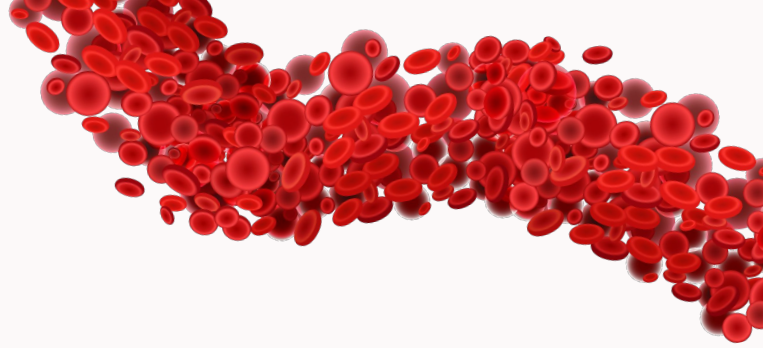


150,000

Big numbers catch your audience's attention

Key numbers

5,000

Mercury

Mercury is the closest planet to the Sun

620

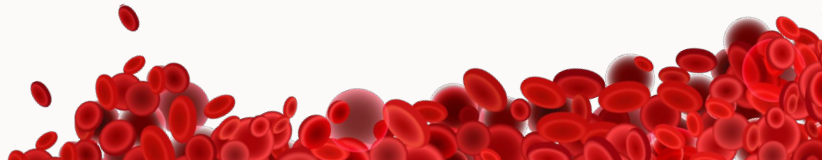
Venus

Venus is the second planet from the Sun

10,120

Mars

Despite being red, Mars is a cold place



“This is a quote, words full of wisdom that someone important said and can make the reader get inspired.”

—**Someone** Famous

Diagnosis

Venus

Venus is the second planet from the Sun

Mercury

Mercury the closest planet to the Sun

Jupiter

Jupiter is the biggest planet of them all

Saturn

Saturn is composed of hydrogen and helium

Mars

Mars is actually a very cold place

Neptune

Neptune is the farthest planet from the Sun

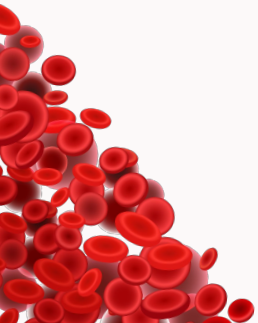
Daily recommendations

What to do

- You can describe what the patient should do here
- You can describe what the patient should do here
- You can describe what the patient should do here

What not to do

- You can describe what the patient shouldn't do here
- You can describe what the patient shouldn't do here
- You can describe what the patient shouldn't do here



Prevention

Habits	Mars	Mercury	Venus
Habit 1	✗	✓	✓
Habit 2	✗	✓	✓
Habit 3	✗	✓	✗

Treatment

01

Venus

Venus is the second planet from the Sun

02

Mercury

Mercury is the closest planet to the Sun

03

Mars

Despite being red, Mars is a cold place

04

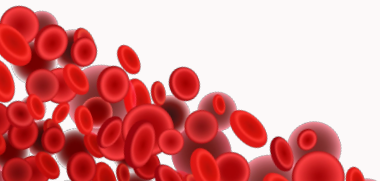
Saturn

Saturn is a gas giant and has several rings

05

Saturn

Saturn is a gas giant and has several rings



Prevalence

Venus

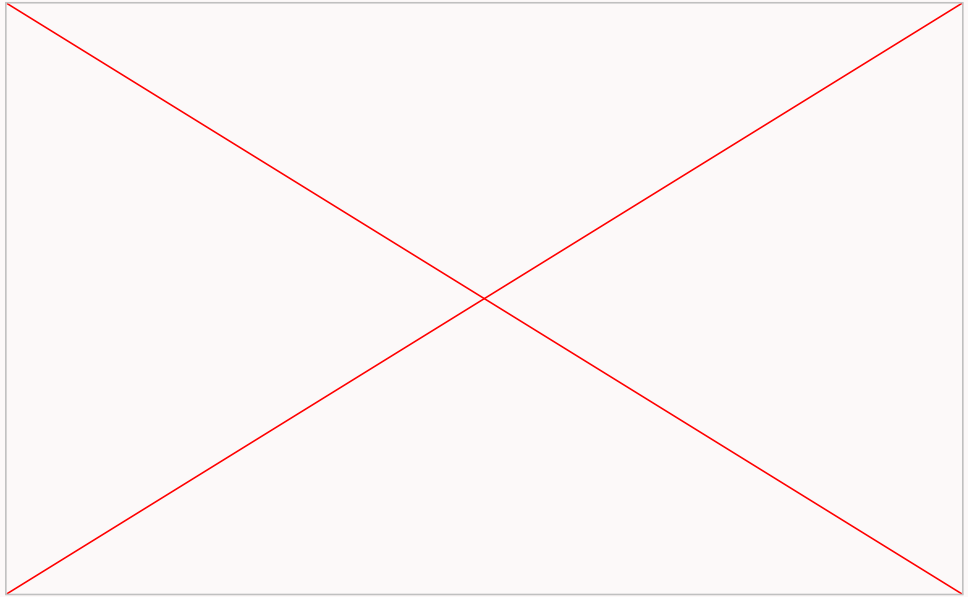
Venus has a beautiful name

Mars

Despite being red, Mars is cold

Mercury

It's the closest planet to the Sun



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Conclusions from the diagnosis

Conclusion 1

Mercury is the closest planet to the Sun and the smallest one in the Solar System

Conclusion 2

Earth is the third planet from the Sun and the only one that harbors life

Conclusion 3

Mars is a cold place. It's full of iron oxide dust, which gives the planet its reddish cast

Our doctors

Jenna Doe

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Sarah James

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References

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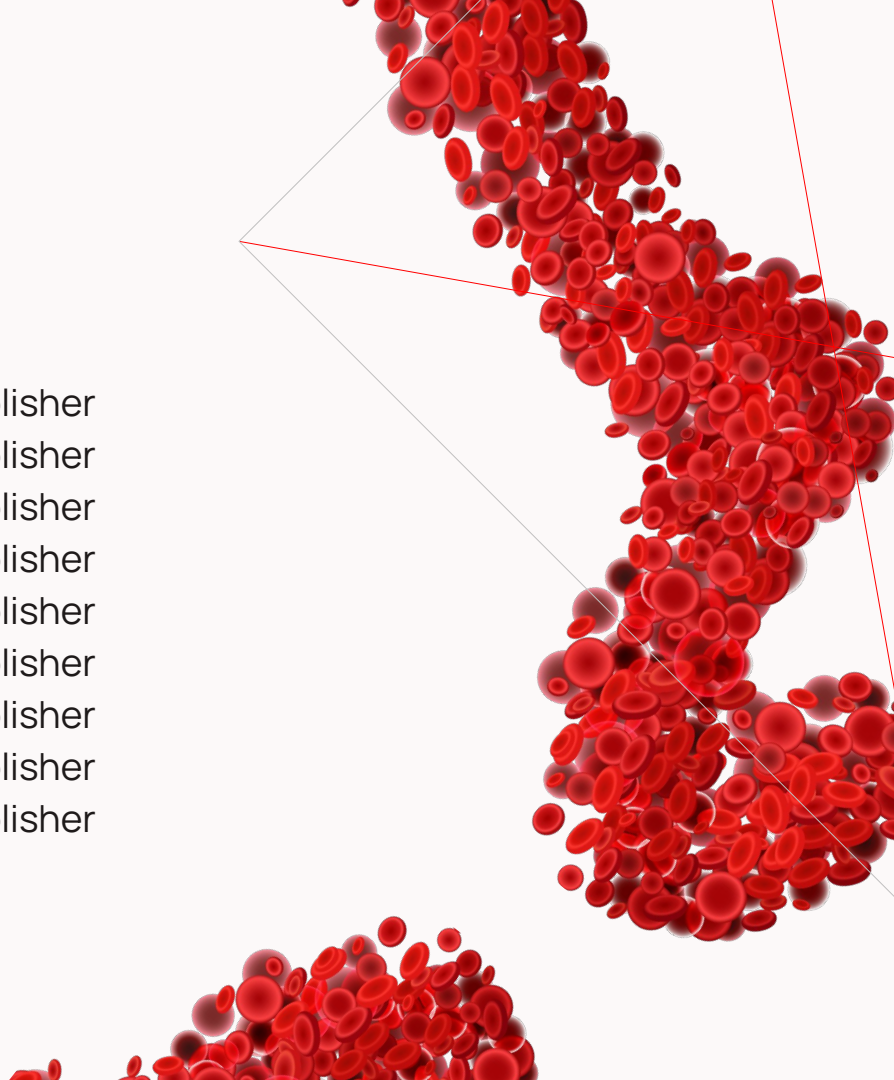

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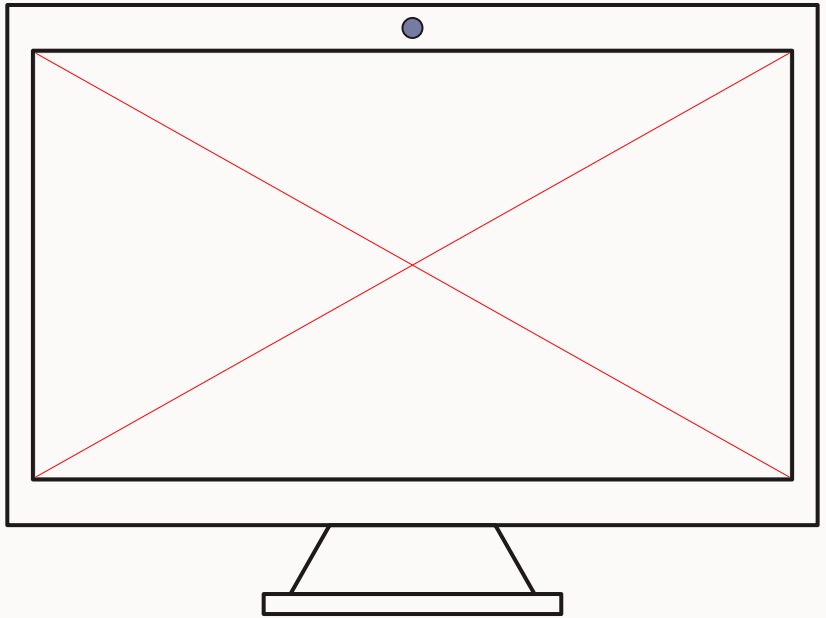

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- Blood donation concept with bloody red cells or erythrocytes in realistic style illustration

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- Drawn circulatory system infographic

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- Back view doctor holding a blood sample
- Nurse and doctor team ready for work day
- Front view doctor with stethoscope smiling

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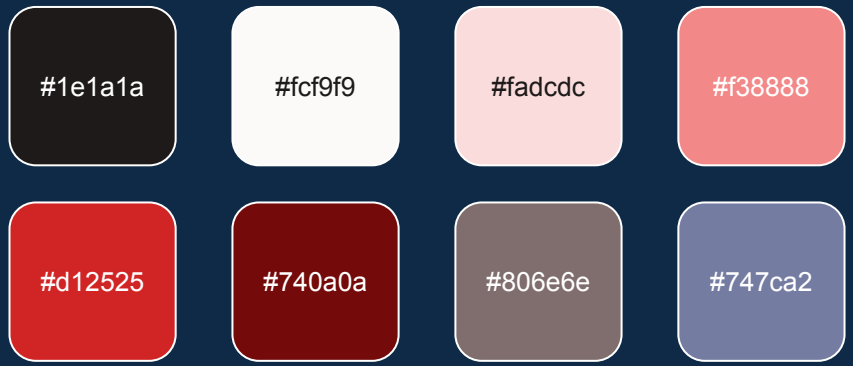

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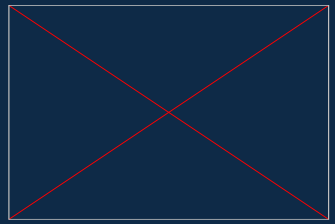

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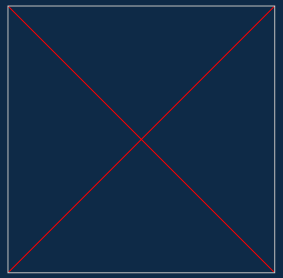

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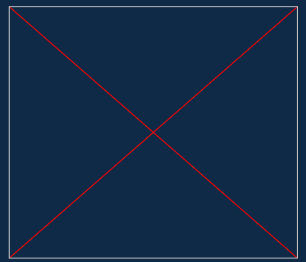

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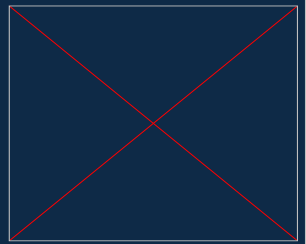

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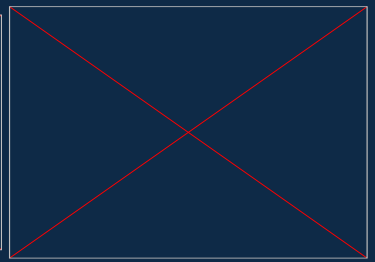

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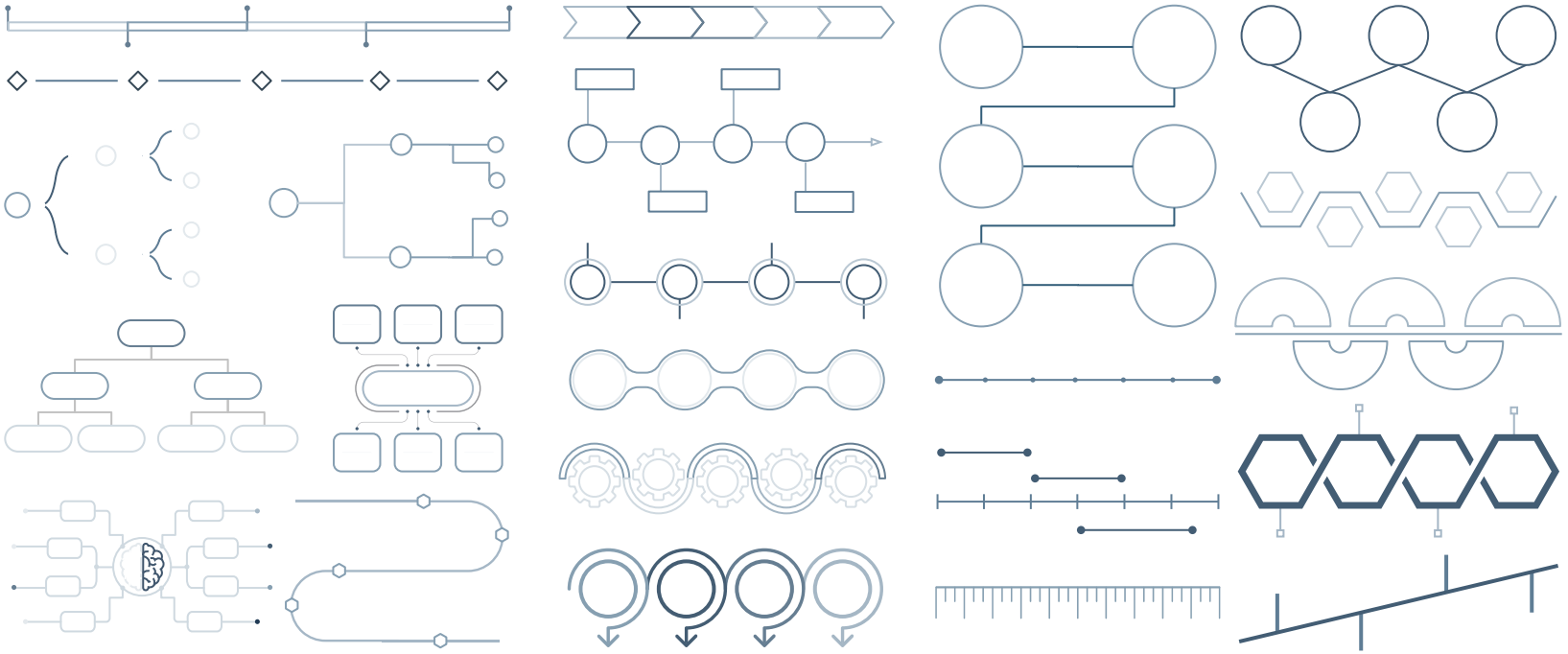
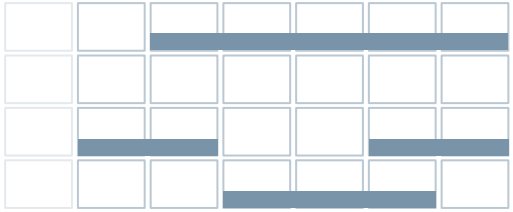
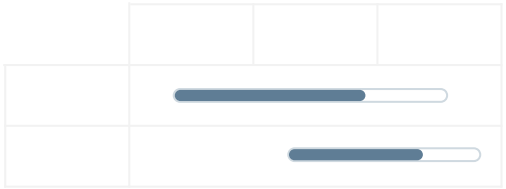
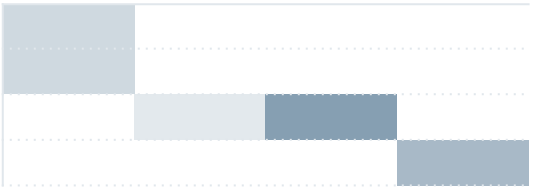
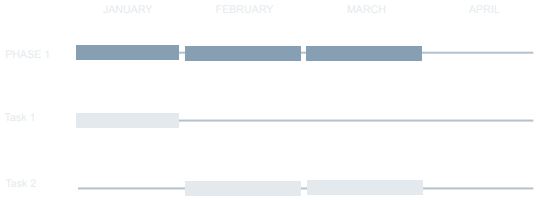
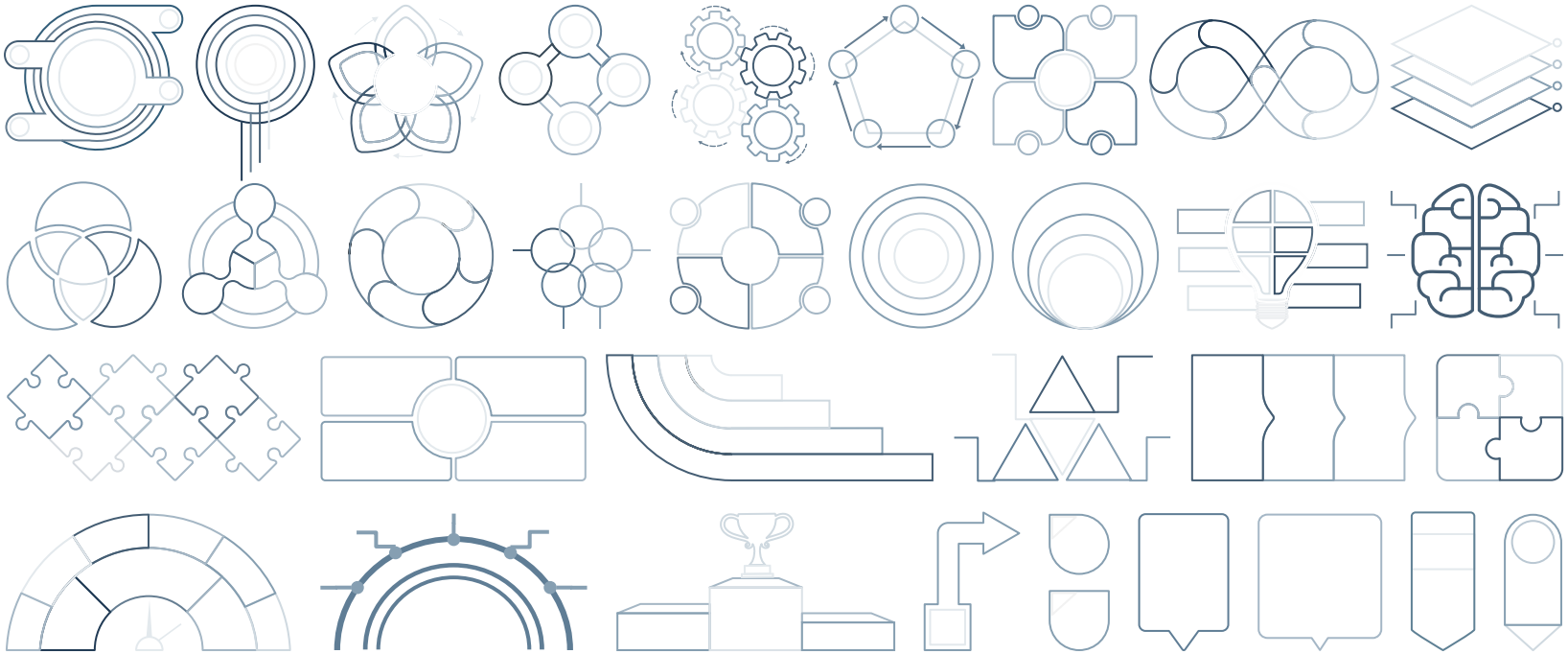









JANUARY
FEBRUARY
MARCH
APRIL
PHASE 1
Task 1
Task 2



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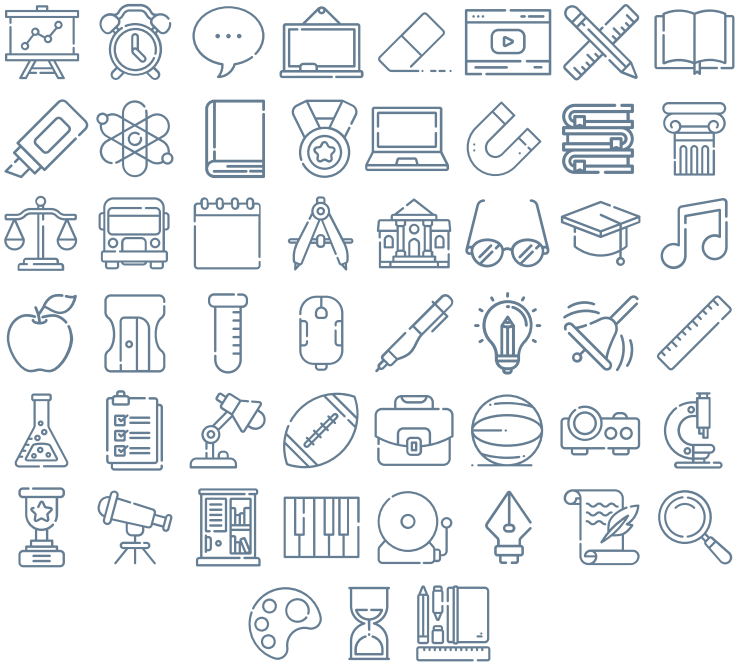

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